

Report of the AMFm Ad Hoc Committee

Todd Summers, Chair

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Eighteenth Board Meeting
New Delhi, India 7-8 November 2008



Affordable Medicines Facility – malaria

Agenda

1. AMFm Overview

2. Previous Decision Points on AMFm

3. AMFm Policy Framework and Implementation Plan

4. Summary of Committee Input and Country Consultations

5. Decision Point



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Overview

- **Objectives:**

- Increase access to ACTs via public, non-profit, and private sectors
- Delay emergence of resistance to artemisinin by displacing use of artemisinin monotherapies

- **Mechanism:**

- Negotiations with manufacturers to achieve reduction in price of ACTs, equivalent to or below the price available to public sector
- Co-payments to manufacturers based on the manufacturers' negotiated sales prices to further reduce cost of ACTs to first-line buyers and ultimately make end-user ACT prices equivalent to or lower than those of CQ and SP
- Incentivized distribution of ACTs through supply chain
- Supporting interventions for broad and safe reach of affordable ACTs
- Robust M&E package including internal M&E, OR and independent evaluation with continued oversight by Board



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Previous Decision Points

- **In November 2007, the Global Fund Board:**
 - Requested the Secretariat to prepare a business plan for hosting and managing the AMFm within the Global Fund
- **In April 2008, the Global Fund Board:**
 - Agreed for the Secretariat to prepare to host and manage the AMFm as a business line within the Global Fund
 - Requested the Secretariat to develop and present for Board decision in November 2008 the policy framework and implementation plan for managing the AMFm Phase 1
 - Agreed that the launch of AMFm should be phased, starting with a small group of countries (AMFm Phase 1)
 - Agreed that an independent technical evaluation of Phase 1 would determine expansion to global roll-out



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Policy framework

The AMFm Policy Framework encompasses:

- Manufacturer negotiations
- Country eligibility
- Country access
- Reaching the poor and vulnerable groups
- Monitoring, Independent Evaluation and OR
- Governance
- Implementation timelines for phasing in AMFm

The Policy Framework is further supported by the AMFm Phase 1 Policy



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Policy framework: Manufacturer negotiations

Objective: Reduce manufacturers' ACT sales prices and determine the level of co-payment in order to reduce the first-line buyer cost of ACTs

- **Eligibility:** Manufacturers must comply with Global Fund Quality Assurance criteria and agree not to market oral artemisinin monotherapies
- **Price negotiations:** Manufacturer prices negotiated based on competitive bids
- **Supply framework:** Non-price factors included in manufacturer negotiations and contracts (including buyer eligibility, payment of freight and insurance, taxation waivers, packaging requirements)
- **Contracts:** Define sales prices, co-payment level and supply framework
- **Responsibilities:** Negotiation agent will lead price negotiations, with guidance by the Co-payment Technical Advisory Group; UNITAID role in forecasting



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Policy Framework: Country Eligibility

Initial criteria recommended by WHO (yielded 25 countries; considered too many for Phase 1)

- High burden *P. falciparum* malaria
- Estimated moderate-to-high malaria mortality
- Multi-year experience with large scale deployment of ACTs

Additional criteria to further refine list of Phase 1 countries

- ACT subsidy experience
- Regulatory environment (OTC status or ACTs deployed at community level)
- High private sector coverage
- Strong M&E system

Country shortlist determined by the Ad Hoc Committee

- Benin, Cambodia, Ghana, Kenya, Madagascar, Niger, Nigeria, Rwanda, Senegal, Tanzania, Uganda



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Policy Framework: Country Access

Integrated application process for AMFm Phase 1:

- Access to the **AMFm co-payment** mechanism
- Funding for **supporting interventions**

Applications must include:

- A budgeted plan for AMFm supporting interventions, including sources of funding
- A statement of preparedness
- A link with holistic national malaria control plans
- An optional 'advance disbursement' request to enable rapid release of funds for supporting interventions



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Policy Framework: Reaching the Poor

- **Applications** must explain how countries will reach the poor and vulnerable groups:
 - Information, education and communication materials
 - Distribution strategies
- Countries may apply for funding for **supporting interventions** specifically designed to reach the poor, such as:
 - Community health workers
 - Social marketing
- RBM Task Force will provide **guidance on promising options** for reaching the poor
- **Monitoring and evaluation** will focus on population access to ACTs, including socio-economic quintile analysis where possible



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Policy Framework: Monitoring and Evaluation

M&E components

- In-country routine M&E
- Independent evaluation
- Operational Research

Initial set of evaluation questions

1. Has the ACT cost to patient been reduced at point of distribution to a price comparable to that of CQ and SP?
2. Has the proportion of ACTs relative to all anti-malarial treatments increased in the public and private sectors?
3. Has the AMFm mechanism helped increase anti-malarial treatment access for the poor?

