

## **AFFORDABLE MEDICINES FACILITY - MALARIA**

### **Frequently Asked Questions**

#### Outline

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- Implementing Phase 1
- Funding AMFm Phase 1
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- Policies and processes for AMFm Phase 1

## Introduction to AMFm

### What is the AMFm?

The AMFm is an innovative financing mechanism to expand access to affordable artemisinin-based combination therapies (ACTs) for malaria, thereby **saving lives** and **reducing the use of inappropriate treatments**. The AMFm aims to enable countries to increase the provision of affordable ACTs through the public, private not-for-profit (e.g., NGO) and private for-profit sectors. By increasing access to ACTs and displacing artemisinin monotherapies from the market, the AMFm also seeks to delay resistance to the active pharmaceutical ingredient, artemisinin.

The AMFm facilitates expanded access to ACTs by **reducing the cost of these drugs** in malaria-endemic countries and by financing **additional activities** ('supporting interventions') to assist the **safe and effective implementation** of the AMFm. By increasing access to ACTs, the AMFm represents one component of a comprehensive response to malaria.

The AMFm is hosted and managed by the Global Fund to Fight AIDS, Tuberculosis and Malaria (the Global Fund), with key financial support provided by UNITAID, the United Kingdom and the Bill & Melinda Gates Foundation and with technical support provided by members of the Roll Back Malaria (RBM) Partnership.

The AMFm has its origins in the 2004 report, 'Saving Lives, Buying Time,' produced by the Institute of Medicine, USA, which called for a global subsidy of ACTs to reduce malaria mortality and delay resistance to artemisinin.<sup>1</sup> The technical design of the AMFm was developed with guidance from the RBM Partnership's AMFm Task Force.<sup>2</sup>

### Why is AMFm needed?

In 2009, approximately 225 million people fell sick with malaria and about 800,000 people died from the disease.<sup>3</sup> Malaria parasites are becoming increasingly resistant to older medicines, such as chloroquine (CQ) and sulfadoxine-pyrimethamine (SP), which are commonly still used for treating the disease because they are relatively inexpensive. The use of artemisinin monotherapies also threatens to lead to the development of parasite resistance to artemisinin. This would compromise ACTs, which are currently the best treatment for uncomplicated *P. falciparum* malaria.

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<sup>1</sup> Arrow, K., Panosian, C., Gelband, H., Editors. *Saving Lives, Buying Time: Economics of Malaria Drugs in an Age of Resistance*. 2004. The National Academies Press. Washington, DC.

<sup>2</sup> The technical design is available online at:

<http://www.rollbackmalaria.org/partnership/tf/globalsubsidy/AMFmTechProposal.pdf>

<sup>3</sup> WHO (2009), *World Malaria Report 2009*, page 27

**Artemisinin-based combination therapies (ACTs) combine artemisinin with another anti-malarial drug and are currently the most effective form of treatment for malaria.** The World Health Organization (WHO) specifically recommends ACTs as first-line treatment for uncomplicated *P. falciparum* malaria. However, ACTs account for only one in five anti-malarial treatments taken and are provided almost entirely by the public sector. Over 60% of patients access anti-malarial treatment through the private sector, where ACTs make up only 5% of treatments provided.

ACTs are not more widely used because they are more expensive than the less-effective alternatives. To ensure equitable access to treatment, ACTs must be made available at affordable prices through the public and private sectors. AMFm Phase 1 enables public, private not-for-profit and for-profit providers in participating countries to purchase ACTs at significantly lower prices and to pass this benefit on to patients. The AMFm Phase 1 is therefore a platform for rapidly increasing access to effective and affordable ACTs.

### **How does AMFm work?**

The objective of the AMFm is to ensure that people suffering from malaria have access to inexpensive, effective antimalarial treatment, in the form of ACTs. The AMFm promotes the use of effective antimalarials and drives out ineffective medicines from the market by: 1) reducing consumer prices to an affordable level through **price negotiations** and a **buyer co-payment**; and 2) ensuring safe and effective scale-up of ACT use by introducing **in-country supporting interventions**.

