Background

The Affordable Medicines Facility – malaria (AMFm) is a funding mechanism designed to increase access to quality-assured artemisinin-containing combination therapies (QAACTs) through three interventions in the market:

- Negotiations with manufacturers to reduce ex-factory prices, especially for supplies to the private sector;
- Buyer co-payment system paid to manufacturers to further reduce the prices of QAACTs to a level similar to existing commonly used but ineffective antimalarials;
- Additional funding to support interventions (e.g. public awareness campaigns, training of health care providers,) to facilitate product and programme recognition and to promote the use of QAACTs.

The original idea for the AMFm came from a report of the US Institute of Medicine (IoM) in 2004 [1], and was further developed by a Task Force of the Roll Back Malaria Partnership (RBM). In 2008, RBM requested that the Global Fund host the new initiative and this was agreed to at the 18th Board meeting of the Global Fund [2]. The Board agreed to pilot the initiative for a two-year period with funding for the co-payment part coming from external donors (UNITAID, The Bill and Melinda Gates Foundation, UK DFID) and held in a separate account, and “supporting interventions” from re-programming of existing Global Fund malaria grants. At the end of this two-year period, the Board would then make a decision on whether to “Expand, Accelerate, Terminate, or Suspend the AMFm Business Line”. These options were subsequently changed and simplified to “Continue, Modify, or Terminate the AMFm Business Line”. Originally it was planned for this determination to be made by the Board at the end of 2010, but delays in the launch of AMFm meant that the Board extended the timeline to mid-2012 [3] and then to the end of 2012 [4].

In the original Board decision and in the funding arrangements, it was anticipated that the mandate to host AMFm would include a 6-month transition or winding-up period after the Board’s determination on the Global Fund’s future involvement at the end of the evaluation. This would allow for an orderly withdrawal of countries from the scheme if needed. Unfortunately in the process of delaying the date of the Board’s determination to the end of 2012, the winding-up period was lost.

---

1 Co-paid QAACTs made available through AMFm are branded with a green leaf logo. In a given country there may also be QAACTs available that are not co-paid and therefore not bearing the green leaf logo. In this report, for simplicity, no distinction is made between the two and both are referred to as QAACTs.
It was agreed that the success or failure of AMFm would be measured based upon 4 parameters:-

1. the increase in availability of QAACTs in public and private sector outlets;
2. the reduction in the price of QAACTs relative to other commonly used antimalarials;
3. the increase in the market share of QAACTs among all antimalarials in public and private sector outlets;
4. the increase in the usage of QAACTs by malaria sufferers, including the most vulnerable and difficult to reach communities.

Parameters 1, 2, & 3 are considered to be “upstream” parameters, and 4 to be a “downstream” one. Before the launch of AMFm, the changes in these “Success Parameters” that would indicate success or failure in the period allowed for evaluation were set in consultation with external experts [5]. Baseline data would be collected before the launch of country programmes and endline data would be collected at the end of 2011. These timings were designed to ensure that there was adequate period for a proper and detailed analysis of the data collected. However, given the short time period for testing the initiative, focus was centred on the “upstream” parameters. This was because, unlike usage, meaningful changes could be measured for these in the time available and within the budget allocated for the evaluation [6]. To ensure objectivity in determining success or failure, an Independent Evaluation (IE) was set up with independent consultants who carried out the baseline and endline market research, and interpreted the results.

After completion of the design of AMFm and the necessary negotiations with manufacturers, country programmes, and first-line buyers (FLBs) to set it up, it was formally launched in June 2010. Eight pilot programmes were included in Phase I. The roll-out and timings of the key events are shown in Table 1. The delay between the arrival of drugs in country and the start of the supporting interventions is due to the time taken to review the proposals and to reach agreement on the reprogramming of the relevant Global Fund grants.

**Table 1: Key Timings for Phase I Programmes:**

<table>
<thead>
<tr>
<th>Country</th>
<th>Baseline Data Collection</th>
<th>Arrival of First Drug In-country</th>
<th>Launch of IEC/BCC Programme</th>
<th>Endline Data Collection</th>
<th>QAACTs availability (mths)*</th>
<th>IEC/BCC Duration (mths)*</th>
</tr>
</thead>
</table>

† Terminated after one month due to regulatory issues prohibiting over-promotion of single brands
---|---|---|---|---|---

* Up to the time of the IE end-line data collection

Note: in some countries the formal launch of the AMFm programme did not coincide with the start of the actual mass communication (IEC/BCC) programmes. Some countries undertook “soft” launches or undertook small scale activities before launching the full national programmes.

