

AFFORDABLE MEDICINES FACILITY – MALARIA

Frequently Asked Questions

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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 will facilitate the increased use of ACTs by **reducing the cost of these drugs** in malaria-endemic countries and also by ensuring that **additional activities** ('supporting interventions') are carried out 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 the global problem of 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.¹ The technical design of the AMFm was developed with guidance from the RBM Partnership's AMFm Task Force.²

Why is AMFm needed?

In 2008, approximately 243 million people fell sick with malaria and about 863,000 people died from the disease.³ 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.

¹ 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.

² The technical design is available online at:

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

³ 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 will enable 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 will AMFm work?

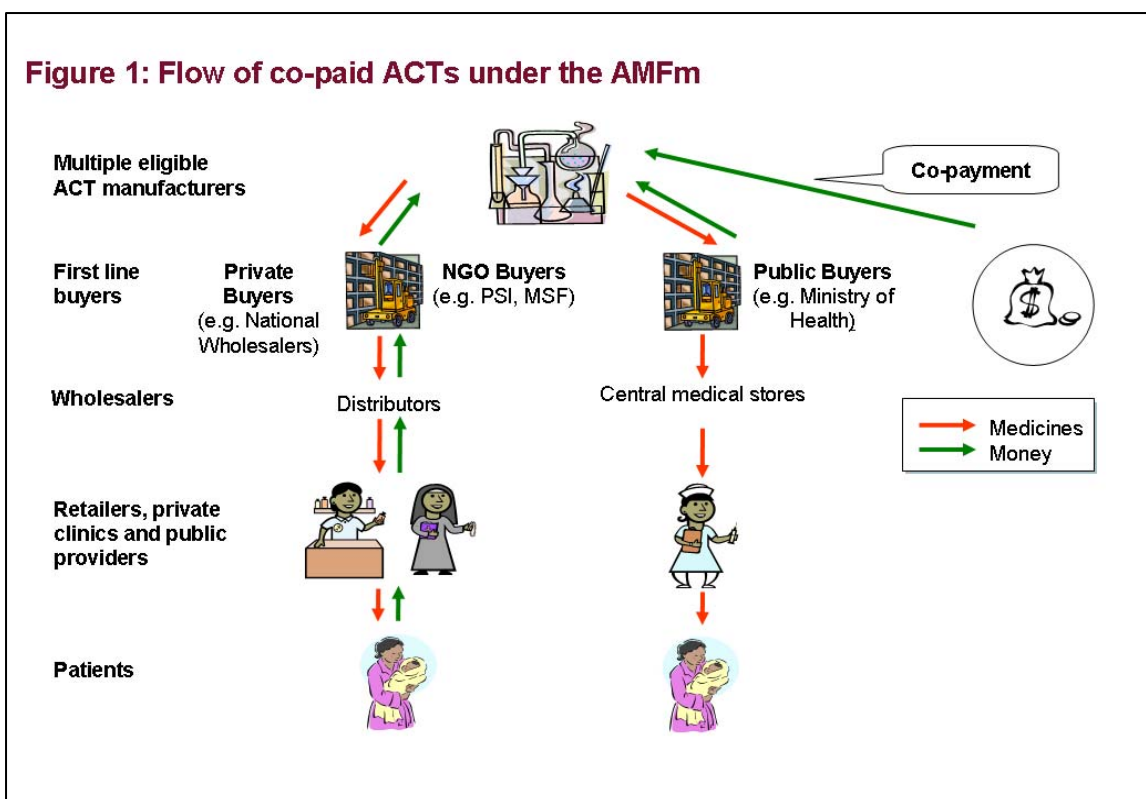
The objective of the AMFm is to ensure that people suffering from malaria have access to inexpensive, effective antimalarial treatment, in the form of ACTs. The AMFm will promote the use of effective antimalarials and drive out ineffective medicines from the market by: 1) reducing consumer prices to 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**.⁴ The Global Fund will pay 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 will be 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 competitive with that of less-effective anti-malaria drugs, such as CQ and SP. The AMFm has the potential to reduce the cost of ACTs to US\$0.20-0.50 for most patients who pay for treatment.

⁴ 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.

The flow of ACTs and payment is shown below in Figure 1.



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 encouraged, 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 will support 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 will benefit from AMFm by being able to purchase quality-assured ACTs at approximately US\$0.05 per treatment, rather than the current public sector purchase price of approximately US\$1.00. The public sector will also play 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 will be able to purchase quality-assured ACTs for approximately US\$0.05. Furthermore, the AMFm will draw 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 will also be able to purchase quality-assured ACTs for approximately US\$0.05 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 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

When does AMFm Phase 1 start?