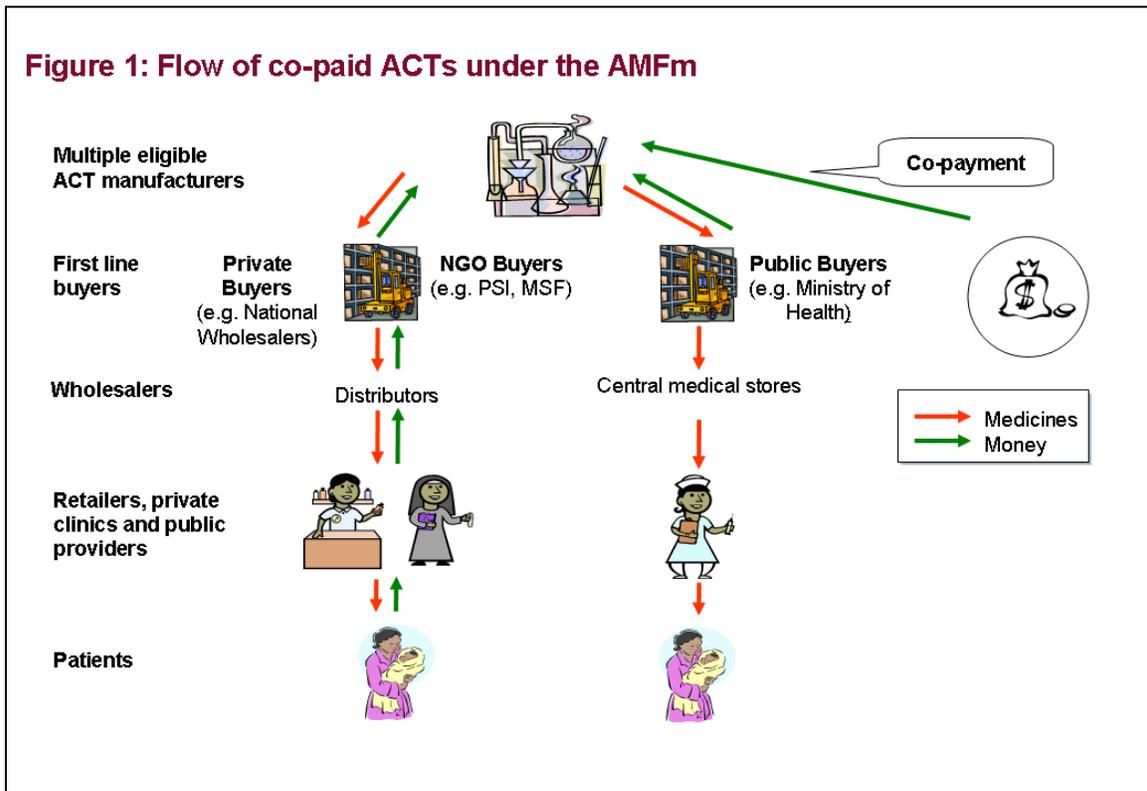
The Global Fund, as host and manager of the AMFm, has negotiated with drug manufacturers to reduce the price of ACTs, with the condition that sales prices must be the same for both public and private sector **first-line buyers**.<sup>4</sup> This has been the first significant achievement of the AMFm. The Global Fund then pays a proportion of this reduced price (a '**buyer co-payment**') directly to manufacturers to further lower the cost to eligible first-line buyers of ACTs purchased from manufacturers. This means that first-line buyers only pay the remainder of the sales price for the ACTs.

First-line buyers are expected to pass on the highest possible proportion of this price benefit so that patients are able to buy ACTs across the public, private not-for-profit and for-profit sectors at a price lower than artemisinin monotherapies and competitive with that of less-effective anti-malaria drugs, such as CQ and SP.

The flow of ACTs and payment is shown on the following page in **Figure 1**.

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<sup>4</sup> First-line buyers for AMFm include international, regional and national buyers from the public, private not-for-profit and for-profit sectors who purchase ACTs directly from the manufacturer, or procurement agents buying on their behalf.



In addition to enabling a lower purchase price for ACTs, the AMFm requires participating countries to implement supporting interventions to improve malaria case management and ensure the safe and effective scale-up of ACTs. These interventions include: public awareness campaigns; training and supportive supervision for ACT providers; policy and regulatory measures; pharmacovigilance planning; and programs to reach poor people and children, specific to the situation in each country. Additional supporting interventions at each country's discretion are also being implemented, including, for example, expanding the use of diagnostic tests for malaria.

### How does the AMFm support the public, not-for-profit sectors and private for-profit sectors?

The AMFm is a platform for achieving public goals - expanding access to ACTs and delaying resistance to artemisinin - through a combination of public sector outlets and private sector outlets. The AMFm is open to and supports buyers across the public, private not-for-profit and for-profit sectors, as it relies on using all existing supply chain channels to distribute affordable ACTs.

Public sector buyers benefit from AMFm by being able to purchase quality-assured ACTs at the greatly reduced ‘co-paid’ price, rather than the previous public sector purchase price of approximately US\$ 1.00 per treatment.<sup>5</sup> The public sector also plays a critical role in implementing AMFm, including continuing to provide malaria treatment through publicly owned and publicly staffed facilities, managing supporting interventions and distributing free ACTs to ensure access for poor people and other vulnerable groups.

Not-for-profit organizations are also able to purchase quality-assured ACTs at the co-paid price. Furthermore, the AMFm draws on the extensive reach and experience of the not-for-profit sector in implementing supporting interventions, including delivering ACTs to poor people and rural residents.

Private for-profit (first-line) buyers are also able to purchase quality-assured ACTs at the ‘co-paid’ price through the AMFm.

Participating countries were able to request additional funding through the AMFm to assist public, not-for-profit and private for-profit sector organizations to implement supporting interventions.

## AMFm Phase 1

### What is AMFm Phase 1?

In November 2008, the Global Fund Board approved the first phase of AMFm (AMFm Phase 1). The Board decided that AMFm should be launched in a small group of countries, to enable lessons to be learned before a potential global roll-out of AMFm. The Board also agreed that AMFm Phase 1 will be assessed through an independent evaluation. The results of this evaluation will be used by the Board to decide whether to proceed to a global roll-out of AMFm.

### Which countries are participating in AMFm Phase 1?

AMFm Phase 1 is being implemented in nine pilots in eight countries:

- Cambodia, Ghana, Kenya, Madagascar, Niger, Nigeria, Tanzania (mainland and Zanzibar) and Uganda.

### When did AMFm Phase 1 start?

The first co-paid ACTs arrived in Ghana and Kenya in August 2010. AMFm co-paid ACTs have also been delivered to all other AMFm Phase 1 countries, with the exception of Cambodia, for which there is currently no eligible ACT. The exact delivery date for co-paid ACTs depends on when the orders are placed, quality control testing and manufacturer delivery times.

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<sup>5</sup> See the RBM ACT pricing fact sheet for further information on co-payment levels available online at: [http://www.theglobalfund.org/documents/amfm/RBM\\_ACT\\_Pricing\\_Fact\\_Sheet\\_en.pdf](http://www.theglobalfund.org/documents/amfm/RBM_ACT_Pricing_Fact_Sheet_en.pdf)

To support the scale-up of ACTs under AMFm, participating countries are implementing related supporting interventions.