**Independent Evaluation & Other Findings**

The design of the IE has been as a set of eight case studies that attempt to put the results in the context of local factors that may influence the success or failure to meet the AMFm success parameter targets. During the design of the IE, it was agreed that it would not be possible to include a control country as individual country differences would make this impractical. It was also agreed that it would not be possible to evaluate the cost-effectiveness of AMFm against other similar interventions, including community case management programmes. It was considered difficult to identify another intervention that could be considered comparable to AMFm.

The IE Team has issued a preliminary report which gives details of the results and their conclusions [7]. The information on usage is still lacking. The IE Team are planning to issue a further additional section on their findings about usage as an addendum to their report in time for the November Global Fund Board meeting. In addition they plan to add the results of studies on the impact of AMFm on availability in remote areas and on user reaction to the AMFm green leaf logo.

The summary of the findings of the IE are shown in the Table in the Appendix. These results may be summarised as follows:

AMFm has been shown to increase availability and to reduce prices to consumers of QAACtTs where it has been implemented, especially in the private sector. It has also increased the market share of QAACtTs compared to other antimalarials. Levels of oral artemisinin-based monotherapies (oAMT) were very low in all countries and this made measuring impact on the market share of oAMT impossible in 5 of 7 countries. The degree to which the success parameters were met depended on the duration of the implementation of the full programme, including the implementation of the supporting interventions (especially the mass public communication programmes and the establishment and dissemination of recommended retail prices).

---

3 Small scale only in the initial phase, full-scale activities only commenced in July 2011.
4 Details are in the IE Endline Full Report (see p. xxiv).
It should be noted that availability of ACTs in countries lasted between 7 and 15 months while the implementation of the supporting intervention only lasted between 1 and 11 months before the collection of endline data. A longer period of implementation and more timely sequencing of supporting interventions may have shown more success in some countries. The Global Fund Board’s Evaluation Review Group has noted in the past that the impact of an initiative of this type should normally only be judged after at least 5 years of implementation [8-10].

The IE found that the private for-profit sector has a major market share of antimalarial medicines, at baseline ranging from 97% (Nigeria) to 40% (Uganda). Approximately 80% of the co-paid QA ACTs have been delivered to the private-for-profit sector, most of the remaining to the public sector. The positive impact of AMFm on availability and price of QA ACTs has been principally in the private for-profit sector. This was attributed to the great speed and flexibility of the private sector in responding to increased demand. The IE report calls this effect a “game changer”. Public sector availability was adversely impacted by procurement delays and traditional Global Fund grant requirements. The IE concluded that supportive interventions were important to ensure successful implementation of AMFm: the Global Fund’s processes related to grant disbursements had delayed the start of or interrupted mass communication programmes in several countries, potentially reducing the impact of AMFm.

In two countries (Niger & Madagascar) problems with the roll-out of mass public awareness campaigns and the regulatory environment caused the programmes to fail to meet all the success parameters. In Zanzibar, where the malaria burden is very low and the programme has entered in the pre-elimination phase, access to antimalarials in the private sector is no longer considered appropriate.

Crowding out AMTs had been a target of AMFm in the early planning stages. However the IE found that in most countries there were already low levels of oAMTs in the market (<5% market share at baseline) and this could be attributed to regulatory changes that have removed them from sale, including a concentrated effort by WHO.

Although the IE has not yet published its results on the impact of AMFm on availability in remote areas, a separate study sponsored by CHAI has shown that in mainland Tanzania any initial differences in QA ACT availability between remote and urban drug outlets disappeared quickly over time, with the implementation of AMFm [11]. This reinforces the hypothesis that the private for-profit sector can supply also to remote rural areas and respond quickly to changes in demand for products, in this case QA ACTs.