AMFm co-paid ACTS cannot arrive in participating countries before 1 June 2010. Eligible first-line buyers in Phase 1 countries are expected to be able to place orders at earliest from May 2010. ACTs are expected to arrive in-country from August 2010. The exact date will depend on manufacturer delivery times.

Countries will also be able to begin implementing new or expanded supporting interventions for AMFm once the 'host' grant amendment has been signed. The grant amendment target of end April 2010 is intended to allow participating countries sufficient time to begin implementing supporting interventions in preparation for the arrival of co-paid ACTs and for baseline survey data to be collected.

How long will AMFm Phase 1 operate for?

AMFm Phase 1 will operate for approximately 24 months 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 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 the poor (which is 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 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.

In addition, the independent evaluation will:

- Examine ACT market dynamics (i.e. trends in, interactions among, and factors influencing demand, supply and price of ACTs); and
- Evaluate structural and functional options for the management and governance of a potential Phase 2 of the AMFm.

Who will conduct 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 survey work in AMFm countries, where needed. The three baseline **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, DRC, Madagascar, Nigeria, Kenya, Tanzania (mainland), Uganda and Zanzibar. These Data Collection Contractors will implement the survey work under the guidance of the Independent Evaluator, and the resulting data will be fed into the analyses that the Independent Evaluator will perform as part of their assessment.

AMFm Phase 1 applications

How did countries apply for AMFm Phase 1?

Eligible countries, through their CCM, were asked to submit an application to the Global Fund for AMFm Phase 1 by **1 July 2009**. The applications period is now closed.

What did an AMFm application need to include?

Applicants were required to provide a detailed description of how the implementation of AMFm 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 are already underway in countries, applicants were required to explain how they are either already implementing or will 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, 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.

Which countries will participate in AMFm Phase 1?

AMFm Phase 1 will be implemented in nine pilots in eight countries:

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

Implementing AMFm Phase 1

What will be the responsibilities of PRs and CCMs during implementation?

The Principal Recipient (PR) of the amended host grant is responsible for the timely and successful implementation of the 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 grant following the amendment process, including overseeing the implementation of AMFm supporting interventions.

What is the Grant Amendment process?

For AMFm Phase 1, funds for supporting interventions will be disbursed through an existing, 'host' Global Fund malaria grant.⁵ This host grant will be amended to incorporate the additional activities and required budget for AMFm supporting interventions. The objective of amending an existing grant, rather than negotiating a

⁵ 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.

new grant for AMFm, is to streamline grant management for participating countries and to accelerate the disbursement of funds for supporting interventions.

At the end of the grant amendment process, there will be an implementation letter amending the 'host' grant agreement. The revised grant agreement will include a revised Face Sheet, Performance Framework, Budget and Workplan. Budgets in the Procurement and Supply Management (PSM) plan will need to be amended if savings have been identified in the ACT budget as a result of AMFm. The AMFm grant amendment process closely follows standard grant amendment processes, with a target date of signing the amendment no later than 1 April 2010.

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

What are participating countries required to monitor through AMFm Phase 1?

Participating countries are required to monitor certain aspects of the implementation of AMFm Phase 1. Participating countries have lead responsibility for monitoring the progress of supporting interventions and making necessary adjustments during program implementation. In addition, countries will be requested to share reports regarding those supporting interventions that are not funded by the Global Fund so that this information may be taken into account in the independent evaluation.

Finally, participating countries are encouraged to undertake operational research regarding AMFm Phase 1, in order to generate knowledge that helps to resolve implementation problems, learn lessons, and test solutions related to AMFm implementation.

Is an LFA assessment required?

If a country has proposed an existing PR for AMFm, the LFA will be requested to conduct an initial review to determine the incremental changes to the PR's responsibilities arising from the AMFm activities. Based on this review and in consultation with the LFA, the Global Fund will determine if an LFA assessment of the PR is required. The Global Fund may recommend a waiver of the PR assessment, or may define the scope of a limited repeat PR assessment.

If the country has proposed a new PR for AMFm, this PR must undergo a capacity assessment by the LFA. The Global Fund, in consultation with the LFA, will decide on the scope of the assessment of the new PR.

Funding AMFm Phase 1

How will AMFm activities be paid for through the Global Fund?

The AMFm will be funded in two ways through the Global Fund. The AMFm co-payment towards the cost of ACTs will be funded from a new, separate account held

with the Global Fund's Trustee. This co-payment will be 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. The co-payment fund is estimated at US\$ 216 million.

Funds for supporting interventions will be provided through the existing Global Fund grant account held with the Trustee. It is also expected that substantial savings will be generated from cheaper ACTs (co-paid by AMFm) in all Global Fund malaria grants with an unspent ACT procurement component. These savings will be reallocated (or 'reprogrammed') within the grant budget to fund required supporting interventions and any additional approved supporting interventions. Funds for supporting interventions are estimated at US\$ 126.6 million. Of this, it is estimated that US\$ 98.1 million will be realized from savings gained from existing grants. A further US\$ 11 million will be provided from other sources. The incremental new funds for supporting interventions are about US\$ 17.5 million.

