Multi-Country Independent Evaluation Report

Independent Evaluation of the

Affordable Medicines Facility - malaria (AMFm) Phase 1

Final Report

September 28, 2012

Submitted to:

Investing in our future
The Global Fund
To Fight AIDS, Tuberculosis and Malaria

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This version of the report includes the following information not previously included in the Preliminary Report of July 18, 2012: (i) results from the remote areas study; (ii) results from the logo study (exit interviews and focus group discussions); (iii) an annex describing the Consultative Forum held in June 2012 in Nairobi; and (iv) some new content to Section 1.2 Overview of the AMFm, including orders requested, approved and delivered as of end September 2012. None of this new information has affected the assessment of the achievements of the Phase 1 benchmarks that were included in the preliminary report of July 18, 2012.

This version of the report does not include findings from the endline household surveys. Those findings will be included in a supplemental report when endline data become available.

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Overview of the Independent Evaluation of AMFm

The success of malaria control efforts depends on a high level of coverage in the use of effective antimalarials such as artemisinin-based combination therapies (ACTs). Although these antimalarials have been procured in large amounts by countries, evidence suggests that ACT use still remains far below target levels. In response to this issue, the Affordable Medicines Facility – malaria (AMFm) hosted by the Global Fund to Fight AIDS, Tuberculosis and Malaria (Global Fund) was set up. AMFm comprises three key elements: (i) price reductions through negotiations with ACT manufacturers; (ii) a buyer subsidy through a 'co-payment' for ACTs at the top of the global supply chain; and (iii) supporting interventions to promote appropriate use of ACTs. Examples of these supporting interventions include training providers and outreach to communities to promote ACT use. All ACTs subsidized through AMFm bear a green leaf logo on their packaging. The four main objectives of AMFm are to: (i) increase ACT affordability; (ii) increase ACT availability; (iii) increase ACT use, including among vulnerable groups; and (iv) "crowd out" oral artemisinin monotherapies, chloroquine and sulfadoxine-pyrimethamine (SP) by increasing the market share for ACTs.

The Independent Evaluation of AMFm was designed to assess whether, and to what extent, AMFm Phase 1 achieves its objectives. The evaluation was carried out in all of the currently operational Phase 1 pilots (Ghana, Kenya, Madagascar, Niger, Nigeria, Tanzania mainland, Uganda, and Zanzibar). The evaluation is based on a non-experimental design with a pre- and post-test intervention assessment in which each participating country is treated independently as a case study. The evaluation includes two major components: (1) a pre-intervention (baseline) and post-intervention (endline) study of key outcomes through nationally representative outlet surveys and use of secondary household survey data; and (2) documentation of key features of the context at baseline and endline and the AMFm implementation process in each country. The results of the outlet and household surveys are compared to the AMFm success benchmarks (see Figure 1), and interpreted using the process and context data to facilitate interpretation of the changes in outcomes over the implementation period and to judge whether any observed changes are likely to be due to AMFm. Availability, price and market share benchmarks focus on quality assured ACTs (QAACTs) defined as products meeting the Global Fund's quality assurance criteria. (At the time this report was written, no endline household survey data were available to measure use of ACTs to treat fever in young children, but it is expected that household data will be available for some countries before November 2012.) In addition, two complementary studies were carried out in selected countries at endline. The remote area study examined the availability, price and market share of ACTs at the end of the main endline outlet survey in areas considered remote and those considered non-remote. The AMFm logo study assessed whether or not the AMFm logo achieved its intended effect with respect to public awareness and marketing.

A number of key findings can be distilled:

1. **Achievement of success benchmarks** – Figure 1 provides an overview of the performance of each pilot against the AMFm success benchmarks. Of the 8 pilots, success benchmarks were clearly met in 5 pilots for availability, 5 pilots for QAACT price relative to the most popular antimalarial that is not a QAACT, and 4 pilots for QAACT market share (all shaded green). It is also possible that benchmarks were met in one additional pilot for availability and price, and in 3 additional pilots for market share, although the evidence is not as strong (shaded amber). The success benchmarks related to artemisinin monotherapy (AMT) price and market share were met in all pilots with sufficient AMTs in the market to make these benchmarks relevant.