Red flags

- Indicate a major fault or failure of AMFm Phase 1
- Derived from the M&E indicators



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Policy Framework: Governance

- **Pre-launch:** AMFm Ad Hoc Committee will continue to oversee the pre-launch preparations of AMFm Phase 1 up to the 19th Board meeting
- **Phase 1:** At 19th Board meeting, the Board will decide on the governance structure for oversight of the implementation of Phase 1
 - The Committee responsible for overseeing AMFm Phase 1 implementation will oversee the independent evaluation and advise the Board on its decision to proceed to global roll-out
 - RBM and UNITAID should be members of the Committee



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AMFm Phase 1 Policy

The AMFm is compatible with core Global Fund policies, including the Framework Document

- Where policy differences were identified, they have been treated as **temporary policy exceptions** given the experimental nature of AMFm Phase 1
- The **AMFm Phase 1 Policy** was developed to accommodate these differences
- The AMFm Phase 1 policy covers co-payment principles, financial principles, fiduciary arrangements, among other areas
- In the event of global roll out, a further policy review will need to be undertaken



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AMFm Financial Requirements

- **Resources required for launch:**
 - To cover ~ 290 million treatments
 - Co-payment: ~ USD 225 - 233 million for Phase 1 (2 years)
 - Supporting interventions: ~ USD 100-125 million (of which USD 80-120 million available from reprogramming)
- **Contributions to date:**
 - UK has pledged GBP 40 million
- **Market forecasting for resource mobilization**
 - UNITAID will lead ongoing market forecasting, working with manufacturers and technical partners



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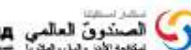
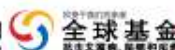
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Organization and budgetary requirements

Category	Description	End 2009 (USD Million)	End April 2011 (USD Million)
Personnel	9 new FTE	~1.4	~3.4
AMFm specific expenses	Including independent evaluation and multi-centric OR, negotiation agent, trust fund fees, consultant fees, legal fees, LFA costs, proposal and review costs, travel, IT, Secretariat support costs.	~5.2	~11.0
Total		~ 6.6	~ 14.4



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Summary of PSC and FAC inputs

Policy and Strategy Committee:

- Agreed that **no fundamental conflicts** exist with established core policies;
- Welcomed **close collaboration with technical partners**
- Noted that **countries not in the AMFm Phase 1** will continue to have access to ACT scale-up via existing Global Fund grant systems
- **Provided written input** to AMFm Phase 1 draft policy

Finance and Audit Committee:

- Noted resource mobilization efforts for AMFm will be **additional** to existing resource mobilization activities and that **UNITAID could be a major donor**
- Noted that the initiative should **complement existing Global Fund grants** by giving greater access to ACTs through the **private and NGO sectors**.



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Summary of country consultations

Consultations with 40 African countries, early 2008

- Countries welcomed AMFm as a multisectoral approach to achieving universal coverage of ACTs

AMFm Expert Consultation in Abuja, Nigeria in August 2008

- Countries welcomed AMFm as a means of expanding access to ACTs
- AMFm application process needs to be light
- AMFm launch date of first order placed in May 2009 is achievable

Consultations with proposed AMFm Phase 1 eligible countries, October 2008:

- Provided detailed information on how AMFm Phase 1 would operate within the Global Fund, including the application process
- Feedback from countries will help to shape the roll-out of AMFm
- Further consultations will be undertaken



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Summary of ACT Subsidy Pilot Schemes

Tanzania – CHAI Pilot Scheme (from 2007)

- ACT subsidy scheme, with supporting interventions implemented by PSI
- ACTs distributed through small drug shops

Results

- 44% of consumers purchase ACTs (up from less than 1%)
- Retail prices fell by roughly 95% - no evidence of price gouging, SRP adhered to
- Increased access in target districts – slower in rural areas but prices stay the same

Uganda – in partnership with MMV (from Sep 2008)

- ACTs procured by MMV and sold to wholesaler at 5% of normal sales price
- Supportive interventions program including OTC, SRP, Provider Training

Early Results

- For under-5s, increase of ACT use to 34% – CQ use cut by half
- For other age-groups, increase of ACT use to 28% - CQ use cut by half

No evidence of price-gouging



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Recommended decision point (1/2)

Decision Point X: Managing the Affordable Medicines Facility - malaria

1. The Board refers to its earlier decisions regarding the Affordable Medicine Facility – malaria (AMFm) (GF/B16/DP14 and GF/B17/DP16).
2. The Board approves the Policy Framework and Implementation Plan set out in the AMFm Ad Hoc Committee Report to the Board (GF/B18/7 – the “AMFm Report”) and reaffirms its decision to host and manage the AMFm for an initial phase (“Phase 1”) in a limited number of countries. The Board requests the Secretariat to begin operation of Phase 1 of the AMFm.
3. The Board requests the AMFm Ad Hoc Committee to continue to oversee the pre-launch preparations of AMFm Phase 1 in keeping with its current committee mandate up to the 19th Board meeting **(and authorizes it to make minor modifications to the Policy Framework and Implementation Plan)**. At the 19th Board meeting, the Board will decide on the governance structure for the oversight and performance monitoring of the implementation of Phase 1.