### **How long will AMFm Phase 1 operate for?**

AMFm Phase 1 will operate until the end of 2012 and will be reviewed through an independent evaluation. The Global Fund Board will consider the results of the evaluation and determine whether to expand, accelerate, modify, terminate or suspend AMFm. It is expected that the Board will make this decision in late 2012.

### **What will be evaluated by the independent evaluation?**

The Independent Evaluation being commissioned by the Global Fund will yield important information about the potential value of the AMFm mechanism for future policy decisions. The evaluation will assess and document the implementation of the AMFm in each country and will distinguish two parts:

- (i) The upstream part, with emphasis on the business model of the AMFm as a financing platform (which includes the innovation of introducing a subsidy at the global level to reduce prices to the consumer); and
- (ii) The downstream part, with emphasis on service delivery to increase access to and use of ACTs, including by poor people (who are expected to benefit from lower prices that result from the upstream part).

The evaluation will assess and learn how and why the new AMFm business model unfolds in a variety of contexts while drawing lessons that can help future operations.

The following parameters will be explored and assessed:

- Availability of quality-assured ACTs in outlets across the public, private not-for-profit and for-profit channels;
- Affordability (price) of quality-assured ACTs to patients in outlets across the public, private not-for-profit and for-profit sectors;
- Access to and use of quality-assured ACTs, including among vulnerable groups, such as poor people, rural residents and children; and
- Market share of quality-assured ACTs relative to artemisinin monotherapies, CQ and SP.

Key indicators will be measured and compared before and after the AMFm, taking into account monitoring information, relevant contextual information and results from operational research that become available.

### **Who is conducting the Independent Evaluation and data collection and how?**

The Global Fund has completed a competitive tender process to identify the **Independent Evaluator**: a consortium led by Macro International Inc. (ICF Macro) with the London School of Hygiene and Tropical Medicine. The Independent Evaluator will prepare a report of the findings and recommendations from Phase 1 for consideration by the Global Fund Board.

Some of the data to be analyzed by the Independent Evaluator will include survey data collected by other agencies for other program evaluation purposes. In addition to this, to fill key information gaps, the Global Fund has engaged several Data Collection Contractors selected through a competitive process to implement baseline and endline survey work in AMFm countries, where needed. The three **Data Collection Contractors** are: Drugs for Neglected Diseases *initiative* for survey work in Ghana, Centre de Recherche pour le Developpement Humain for survey work in Niger and Population Services International (PSI) for survey work in Cambodia, Kenya, Madagascar, Nigeria, Tanzania (mainland), Uganda and Zanzibar. These Data Collection Contractors have implemented the baseline survey work and are conducting the endline work under the guidance of the Independent Evaluator. The resulting data will be fed into the analyses that the Independent Evaluator will perform as part of their assessment.

#### **What information is being collected on ACT sales prices?**

In addition to the data collected for the independent evaluation, the Global Fund has commissioned price-tracking studies that will provide information throughout 2011 and 2012 on the retail prices of ACTs in a number of participating AMFm Phase 1 countries. The studies are being carried out by HAI Africa on a bi-monthly basis in Ghana, Kenya, Madagascar, Nigeria, Tanzania and Uganda. The studies provide information on both the cost of ACTs co-paid by the AMFm in outlets and the cost of other, less-desirable antimalarials.<sup>6</sup>

#### **What ACT price levels have been observed so far in Phase 1 of the AMFm**

AMFm prices vary between countries, but less so within each country's formal and informal private sectors. Based on the price-tracking studies from mid- to end-2011, Kenya achieved the lowest AMFm adult AL median retail prices (6x4 tablets) across the private sector facilities surveyed. The highest retail prices were found in Nigeria and Uganda.

- **The availability of AMFm co-paid ACTs is high** (see successive rounds of the "Report of price-tracking surveys"). This is with reference to the duration of implementation. The report on Estimating Benchmarks of Success is relevant in discussing what might be expected after about one year of operations (available at <http://www.theglobalfund.org/en/amfm/>).
- **AMFm co-paid ACTs are far less expensive than originator brand ACTs** in all countries. They are also generally less expensive than the lowest-priced generic ACTs.
- **There is considerable price variation within countries**, particularly in Nigeria, Tanzania and Uganda. This may narrow with a combination of increased supply, public information campaign and marketing by the distributors.

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<sup>6</sup> The HAI Price Tracking Studies are available at <http://www.theglobalfund.org/en/amfm/>

- **The absolute availability of pediatric formulations is less than that of adult pack sizes.** This is predictable from the pattern of orders during 2010 and early 2011. It has been improved partly by efforts made to influence retail-level demand (through public information and interventions of health workers), which drives the pattern of orders placed by first-line buyers, and also by efforts to prioritize co-payment requests for pediatric formulations.

## AMFm Phase 1 applications

### Which countries were eligible to apply for AMFm Phase 1?

The following countries were invited to apply for AMFm Phase 1: Benin, Cambodia, Ghana, Kenya, Madagascar, Niger, Nigeria, Rwanda, Senegal, Tanzania (including Zanzibar) and Uganda.

These countries were selected based on the following criteria:

- High burden of *P. falciparum* malaria
- Moderate to high malaria mortality
- Experience with large-scale ACT deployment
- High private sector involvement in distribution of malaria treatment
- Strong monitoring and evaluation systems
- Community deployment or 'over the counter' sale of ACTs
- Existing or planned ACT subsidy schemes

### How did these countries apply for AMFm Phase 1?

These 12 eligible countries were invited to submit an application to the Global Fund, through their Country Coordinating Mechanism (CCM), to participate in AMFm Phase 1. The deadline for applications was **1 July 2009**.