2. **AMFm and the private for-profit sector** – AMFm has been a "game changer" in the private for-profit sector for all pilots except Niger and Madagascar, with a dramatic impact on the antimalarial market, through large increases in QAACT availability, decreases in QAACT prices, and increases in QAACT market share. These changes were substantial and achieved in only a few months, demonstrating the power of tapping into the distributional capacity of the private sector. The changes are very likely to be largely attributable to AMFm. The private for-profit sector response was similar in rural and urban areas, in some cases reducing or closing a rural-urban gap in availability and market share. There was considerable penetration of copaid QAACTs even in remote areas in Ghana and Kenya, where this was evaluated.

3. **AMFm and the public sector** – AMFm led to fewer fundamental changes to public sector antimalarial supply, where QAACT supply continued to be hindered by problems with procurement and grant requirements, leading to substantial delays in ordering. Increases in QAACT market share were seen in the public sector in four pilots (Ghana, Nigeria, Uganda and Zanzibar), although in Nigeria most QAACTs distributed through the public sector were not copaid. QAACTs were available in less than 80% of all public facilities at endline in five pilots, and there was generally no change in public sector QAACT prices as most countries already provided QAACTs for free at baseline (except Ghana where public sector QAACT prices fell).

4. **Limited impact in Madagascar and Niger** – The impact of AMFm on the private for-profit sector was limited in Madagascar and Niger, where orders of copaid ACTs were very low. Explanations may include (i) the lack of full-scale mass media campaigns; (ii) the structure of the private for-profit antimalarial sector, which had a much higher proportion of general stores, and in Niger itinerant vendors, who are not allowed to stock QAACTs; and (iii) an unfavourable context of political and/or economic instability and severe weather conditions.

5. **Effect of duration of implementation –** Longer duration of implementation appears to be positively correlated with performance, if the combined presence of copaid ACTs and the operation of a large-scale sustained IEC/BCC campaign is considered a proxy for full

AMFm implementation. With the exception of Zanzibar, pilots with earlier start dates achieved more success benchmarks. No large-scale sustained IEC/BCC campaign was in place by the end of 2011 in Madagascar, Niger or Uganda, and these pilots achieved fewer benchmarks. However, it is possible that delayed start dates reflect weaker implementation capacity in general, and therefore one should be cautious in attributing performance to duration of implementation alone.

6. **Prices and markups in the private for-profit sector** – The price of copaid QAACTs in the private for-profit sector at endline was very variable across pilots, ranging from USD 0.51 in Madagascar to USD 1.96 in Uganda. Reasons for this variability are unclear but may include (i) variations in the recommended retail price and its promotion through national IEC/BCC campaigns; (ii) guidelines on markups (in Madagascar); (iii) differences in cost structure including tax components; and (iv) time since copaid ACTs first arrived in each country. The median retail gross markup on copaid QAACTs was less than 70% in all pilots (which can be considered reasonable for the retail sector), except Uganda (133%) and Zanzibar (100%).

7. **Crowding out oral artemisinin monotherapy** – Even at baseline, market share for oral AMT was less than 4% in Ghana and less than 1% in Kenya, Madagascar, Niger, Tanzania Mainland and Uganda. In Nigeria and Zanzibar where oral AMT market share was somewhat higher at baseline, large and significant falls were observed, likely reflecting a combination of the AMFm subsidy and complementary regulatory measures with particularly strong enforcement of the latter in Zanzibar.

8. **Availability of non-artemisinin therapies** – Availability of non-artemisinin therapies such as chloroquine and sulphadoxine-pyrimethamine fell in some countries, but remained very high in most countries. However, most of the increase in QAACT market share was at the expense of the market share of non-artemisinin therapies.

9. **Market structure** – The private sector was a major player in the antimalarial market in all pilots, accounting for between 40% and 97% of antimalarial sales volumes at baseline, and between 49% and 92% at endline. There was no clear pattern across pilots in the change in private for-profit market share between baseline and endline.

10. **Availability of malaria diagnosis** – Diagnostic availability (rapid diagnostic tests or microscopy) varied substantially in the public sector, from 29% in Nigeria to 98% in Zanzibar at endline. However, in private for-profit outlets, only three pilots had substantial availability at endline (Kenya - 14%, Uganda – 21%, Zanzibar - 32%). In this sector, health facilities/pharmacies have higher availability of diagnostics than drug and general stores.