As the scale of these savings varies from country to country, they do 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 had the option of requesting full funding from the Global Fund for supporting 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 expected to be made available through savings gained in ACT procurement, AMFm will not reduce funding for other malaria interventions.

How much is the co-payment and how will it be 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, first-line buyers will be able to buy ACTs from manufacturers for an average price of approximately US\$0.05 per treatment course depending on formulation and weight pack size. This will then enable patients to purchase ACTs at a price comparable to those of less effective and inappropriate first-line treatments, such as CQ and SP.

AMFm Maximum Prices and co-payment amounts (as of 29 March 2010)

Eligible ACT Product	Maximum Acceptable Supplier Sales Price ¹ (per Course of Treatment, in US\$)		Co-Payment Amount ² (per Course of Treatment, in US\$)	
	Hospital Pack	Individual Pack	Hospital Pack	Individual Pack
Artemether Lumefantrine (20/120mg)				
6x4	1.40	1.43	1.21	1.21
6x3	1.11	1.14	1.00	1.00
6x2	0.74	0.77	0.67	0.67
6x1	0.37	0.40	0.33	0.33
Artemether Lumefantrine (40/240mg)				
3x4	1.40	1.43	1.21	1.21
3x3	1.11	1.14	1.00	1.00
3x2	0.74	0.77	0.67	0.67
3x1	0.37	0.40	0.33	0.33
Artemether Lumefantrine (20/120mg) dispersible				
6x2	0.74	0.77	0.68	0.68
6x1	0.37	0.40	0.34	0.34
Artesunate Amodiaquine Co-blister (50/153mg or 50/150mg)				
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
Artesunate Amodiaquine Fixed-dose Combination (2.7 AQ:AS ratio)				
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
<p>⁽¹⁾ Manufacturers may quote lower prices.</p> <p>⁽²⁾ The co-payment will always be less than the maximum acceptable supplier sales price (MSP) for a product. If the quoted MSP is equal to or less than the listed co-payment amount, the Global Fund reserves the right to adjust the co-payment.</p>				

Policies guiding AMFm

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 AMFm will co-pay 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 AMFm will only co-pay 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 to not market oral artemisinin monotherapies. Participating manufacturers will sign a contract with the Global Fund which sets out the conditions of supplying ACTs under the AMFm. Eligible manufacturers are currently Ajanta, Cipla, Guilin, Ipca, Novartis 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 will purchase ACTs directly from the manufacturer, or 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 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.
 - 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 carriage 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, carriage 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