The IE also reviewed a series of small-scale studies, mostly sponsored by CHAI, looking at various operational and implementation issues of interest in assessing the impact of AMFm and to inform future modifications to the model. These included looking at the impact of varying the level of subsidy and on the impact of subsidised RDTs on the usage of QA ACTs. All these studies are small scale feasibility studies and need to be scaled up before robust
conclusions can be drawn on how they may inform future ways to improve access to high quality diagnosis and treatment.

The following issues were not addressed as these were not part of the original design:

- proportion of co-paid QAACTs given to people with proven malaria parasitaemia
- impact of providing co-paid QAACTs to people with proven parasitaemia;
- impact of advice given to care seekers along with dispensing QAACTs;
- adherence to QAACTs dosing regimens;
- impact of AMFm on the global artemisinin supply;
- impact on the prevalence of counterfeit and substandard ACTs.

The findings of the IE were reviewed with the Phase I country teams in July 2012. The feedback from the countries also was that AMFm had been a “game changer” in increasing availability of QAACTs, especially in the private retail sector. It had also been a game changer in bringing the public and private sectors together in planning and executing the pilot programmes.

The IE Report was also reviewed by a Global Fund Expert Advisory Group (EAG) and they have issued a preliminary report [12]. They concluded that the major upstream benchmarks for success had been achieved in 6 out of the 8 pilots. They noted that the progress had been found in both urban and rural areas, and that this was despite the short evaluation period. The report notes that a longer implementation period, especially with more time for the supporting interventions, would probably have resulted in better results.

By mid-2011 the demand for co-payments from manufacturers was much greater than anticipated and the rate of disbursements was at a rate where the available funds would be used up before the end of the Phase I programme. Therefore, since August 2011, the AMFm Unit in the Fund Secretariat imposed a series of “demand levers” to control the rate of disbursements and to stretch out the available funds for as long as possible. In view of the lead times between order approvals, delivery and in-country distribution, this has probably not distorted the findings of the IE, but will have affected AMFm’s implementation in 2012. Additional funds had to be made available in early 2012 by UNITAID, DFID, and the Canadian International Development Agency (CIDA) to ensure the continuation of Phase I until the end of 2012.

**Global Malaria Context**

Since the inception of AMFm in 2004, the context in which it has to operate has changed significantly. Programmes to achieve universal coverage with bednets (especially long-lasting impregnated nets) and the increasing use of indoor residual spraying have resulted in falling endemicity of malaria in many countries. This is reflected in the findings of studies by CHAI on the probability that a fever is caused by malaria or by another cause (Fig. 1) [13]. In turn this means that care-seekers buying antimalarials in the private retail sector to treat a fever in some places are increasingly not actually treating malaria. The WHO changed its treatment guidelines in March 2010 to include parasitological confirmation of malaria also in
children under five in areas of high transmission; testing is therefore now recommended for all suspected cases of malaria in all settings. High quality rapid diagnostic tests (RDTs) are now readily available and their price is falling to more affordable levels. However there remain significant operational issues to widening access to diagnostic testing, especially in countries where most treatment is accessed through the private retail sector.
Any new approach that builds on the experience of AMFm in widening access to QAQCTs must take into account the need to incorporate diagnostic testing. This will both improve patient treatment and outcomes, and also could reduce drug wastage and cost.

Originally it was planned to include Cambodia as one non-African country participating in Phase I, and so test the AMFm model outside of Africa. However it was not possible to include it in the IE for a variety of reasons. A modified model for AMFm must be able to be applied outside Africa. In addition the applicability of the new model to appropriate treatments in different countries with different malaria epidemiologies will need to be examined.

**The Global Fund Working Group and RBM Task Force on AMFm**

At the moment, both the Global Fund and RBM have established dedicated groups to advise on the future of the AMFm initiative. The deliverables of the two groups are as follows:-

- **Global Fund WG:** to recommend options for future hosting and support to AMFm by the Global Fund based on the Independent Evaluation (IE);
- **RBM TF:** to develop broader implementation approaches to improve access to high quality diagnostic testing & treatment in line with WHO recommendations, especially in the private retail sector (integrating learnings from AMFm).
To ensure the most efficient way to co-ordinate work between the two groups, they have agreed to work as one group with these two deliverables.