### What did an AMFm application need to include?

Applicants were required to provide a detailed description of how the implementation of AMFm Phase 1 would be supported by in-country interventions. These interventions would be designed to ensure increased access to ACTs in the private and public sectors, with additional emphasis on reaching poor people.

The exact package of supporting interventions would need to be tailored to the specific conditions and priorities of each country while ensuring that patient demand for ACTs (in relation to other antimalarials) would be increased alongside the promotion of the proper use of ACTs. At a minimum, participating countries must implement the following supporting interventions:

- Public education and awareness campaigns regarding ACT effectiveness and affordability;
- Training, supervision and ongoing support for ACT providers;

- Planning for national policy and regulatory preparedness to ensure broad and safe access to ACTs;
- Planning for monitoring of drug quality, including pharmacovigilance, resistance monitoring and quality surveillance; and
- Interventions to reach poor people and other vulnerable groups.

Given that a number of these interventions were already underway in countries, applicants were required to explain how they were either already implementing or would implement these activities.

Countries were also encouraged to implement additional supporting interventions to improve malaria case management, such as expanding the use of diagnostics and introducing patient-friendly packaging.

Applicants were also required to explain their plans for monitoring AMFm Phase 1 and could propose operational research, in alignment with the Global Fund's AMFm Phase 1 Monitoring and Evaluation Framework.

### **How were AMFm Phase 1 applications reviewed?**

Applications to AMFm Phase 1 were reviewed by the Technical Review Panel of the Global Fund (TRP) at the same TRP meeting as Round 9 proposals were reviewed (July-August 2009), but in a separate process. In reviewing applications, the TRP had to be satisfied that an overall proposal, including supporting interventions, would enable the AMFm Phase 1 objectives of increasing availability and affordability of ACTs to be met, to the extent that is feasible within the Phase 1 period.

The TRP made funding recommendations to the Board according to three categories:

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

The Board considered the TRP's recommendations at its meeting in November 2009 and decided to approve ten applications for AMFm Phase 1:

- Cambodia, Madagascar, Niger, Tanzania (mainland), Zanzibar in Category 1: no TRP clarifications;
- Ghana, Kenya, Nigeria, Rwanda and Uganda in Category 2: pending successful TRP clarifications.

The TRP clarifications process took place following the Board meeting with a deadline for completion of 1 February 2010. Four out of five countries requiring the submission of technical clarifications to the TRP successfully completed the process. During the clarifications process, Rwanda withdrew its application to participate in AMFm Phase 1.

The following countries are implementing AMFm Phase 1:

- Cambodia, Ghana, Kenya, Madagascar, Niger, Nigeria, Tanzania (mainland and Zanzibar) and Uganda.

## Implementing AMFm Phase 1

### **What are the responsibilities of PRs and CCMs during implementation?**

The **Principal Recipient (PR)** of the AMFm ‘host’ grant is responsible for the timely and successful implementation of the host grant, including the AMFm supporting intervention plan, as specified in the general conditions of the grant agreement. The PR should report to the CCM on progress in program implementation and advise the CCM of any issues that may affect the successful implementation of the grant.

The **CCM** oversees the grant amendment process to ensure it is on track and facilitates technical support, if needed, in accordance with standard Global Fund processes and procedures. The CCM is also responsible for ongoing oversight of the host grant following the amendment process, including overseeing the implementation of AMFm supporting interventions.

### **What was the Grant Amendment process?**

For AMFm Phase 1, funds for supporting interventions are disbursed through existing, ‘host’ Global Fund malaria grants.<sup>7</sup> These host grants have been amended to incorporate the additional activities and required budget for AMFm supporting interventions. The reason for amending an existing grant, rather than negotiating a new grant for AMFm, is to streamline grant management for participating countries and to accelerate the disbursement of funds for supporting interventions.

The revised grant agreement includes a revised Face Sheet, Performance Framework, Budget and Workplan. Budgets in the Procurement and Supply Management (PSM) plan were amended if savings were identified in the ACT budget as a result of AMFm. The AMFm grant amendment process closely followed standard grant amendment processes.

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<sup>7</sup> A new grant agreement is expected to be required for Madagascar as the Country Coordinating Mechanism (CCM) proposed a new PR for the management of AMFm activities.

Funding for AMFm supporting interventions is requested and disbursed through the 'host' grant in accordance with standard Global Fund procedures for performance-based funding.

### **Was an LFA assessment of the PR required?**

If a country proposed an existing PR for AMFm, the LFA was requested to conduct an initial review to determine the incremental changes to the PR's responsibilities arising from the AMFm activities. If the country proposed a new PR for AMFm, this PR had to undergo a capacity assessment by the LFA.

## **Funding AMFm Phase 1**

### **How are AMFm activities paid for through the Global Fund?**

The AMFm is funded in two ways through the Global Fund. The AMFm co-payment towards the cost of ACTs, and the costs of Freight and Insurance is funded from a new, separate account held with the Global Fund's Trustee. This co-payment is paid directly by the Global Fund to manufacturers on behalf of first-line buyers (e.g., PRs, eligible private-for-profit and not-for-profit sector buyers, as described below). The Global Fund has received funding for the co-payment fund for AMFm Phase 1 from UNITAID, the United Kingdom's Department for International Development and the Bill & Melinda Gates Foundation. Donations to the co-payment fund total approximately US\$ 216 million, as of December 2011.