11. **Results of operational research** – Results from studies of interventions to enhance the implementation of antimalarial subsidies by improving targeting and/or drug use show that implementation of such interventions is feasible on a small scale, but more evidence

on effectiveness and cost-effectiveness of large-scale programs is needed to inform policy.

12. **Issues not covered by the Independent Evaluation** – A number of important issues related to AMFm policy decisions were beyond the scope of the Independent Evaluation, including the impact on targeting copaid ACTs to persons with parasitemia; advice provided to patients; adherence to dosing regimens; global artemisinin supply; and prevalence of counterfeit products.

13. **Possible hindering factors for AMFm in some countries include**:
    - Delays in the public sector procurement process for copaid ACTs
    - Issues with Global Fund grants and delays in procurement of supporting interventions, meaning that implementation of most interventions lagged behind the arrival of copaid ACTs by several months
    - Suspension of Global Fund disbursements or grants interrupting implementation of supporting interventions
    - Application of Global Fund demand levers to ration orders
    - Political and/or economic instability
    - An antimalarial provider market dominated by highly informal outlets operating outside of regulated distribution channels (in Madagascar and Niger)

14. **Possible facilitating factors for AMFm in some countries include**:
    - Strong AMFm governance structures (including steering committees), involvement of the private sector and technical assistance from the Clinton Health Access Initiative
    - Generally smooth operation of the registration process for first-line buyers and ordering through the copayment mechanism
    - Strong, large-scale mass media campaigns, including promotion of the AMFm logo
    - Longer duration of implementation
    - Establishment and promotion of a recommended retail price set at an appropriate level
    - Complementary regulatory changes, such as giving ACTs over-the-counter status, and implementation of the AMT ban
    - AMFm training in some countries (although only Ghana and Zanzibar had over 20% training coverage)

Figure 1: Overview of the achievement of the AMFm Success Benchmarks by county, indicating benchmarks achieved (in green), nearly or possibly achieved (in amber) and not achieved (in red), (point estimate, and p-value for statistical test of whether the level stated in the benchmark was achieved)

Benchmark	Ghana	Kenya	Madagascar	Niger	Nigeria	Tanzania mainland	Uganda	Zanzibar*
1. 20 percentage point increase in QAACT availability	52 (p<0.01)	35 (p<0.01)	4.6 (p=0.99)	10 (p=0.99)	26 (p=0.14)	44 (p<0.01)	46 (p<0.01)	39
2. Median price of QAACTs with AMFm logo is <3 times the median price of the most popular antimalarial in tablet form that is not a QAACT (ratio)	3.0 (p=0.81)	1.0 (p<0.01)	1.6 (p<0.01)	2.5 (p<0.01)	3.1 (p=0.99)	1.0 (p<0.01)	3.3 (p=0.99)	1.5
3. Median price of QAACTs with AMFm logo is less than the median price of AMT tablets (difference, QAACT – AMT)	-0.94 (p<0.01)				-1.17 (p<0.01)			-6.3
4. 5 percentage point increase in percentage of children with fever who received ACT treatment	na	na	na	na	na	na	na	na
5. 10 percentage point increase in market share of QAACTs	40 (p<0.01)	31 (p=0.01)	8.6 (p=0.61)	-8.8 (p=0.99)	18 (p<0.01)	16 (p=0.23)	17 (p=0.08)	48
6. Decrease in market share of oral AMTs (percentage point change)					-3.9 (p=0.03)			-12

Notes: Green shading = the benchmark was achieved, with strong statistical evidence (generally p<0.01); Amber shading = either the benchmark was nearly, but not fully, met, or the evidence that the change seen was unlikely to be due to chance is weak (p≥0.05). However, the power to detect a 10 percentage point increase in market share was only 35% in Tanzania, 66% in Uganda and 70% in Madagascar, compared with the usual minimum standard of 80%; therefore, p-values should be interpreted with caution. Red shading = the benchmark was not met; Grey shading for Benchmarks 3 and 6 = not relevant because the number of AMT products was very low at baseline. * p-values not shown for Zanzibar because a complete census of antimalarial stocking outlets was undertaken; na = not available; ACT= artemisinin-based combination therapy; AMT= artemisinin montherapy; QAACT= quality-assured artemisinin-based combination therapy