It has been recognised that any future model to follow-on from AMFm Phase 1 must fit into a wider context of improving access to high quality diagnostic testing and treatment, and to recognise the current importance of the retail private sector in many countries for case management. There are many operational questions that remain unanswered on how best to incorporate diagnostic testing outside of the formal health care sector (hospitals, clinics). However there is a pressing need to decide on how the countries involved in the initial pilot should plan for the period after the end of AMFm Phase 1 in December 2012. Therefore five workstreams have been established to address the key issues:-

**Workstream A**
“Immediate Challenges”
Tackling the immediate challenges from the end of AMFm Phase 1 by developing recommendations for any “interim arrangements” that may be needed to ensure that disruption to the supply of QAACTs in the private sector is minimised in 2013.

**Workstream B**
“Communicating Key Learnings”
Identifying and communicating the key learnings from AMFm Phase 1 and other relevant studies.

**Workstream C**
“Introducing Diagnosis”
Identifying the work required to inform and develop a strategy for improving access to diagnostic testing, especially in the private retail sector

**Workstream D**
“Options for the Future”
Developing a future integrated strategy for improved access to high quality diagnostic testing and treatment, especially in the private retail sector

**Workstream E**
“Charting the Future Course”
Charting a course to introduce and implement the strategy from workstream D

**Preliminary Conclusions & Recommendations**
Given the findings identified by the IE, the Global Fund Working Group and the RBM Task Force see value in continuing a QAACT-subsidy scheme to increase access and affordability to QAACTs in the private sector in countries meeting specific criteria, including high burden and current high proportion of treatment seeking in the private sector. However, given changes in the malaria environment since the current AMFm model was designed, the
Working Group and Task Force do not see that the current model can be continued in an unchanged form. A transition to a model that incorporates diagnostic testing will have to be developed. Also, the challenges over funding that the current model has encountered mean that the design will have to be modified to ensure that any successor approach will be sustainable financially over the long-term.

The initial idea of the need for AMFm to counter resistance development has been shown not to be a major factor, as this has been more rapidly achieved through regulatory changes. This is evidenced by the low levels of AMTs found in the baseline surveys. Therefore the original need identified in the IoM Report for a global programme to crowd out AMTs is no longer considered essential. The Global Fund EAG did point out that there will be a need to ensure that QA ACTs are available to fill any gap in demand resulting from the removal of AMTs from the market.

The observations on the situations in Niger, Madagascar, and Zanzibar (see “Independent Evaluation & Other Findings” above) have led the two groups to conclude that any successor model to AMFm Phase 1 will need to recognise better the different circumstances of countries and build in flexibility to take account of this.

Therefore the Working Group will not be recommending that the “Continue” option is adopted since in countries that the group will suggest an extension it will only be with modifications to the model.

**Workstream C (Introducing Diagnostic testing):**
This Workstream has already identified a wide range of research questions and also the work currently being undertaken. This is in the process of being prioritised to allow for a programme that will properly meet the decision-making needs of all relevant stakeholders.

**Workstream D (Options for the Future):**
This Workstream has already started working with consultants to develop a variety of options that meet the needs of improving access to high quality diagnostic testing and treatment, recognising the importance of the private sector in many countries. These analyses are not quite ready. However it is already clear that the recommendations will include a range of options for countries to choose from. This recognises the conclusions from the IE that countries differ in their requirements and so a “one size fits all” model is no longer appropriate.

**November Global Fund Board Presentation:**

It is planned that the Global Fund Board will be presented with the following background and recommendations at the November meeting:-

- Environmental & policy changes that the Global Fund needs to take into account when agreeing to the future approach to supporting improved high quality diagnosis
and treatment for malaria (e.g. CHAI findings, MPAC determinations, further IE findings).

- Proposals (costed) for interim arrangements to immediate challenges and depending on the future scenarios being recommended. (Workstream A).
- Proposals (costed) for long-term arrangements to build on the learnings from AMFm Phase I and changes in the environment to deliver high quality diagnostic testing and treatment. (Workstream D).
- Proposals (costed) for transition to the long-term arrangements. (Workstream E).
- Specific recommendations on how the new arrangements will be funded, hosted, and how the funding will be structured (standalone fund, incorporated into mainstream Global Fund grants, or another model).
- Termination option (costed).
References

13. CHAI. Submitted for publication in Science
APPENDIX

Summary of the Findings of the Independent Evaluation:

![Table showing the summary of the findings of the independent evaluation.](image)