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Recommended decision point (2/2)

Decision Point X: Managing the Affordable Medicines Facility - malaria

4. The Board requests the Secretariat to commission an independent technical evaluation of the roll-out of the AMFm in the AMFm Phase 1 countries. The Board requests the committee with oversight of AMFm Phase 1 to review the findings of such an evaluation and to make a recommendation to the Board ~~at its last meeting in 2010~~ **on its completion (estimated for the fall of 2010)**, at which time the Board will determine whether to expand, accelerate, terminate or suspend the AMFm business line.
5. The Board acknowledges the work and support of the RBM Task Force, UNITAID and other partners and requests its partners to continue to support the development and implementation of AMFm.
6. **The budgetary implications of this decision amount to \$6,600,000 for pre-launch and 2009, which includes an allocation for 9 new positions.**



Backup



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 **El Fondo Mundial**
De la lucha contra el SIDA, la tuberculosis y la malaria

 **全球基金**
关注艾滋病、肺结核和疟疾

 **The Global Fund**
To Fight AIDS, Tuberculosis and Malaria

 **Le Fonds mondial**
De la lutte contre le SIDA, la tuberculose et le paludisme

 **Глобальный фонд**
для борьбы со СПИДом, туберкулезом и малярией

 **الصندوق العالمي**
لمكافحة الإيدز والتبؤ و الملاريا

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Country Access – Application Window Options

One application window - as per Board submission

- Application deadline mid-March 2009
- TRP Review with RCC Wave 6 applications in late April 2009
- Board approval & launch May 2009

Two application windows

- First application window – as above
- Second application window either:
 - Matches Round 9 if deadline extended to June 1 2009, or
 - Separate AMFm application deadline by May 2009
 - Convene special session of TRP + electronic Board approval for fast track implementation for second application window
- Allows second wave countries to access AMFm in August or September 2009



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Policy Framework: Implementation milestones

Dec 2008

- Invitation to apply for AMFm Phase 1

Mar 2009

- Deadline for submission of AMFm applications

Apr 2009

- TRP review with Wave 6 RCC

May 2009

- Approval by Global Fund Board and AMFm Launch

Jul 2009

- Baselines collected for evaluation

Jul 2010

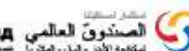
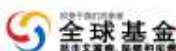
- Final data collection for evaluation

Nov 2010

- Board decision on global roll-out



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AMFm and the Framework Document

The AMFm is compatible with the Global Fund Framework Document

Purpose

- The AMFm is expected to attract, manage and disburse additional resources to make a sustainable and significant contribution to the reduction of illness and death caused by malaria

Principles

- Financing mechanism, not an implementing agency - **Principle A**
- Additional financial resources to fight malaria - **Principle B**
- Country-driven - **Principle C**
- Response to malaria treatment, accessible to all countries, pending approval of global roll-out - **Principles D and E**
- Involves independent technical review panel - **Principle F**
- Employs efficient disbursement mechanisms, drawing on existing Global Fund disbursement processes - **Principle G**
- Supports country applications that satisfy Global Fund funding requirements - **Principle H**



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USD 80-120M available for reprogramming

Rounds 1 – 7

- Max. USD 86 million available funding from reprogramming Round 1–7 grants in 11 eligible AMFm Phase 1 countries
- Min. USD 79 million if only largest grant per country is reprogrammed
- Based on predicted disbursed funds for ACTs

Round 8

- Max USD 34 million available funding for reprogramming from Round 8 grants
- Min USD 1 million available
- Assumes 75% of budgeted ACT funds will be disbursed during first 2 years and are therefore reprogrammable

Assumption

- 95% can be reprogrammed (as 5% of funds still needed by grantees for buying ACTs through AMFm)



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Organization and budgetary requirements

Category	Description and assumption	USD M for pre-launch and Phase 1 to 31 December 2009	USD M for pre-launch and Phase 1 to April 2011
Personnel costs	Pre-launch: 5 FTE Phase 1: 4 new FTEs (5 carried over from pre-launch)	~0.4 ~1.0	~0.4 ~3.0
	Sub-total: Personnel costs	~1.4	~3.4
AMFm specific expenses	<ul style="list-style-type: none"> • Legal counsel for manufacturer negotiations • Negotiation agent • Independent evaluation and multi-centric OR • Consultant fees • Trust Fund fees • Proposal and review costs • Local Fund Agent costs • IT • Travel expenses • Global Fund support functions including HR, Facilities 	~0.025 ~0.3 ~2.0 ~0.65 ~0.6 ~0.06 ~0.4 ~0.05 ~0.5 ~0.6	~0.025 ~0.3 ~6.0 ~0.65 ~1.1 ~0.06 ~0.8 ~0.05 ~0.6 ~1.4
	Sub-total: AMFm specific expenses	~5.2	~11.0
	TOTAL	~ 6.6	~ 14.4



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