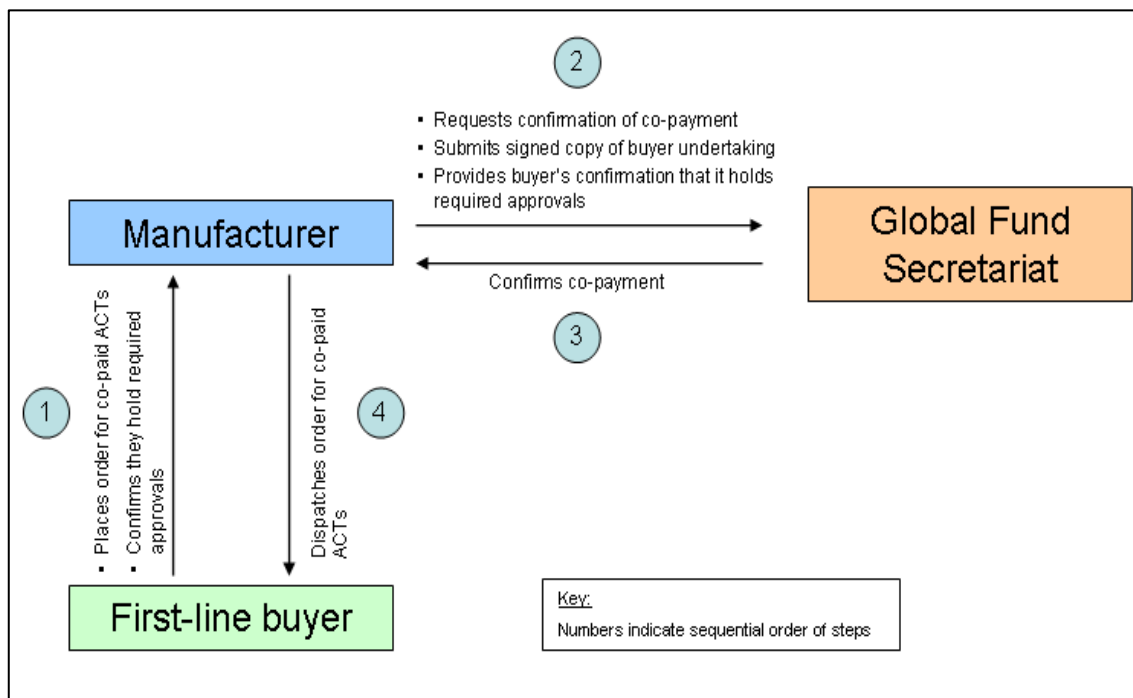
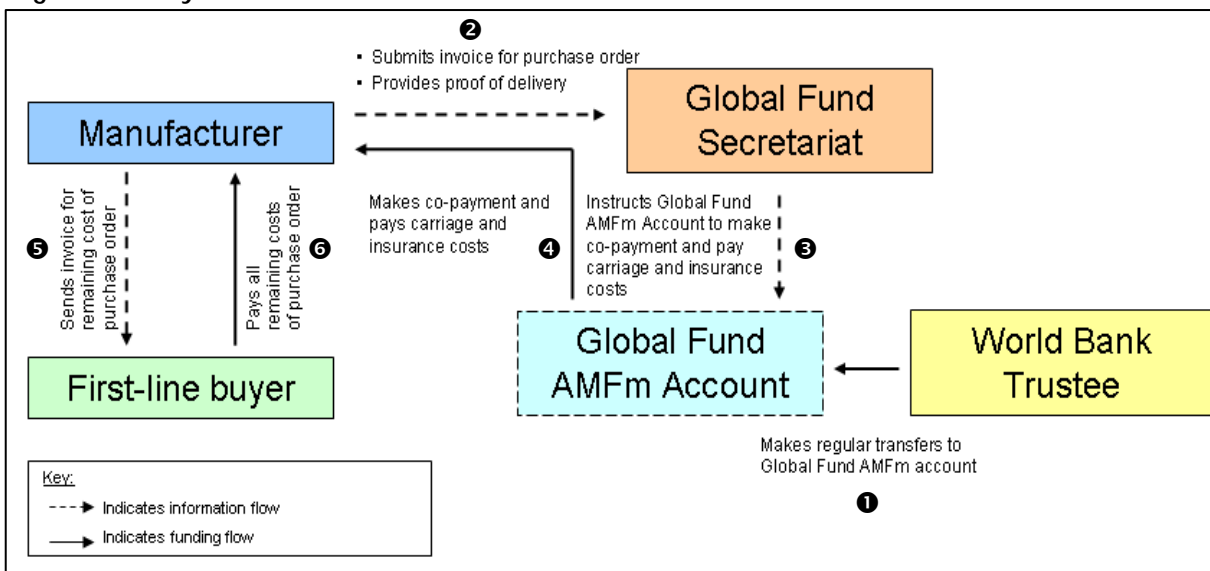


Figure 3: Payment Flow for Co-Paid ACTs



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 should firstly use any savings gained to fund required supporting interventions and then additional supporting interventions. If any additional savings remain, countries are encouraged to return these to the Global Fund. Alternatively, countries could 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 has decided that all AMFm co-paid ACTs should bear a logo (the 'universal logo') to facilitate communication campaigns and product identification. The Global Fund is working with partners to facilitate the design and development of this universal logo which will be applied to all quality-assured ACTs purchased through AMFm. The use of a universal logo will be 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.
4. Facilitate the identification of those drugs that have leaked across borders to non-AMFm countries.

It is anticipated that the logo design will be finalized and available for use both on ACT packaging and in national level marketing campaigns by end April 2010.

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 AMFm will co-pay 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.

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

Any AMFm supporting interventions that are funded by Global Fund will be subject to the Global Fund's established principles, policies and practices for performance-based funding. Participating countries will be required to set out the 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 manufacturer compliance with the terms of its contract. Further information about performance management of manufacturers and first-line buyers is provided in the *AMFm Phase 1 Policy*.⁶

Will the AMFm subsidize rapid diagnostic testing 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 has been debated at length for the past two years. 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. In its review of AMFm applications, the TRP welcomed this as a sound approach to malaria case management.⁷

Where the private sector has not yet been involved in the wide-spread use of RDTs, participating countries may firstly wish to undertake operational research to determine the best way to introduce RDTs into this sector. While such research is being undertaken, participating countries may wish to continue to scale-up their diagnostic capacity through other channels.

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 will also be available throughout implementation of AMFm Phase 1. This will be coordinated by the AMFm workstream of the Roll Back Malaria Harmonization Working Group, co-chaired by WHO and the Clinton Foundation.

Further Questions

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

⁶ 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

⁷ 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.