

## Affordable Medicines Facility – malaria (AMFm)

Pre-Board Briefing for the  
Roll Back Malaria (RBM) Partnership Board  
13<sup>th</sup> May 2009

## Agenda

1. Introduction to AMFm Phase 1
2. November 2008 Global Fund Board decision point
3. Preparations for launch of AMFm Phase 1
4. May 2009 Global Fund Board decision point

## Why is AMFm needed?

- In 2006, approximately **250 million people contracted malaria** and nearly one million people died, mostly children (WHO, 2008)
- Malaria parasites increasingly **resistant to older, cheaper treatments**, such as Chloroquine (CQ) and Sulfadoxine-Pyrimethamine (SP)
- WHO recommends **artemisinin-based combination therapies (ACTs)** but they:
  - Are **unaffordable** compared with CQ and SP
  - Account for about **only 1 in 5** anti-malarial treatments taken
  - Have very **limited availability** in the private sector
- Furthermore:
  - Artemisinin monotherapies increase the **risk of resistance**



## What will AMFm achieve?

### Goal 1

- **Contribute to Malaria Mortality Reduction**

### Goal 2

- **Delay Resistance to Artemisinin**

These goals will be achieved by:

#### 1 – Increasing affordability of ACTs

- Price equivalent to or lower than CQ/SP

#### 2 – Increasing availability of ACTs

- Scale up through public, private, NGO sectors

#### 3 – Crowding out artemisinin monotherapies

- Decrease likelihood of artemisinin resistance

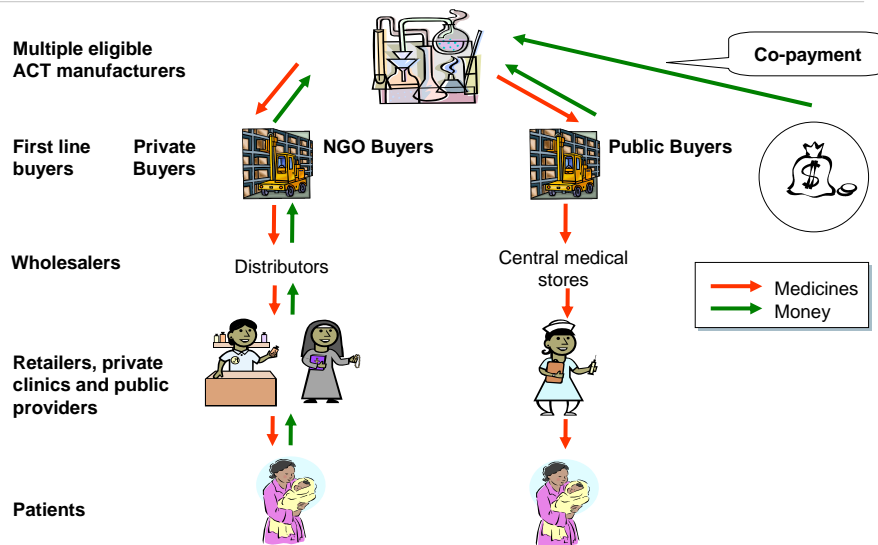


## How will AMFm work? (1/2)

- **Negotiations with manufacturers** to reduce price of ACTs
  - Same price to public and private sector buyers
- **Co-payments to manufacturers** to further reduce price of ACTs
  - Target price to first line buyers - \$0.05
- **Supporting interventions** to ensure safe and effective ACT scale-up
  - Public education and awareness campaigns
  - Training, monitoring and supervision for ACT providers
  - Planning for national policy and regulatory preparedness
  - Planning for monitoring of drug quality
  - Interventions to reach poor people and other vulnerable groups



## How will AMFm work? (2/2)



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## Previous decision point

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- **In November 2008, the Global Fund Board:**
  - Approved the Policy Framework and Implementation Plan and reaffirmed its decision to host and manage the AMFm for an initial phase ("Phase 1") in a limited number of countries
  - Requested the Secretariat to begin operation of Phase 1 of the AMFm
  - Requested the AMFm Ad Hoc Committee to continue to oversee the pre-launch preparations of AMFm Phase 1 up to the 19th Board meeting
  - Agreed that it would decide on the governance structure for the oversight and performance monitoring of the implementation of Phase 1 at its 19th meeting
  - Requested the Secretariat to commission an independent technical evaluation of the roll-out of the AMFm in the Phase 1 countries
  - Requested the committee with oversight of AMFm Phase 1 to review the findings of such evaluation and to make a recommendation to the Board on its completion (estimated for the second half of 2010), at which time the Board will determine whether to expand, accelerate, terminate or suspend the AMFm
  - Acknowledged the work and support of the RBM Task Force, UNITAID and other partners and requested its partners to continue to support the development and implementation of the AMFm



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## Preparations for launch of Phase 1

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- Key areas of activity:
  1. Country access and applications, including timelines
  2. Manufacturer negotiations (including Co-payment Strategy)
  3. Monitoring and evaluation
  4. Resource mobilization and funding supporting interventions

## Country access and applications

Eligible Phase 1 countries:

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



## Country access and applications

### Gathering country views and input

- Individual consultations
  - Conducted by Global Fund Secretariat with other partners
- AMFm Consultative Workshop – Nairobi, 12-14 February
  - Organized by RBM Harmonization Working Group (coordinating technical support for AMFm applications)
  - Key discussion points: private-public sector coordination, safety and the regulatory status of ACTs, scope of supporting interventions, potential roles and economic viability of local ACT manufacturers
- Input received informed AMFm application form and policy decisions
- Call for applications issued 20 March