### **How much is the co-payment and how is it applied?**

The exact co-payment amount varies across different ACT combinations and finished ACT products. It is expected that once the co-payment has been applied patients will be able to purchase ACTs at a price lower than artemisinin monotherapies and competitive with less effective and inappropriate first-line treatments, such as CQ and SP. Please refer to the table on the following page.

**AMFm Maximum Prices and co-payment amounts**

Eligible ACT Product	Maximum Price (being the maximum acceptable supplier sales price under AMFm) per Course of Treatment FCA, in USD)		Co-Payment Amount (per Course of Treatment in USD) <sup>1</sup>	
	Hospital Pack	Individual Pack	Hospital Pack	Individual Pack
<b>Artemether Lumefantrine (20/120mg)</b>				
6x4	1.59	1.62	1.44	1.47
6x3	1.25	1.28	1.14	1.17
6x2	0.84	0.87	0.82	0.85
6x1	0.42	0.45	0.41	0.44
<b>Artemether Lumefantrine (20/120mg) dispersible</b>				
6x2	0.84	0.87	0.83	0.86
6x1	0.42	0.45	0.415	0.445
<b>Artesunate Amodiaquine Co-blister (50/153mg or 50/150mg)</b>				
12+12	0.78	0.81	0.59	0.62
6+6	0.42	0.45	0.32	0.35
3+3	0.24	0.27	0.18	0.21
<b>Artesunate Amodiaquine Fixed-dose Combination (2.7 AQ:AS ratio)</b>				
100/270mg 3x2	1.00	1.09	0.92	1.01
100/270mg 3x1	0.59	0.68	0.55	0.64
50/135mg 3x1	0.39	0.47	0.37	0.45
25/67.5mg 3x1	0.30	0.38	0.29	0.37

<sup>1</sup> With regard to the sales price quoted by a manufacturer (at or below the Maximum Price), the Global Fund reserves the right to adjust the co-payment such that the First-line Buyer will pay at least the following “Buyer Floor” prices for the products specified below:

AL 6x4: US\$ 0.08  
 AL 6x3: US\$ 0.04  
 AL 6x2: US\$ 0.02  
 AL 6x1: US\$ 0.01  
 AL dispersible 6x2: US\$ 0.01  
 AL dispersible 6x1: US\$ 0.005

For further information on the co-payment mechanism, please refer to the RBM fact sheet at the following link:

[http://www.theglobalfund.org/documents/amfm/RBM\\_ACT\\_Pricing\\_Fact\\_Sheet\\_en.pdf](http://www.theglobalfund.org/documents/amfm/RBM_ACT_Pricing_Fact_Sheet_en.pdf)

### **How are the supporting interventions funded?**

Funds for supporting interventions are provided through the existing Global Fund grant account held with the Trustee: the World Bank. Substantial savings have been generated from cheaper ACTs (co-paid by AMFm) in all Global Fund malaria grants with an unspent ACT procurement component. These savings are reallocated (or 'reprogrammed') within the grant budget to fund required supporting interventions and any additional approved supporting interventions. Funds for supporting interventions were estimated at US\$ 127 million.

As the scale of these savings varies from country to country, they did not constitute a funding 'ceiling' for supporting interventions and, if necessary, a country was able to request additional funding for supporting interventions. Countries were not requested to reallocate grant funds away from other malaria activities, such as long-lasting insecticide treated nets or indoor residual spraying.

Countries were **not required** to have unspent ACT funding that could be reallocated (or 'reprogrammed') in order to apply for AMFm Phase 1. Applicants with no expected savings in existing malaria grants were able to request full funding from the Global Fund for supporting interventions.

### **How does AMFm affect funding for other malaria interventions?**

Given that the AMFm co-payment on ACTs is financed through a separate account and that the majority of funding for supporting interventions is made available through savings gained in ACT procurement, AMFm will not reduce funding for other malaria interventions.

## **How to order AMFm co-paid ACTs**

### **Which ACTs can be co-paid under AMFm?**

The Global Fund has developed the following guidelines on ACT regimen and quality assurance for AMFm based on the technical recommendations of WHO. These guidelines are also designed to reflect the importance of country-based decision-making in the AMFm.

The Global Fund only makes co-payments for ACT combinations and regimens that meet all of the following criteria:

1. ACT combinations and, where specified, regimens listed in the latest version of WHO Guidelines for the Treatment of Malaria;

2. ACT combinations and, where specified, regimens currently listed in the national treatment guidelines of the country;
3. ACT combinations and, where specified, regimens which are authorized for use by the National Drug Regulatory Authority (or the relevant entity) in the country of use.

In order to include an ACT combination or regimen in AMFm that is listed in the national standard treatment guidelines but not in WHO standard treatment guidelines, or vice versa, countries were required to submit a technical rationale for this request, as part of their application to AMFm Phase 1. The rationale should have provided clear evidence that the requested combination or regimen is appropriate for use in the country. Applicants were recommended to seek the advice of WHO regarding the appropriateness of the requested ACT for use in their country and to submit this advice as part of their technical rationale.

The Global Fund only makes co-payments for finished ACT products that follow the guidelines above and also meet the Global Fund's Quality Assurance Policy (as approved by the Global Fund Board at its meeting in November 2008). In order to meet the Global Fund's Quality Assurance policy, a finished ACT product must be either WHO pre-qualified and/or authorized for marketing by a Stringent Drug Regulatory Authority (associated with the International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH)).

Products that have not yet been WHO pre-qualified or approved by a Stringent Drug Regulatory Authority must be evaluated and recommended for use by an independent panel of technical experts (the 'Expert Review Panel' or ERP), hosted by WHO's Department of Essential Medicines and Pharmaceutical Policies. This evaluation and time-limited recommendation will be based on criteria aligned with those of key technical partners, including WHO, UNITAID and UNICEF.

### **Which manufacturers are eligible to supply ACTs under AMFm?**

In order to be eligible to supply ACTs under the AMFm, a manufacturer must meet the criteria set out in the Global Fund's Quality Assurance Policy. In keeping with the AMFm objective of countering resistance to artemisinin, manufacturers must also commit not to market oral artemisinin monotherapies. Participating manufacturers sign a contract with the Global Fund which sets out the conditions of supplying ACTs under the AMFm. Eligible and signed-up manufacturers are currently Ajanta, Cipla, Guilin, Ipca, Novartis, Quality Chemical Industries and Sanofi-Aventis. This list will be updated as new manufacturers become eligible.

### **Which first-line buyers are eligible to purchase co-paid ACTs under AMFm?**

First-line buyers for AMFm may include national, regional and international buyers from the public, private not-for-profit and for-profit sectors who can purchase ACTs directly from the manufacturer, or through procurement agents buying on their behalf.

To be eligible to purchase ACTs under AMFm, first-line buyers must:

- Be registered with the national drug regulatory authority (NDRA) or the relevant national entity; and
- Sign a short, standard non-negotiable undertaking 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 AMFm;
  - 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, as appropriate.

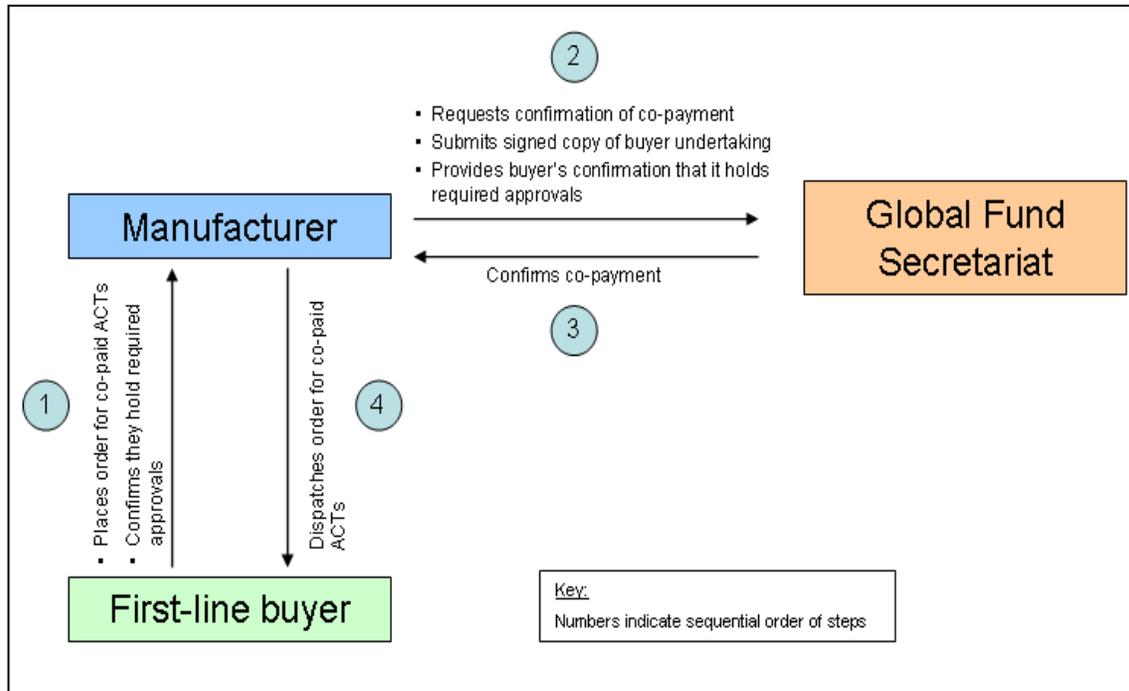
### **What is the process for ordering and paying for AMFm co-paid ACTs?**

The process for ordering co-paid ACTs through AMFm follows, as closely as possible, a buyer's normal process for ordering anti-malarial treatments from a manufacturer.

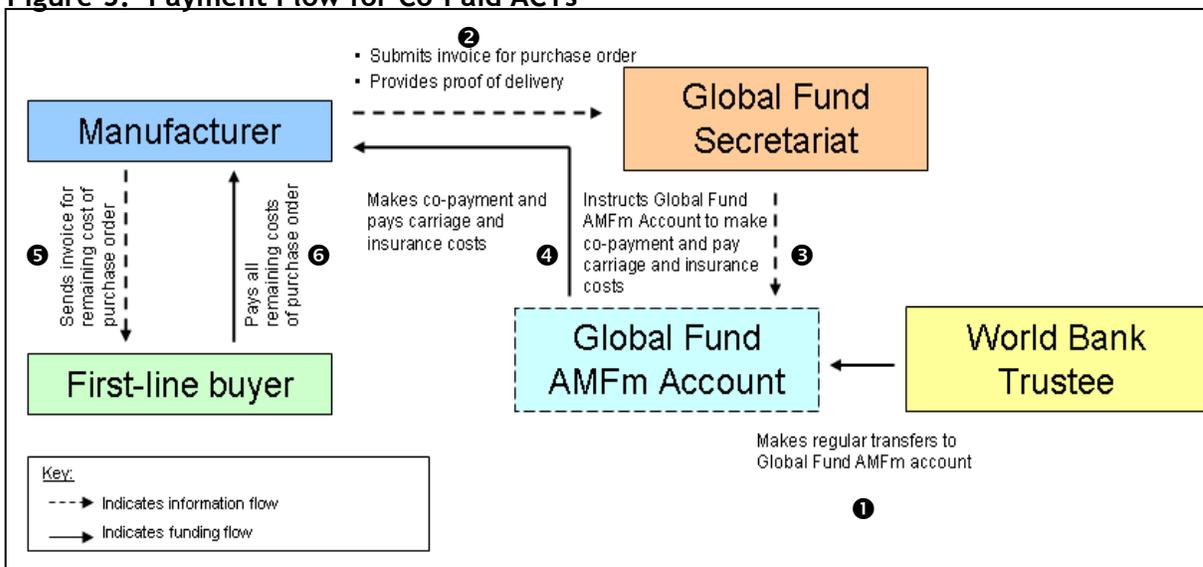
There are 4 key steps in the order process:

1. First-line buyer places the order with the manufacturer.
  - The *first* time a buyer places an order for co-paid ACTs they must also sign a standard, non-negotiable undertaking with the Global Fund (as outlined above).
  - The first-line buyer selects, following the applicable procurement policy, the manufacturer and places an order for co-paid ACTs.
  - For each order, the first-line buyer must provide written confirmation to the manufacturer that they hold all necessary licenses, waivers or other approvals to export, import, sell and/or distribute co-paid ACTs within the participating country.
2. The manufacturer forwards the order to the Global Fund.
  - This should include detail of the co-payment amount to be made and the estimated freight and insurance costs of the order.
  - The manufacturer must also provide written confirmation of the buyer's permission to buy (as stated above) and, at the time of a buyer's first order, the original copy of the buyer's signed undertaking (if not already provided directly to the Global Fund by the Buyer).
3. The Global Fund confirms that it will pay the co-payment, freight and insurance costs for the order.
  - The Global Fund will only issue the 'confirmation of co-payment' if all eligibility criteria are met, if there are sufficient assets available in the AMFm Co-Payment Fund and if there are no other reasons to reject the order.
4. The manufacturer confirms the order with the first-line buyer and proceeds with the order including arranging the delivery of the ACTs.

**Figure 2: Order Flow for Co-Paid ACTs**



**Figure 3: Payment Flow for Co-Paid ACTs**



## Policies and processes guiding AMFm

### What can Global Fund grant savings gained from purchasing ACTs through the AMFm be spent on?

As set out in the AMFm Phase 1 application form, participating countries firstly use any savings gained from the lower purchase price of ACTs to fund required supporting interventions and then additional supporting interventions. If any additional savings remained, countries were encouraged to return these to the Global Fund. Alternatively, countries were able to propose to use these remaining savings to fund additional ACT procurement and additional ACT-related activities to strengthen the health system.

### A Universal Logo for all Global Fund co-paid ACTs?

The Global Fund Board decided that all AMFm co-paid ACTs should bear a logo (the 'ACTm-leaf logo') to facilitate communication campaigns and product identification. The Global Fund has worked with partners to facilitate the design and development of this universal logo which is applied to all quality-assured ACTs purchased through AMFm. The use of a universal logo is in addition to the AMFm 'identifier'. The purpose of the logo will be to:

1. Enable the marketer/distributor to communicate the affordability and effectiveness of AMFm co-paid ACTs.
2. Enable providers, retailers, and end-users seeking treatment to easily recognize the quality-assured, affordable, AMFm co-paid ACTs.
3. Enable the independent evaluation to more easily collect data on affordability, availability, market share and use of co-paid ACTs.

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4. Facilitate the identification of those drugs that have leaked across borders to non-AMFm countries.

The logo design is available for use both on ACT packaging and in national level marketing campaigns.

**AMFm (ACTm-leaf) logo:**



**What is Voluntary Pooled Procurement, and can AMFm Phase 1 countries purchase co-paid ACTs through this mechanism?**

Voluntary Pooled Procurement (VPP) is a mechanism to enable Global Fund Principal Recipients to purchase core health products (including ACTs) through a pooled procurement service. Participating Principal Recipients will purchase these products through a procurement agent, who places orders with manufacturers, organizes delivery, ensures compliance with the Global Fund Quality Assurance Policy, inputs procurement data into the Price Quality Reporting Mechanism on their behalf and charges a fee for these services. (More information on the VPP can be found at the following link: <http://www.theglobalfund.org/en/procurement/vpp/?lang=en>)

Principal Recipients participating in AMFm Phase 1 may choose to purchase AMFm co-paid ACTs through the VPP procurement agent. Once registered as a first-line buyer for AMFm, the VPP procurement agent will be able to purchase ACTs on behalf of Principal Recipients at a much lower price than is currently available and therefore rapidly increase access to effective and affordable treatment. Principal Recipients will then benefit from both the lower price of AMFm and the supply and delivery conditions offered through VPP. Private sector first-line buyers will not be able to purchase AMFm co-paid ACTs through VPP.

**Will the AMFm co-pay both fixed-dose combination ACTs and co-blistered ACTs?**

In accordance with the Global Fund's Quality Assurance Policy for pharmaceutical products, the Global Fund will only make co-payments for ACTs that are either formulated as fixed-dose combinations or in a co-blistered package. However, based on WHO guidelines that express a preference for fixed-dose combinations and also

permit the use of co-blistered formulations, the Global Fund encourages countries to purchase ACTs in fixed-dose combination wherever possible, as this facilitates adherence to treatment regimes.

At its Nineteenth Meeting in May 2009, the Global Fund Board reiterated this position and noted that, pending WHO guidance on this issue, fixed-dosed combination ACTs are strongly preferable to co-blistered ACTs and may help to delay resistance to artemisinin. At its Twenty-third meeting in May 2011, the Global Fund Board adopted recommendations to expedite the transition to fixed-dose combination ACTs.<sup>8</sup>

### **How will the Global Fund's performance-based funding be applied to AMFm Phase 1?**

Any AMFm supporting interventions funded by the Global Fund will be subject to the Global Fund's established principles, policies and practices for performance-based funding. Participating countries are required to set out targets and indicators for AMFm supporting interventions, as part of the performance framework for the 'host' grant and against which the performance of the Principal Recipient will be measured. If a Principal Recipient purchases AMFm co-paid ACTs using funds from a Global Fund grant, they will be subject to the Global Fund's existing performance-based funding system.

Other first-line buyers that *are not* purchasing AMFm co-paid ACTs through a Global Fund grant will not be subject to the Global Fund's established performance-based funding system. However, they will be monitored by the Global Fund Secretariat for compliance with the conditions of participating in AMFm Phase 1. The Secretariat will also monitor manufacturers' compliance with the terms of their contracts. Further information about performance management of manufacturers and first-line buyers is provided in the *AMFm Phase 1 Policy*.<sup>9</sup>

### **What is the relationship between AMFm Phase 1 and rapid diagnostic test kits for malaria?**

The issue of whether to promote and include the wide-scale use of rapid diagnostic tests (RDTs) as part of the AMFm was examined in-depth by the Roll Back Malaria (RBM) Partnership before the Global Fund Board decided to host the AMFm (November 2008). Although RDTs will not be funded through the AMFm co-payment mechanism, the importance of expanding access to diagnostic tests is recognized, and countries that wished to support the use of RDTs alongside the AMFm were able to include this as a supporting intervention and to request funding through their AMFm application, subject to review by the TRP. Several countries did this, and in its review of AMFm applications, the TRP welcomed this as a sound approach to malaria case

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<sup>8</sup> See Decision Point GF/B23/DP22 of the Twenty-third Board meeting available at: <http://www.theglobalfund.org/en/board/decisions/>

<sup>9</sup> See Annex 1 (pages 11-20) of the November 2009 Report of the AMFm Ad Hoc Committee (GF/B20/7): [http://www.theglobalfund.org/documents/board/20/GF-BM20-07\\_Report\\_of\\_AMFm\\_Ad\\_Hoc\\_Committee.pdf](http://www.theglobalfund.org/documents/board/20/GF-BM20-07_Report_of_AMFm_Ad_Hoc_Committee.pdf)

management.<sup>10</sup> Based on recommendations by the TRP, the Global Fund Board approved AMFm applications in November 2009.

In the context of AMFm, RDTs (for expanded use and also for implementation research) are financed from funds for supporting interventions, not from the AMFm Co-payment Fund for ACTs. At least ten implementation research projects have been identified that are addressing the issue of scaling-up access to malaria diagnostics through the use of rapid diagnostic tests (RDTs). In addition, four AMFm Phase 1 countries have proposed research to be funded through their AMFm grants related to scaling-up access to malaria diagnostics in the private sector. These include: Ghana (private sector), Madagascar (through community-based agents), Nigeria (both public and private sectors) and Zanzibar (private sector).

WHO updated its guidelines in 2010 for the parasitological confirmation of malaria. Universal access to diagnostic tests will help limit the use of ACTs to only those with parasitemia. A large proportion of presumptive diagnosis and treatment of malaria takes place in the private sector. For example, in the Democratic Republic of Congo, the private sector dominates the market for antimalarials, distributing about 85.6% of all antimalarials. In Nigeria, the private sector accounts for about 95% of all antimalarials. These two countries alone account for about 36 percent of all estimated malaria cases in the WHO Africa Region in 2006. It is unlikely that formal public sector services will cover all cases of suspected malaria in the near-to-medium term. Therefore, universal access to diagnostics requires that all such cases in the private sector be tested with suitable diagnostic tests. Yet, knowledge of scalable approaches to doing so in the private sector is very limited. AMFm Phase 1 provides an opportunity to learn about scalable approaches before a potential global roll-out of the AMFm. According to the report of a Global Fund-WHO “Consultation on the economics and financing of universal access to parasitological confirmation of malaria”, 31 May - 1 June 2010 (Page 11):

“In the current context, financial architecture refers to the mechanisms and routes of resource flows to fund the RDT package. Unlike the global subsidy for ACTs, for which a single system (AMFm) was deemed optimal to operate globally, the optimum architecture of financing an expansion of RDTs from the status quo to universal access is unknown. It is not clear if an expansion (of access to RDTs and supporting interventions) is best done through multiple financial support systems, or if a single global pricing and financing mechanism would be required. The consultation brought out the modesty of collective knowledge on this point.”<sup>11</sup>

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<sup>10</sup> Report of the Technical Review Panel and the Secretariat on Applications to the First Phase of the Affordable Medicines Facility-malaria (AMFm Phase 1). GF/B20/10. Page 7.

<sup>11</sup> The report of the consultation is available at <http://www.theglobalfund.org/en/amfm/>

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### **What technical assistance is available to countries in implementing AMFm Phase 1?**

Following the support provided to countries during the development of AMFm Phase 1 applications, technical assistance is also available throughout implementation of AMFm Phase 1. Technical assistance is coordinated by the AMFm workstream of the Roll Back Malaria Harmonization Working Group, co-chaired by the World Health Organization (WHO) and the Clinton Health Access Initiative (CHAI).

### **Further Questions**

Further information on the AMFm is available on the Global Fund website at: <http://www.theglobalfund.org/en/amfm/>

If you have any further questions on the AMFm you may contact the AMFm Unit of the Global Fund through the following email address: [amfmconsult@theglobalfund.org](mailto:amfmconsult@theglobalfund.org).