## Country access and applications timeline

Date	Milestone
1 July 2009	AMFm Phase 1 applications due
July 2009	Screening by Global Fund Secretariat
Late August/ early September 2009	Technical Review Panel assessment, in conjunction with Round 9 applications
Late September 2009	TRP report submitted to the Board
November 2009	Board vote on TRP recommendations
January 2010	Grant amendment for AMFm Phase 1 (target) <ul style="list-style-type: none"> <li>• Supporting interventions begin</li> <li>• Confirmed orders of co-paid ACTs</li> </ul>



## Co-payment strategy

- Secretariat constituted and sought advice from Co-payment Technical Advisory Group (CTAG), followed by former RBM AMFm Task Force
- Co-payment guiding principles:
  - ACT prices comparable to CQ and SP
  - Monotherapies replaced by ACTs
  - Minimal disruption to current business practices, preserve competition
- Key elements of strategy:
  - Price for ACT combinations negotiated with manufacturers on individual basis, to account for varying cost structures and encourage firms to enter market. Maximum price linked to most efficient known cost structure.
  - Prices renegotiated at least once per year
  - Fixed co-payment for each ACT formulation from a particular manufacturer
  - Preferential co-payments to favor fixed-dose combination over co-blistered ACTs
  - Targeted first-line buyer price is about US\$0.04-0.06
  - Global Fund Secretariat to monitor and take corrective actions, if needed
- Co-payment Strategy informs negotiations with manufacturers



## Fixed-dose combination or co-blistered ACTs

- WHO currently allows both FDC and co-blistered ACTs
- Under policy framework and implementation plan approved at 18<sup>th</sup> Board meeting, AMFm will co-pay for both FDC and co-blistered ACTs
  - All co-paid ACTs must meet Global Fund QA Policy
- Consensus that FDC products are preferable
  - AMFm application guidelines encourages use where possible
  - Global Fund should explore opportunities to support transition to FDCs
  - Co-payment strategy favors FDCs over co-blistered products
- Co-payment of co-blistered products will be updated as and when needed to comply with guidelines from the WHO and Global Fund QA Policy
- Secretariat will track effects through in-country monitoring, operational research and independent evaluation



## Monitoring and evaluation

### Independent Evaluation

- The Board will consider the results of the Independent Evaluation when deciding whether to proceed to global roll-out of AMFm
- The main assessment parameters of the independent evaluation are:
  - **Availability** of artemisinin-based combination therapy (ACTs) in outlets across the public, NGO and private sectors
  - **Affordability** of ACTs to patients in outlets across the public, NGO and private sectors
  - **Market share** of ACTs relative to monotherapies
  - **Use** of and access to ACTs by vulnerable groups of interest
- In addition, the independent evaluation will:
  - Examine ACT market dynamics (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



## Monitoring and evaluation

### Monitoring and Evaluation Framework

- Draft M&E Framework has been developed
  - Undergoing expert review by RBM MERG and Ad Hoc Committee
  - Will be discussed in detail with countries during M&E workshop (Dar-es-Salaam, 10-11 June 2009)
  
- Sets out approach to:
  - Monitoring supporting interventions
  - Operational research (including country specific and multi-country research)
  - Independent evaluation of AMFm Phase 1
  
- Establishes 'red flags' for AMFm Phase 1



## Updated timeline for independent evaluation

Event	Previous timeline	New timeline
Board approval of applications	May 2009	November 2009
Baseline data collection for independent evaluation	June-August 2009	November 2009 – January 2010
Grant signature (target) <ul style="list-style-type: none"> <li>• Supporting interventions begin</li> <li>• Order co-paid ACTs</li> </ul>	July 2009	January 2010
End point data collection for independent evaluation	June-August 2010	November 2010 – January 2011
Board decision on global roll-out	November 2010	November 2011 (Possibly May 2011?)



## Resource mobilization

- Resources required for **ACT co-payments** estimated at US\$225-233 million
- UK pledged GBP £40 million
- UNITAID pledged up to US\$130 million
- The Netherlands considering a financial contribution of €10 million
- Secretariat undertaking additional resource mobilization
  - Requesting \$20 million from Gates Foundation
  - Others to be explored
- Expected that adequate funds will be pledged before Board decision on AMFm applications



## Funding supporting interventions

- AMFm supporting interventions funded from savings in existing ACT budgets
  - Will not divert funds from other activities
  - Will not divert funds from public to private sector
  - Will not reduce existing grant targets
- If savings insufficient, countries may request funding for supporting interventions through Global Fund Trust Fund
- If countries have 'excess' savings in their ACT budgets, they are encouraged to return these to Global Fund
- Alternatively, 'excess' savings may be reallocated to:
  1. Additional ACT procurement through public sector
  2. Additional ACT-related HSS activities



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## May 2009 GF Board decision point

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- Notes that it will vote on the AMFm Phase 1 proposals at its 20<sup>th</sup> meeting in Nov 2009
- Decides to maintain AMFm Ad Hoc Committee as a separate committee of the Board throughout Phase 1
- Confirms that the TERG will provide guidance with regard to the technical parameters of the design of the Independent Evaluation of AMFm, under the oversight of the AMFm Ad Hoc Committee
- Confirms that the Global Fund Secretariat will continue to have responsibility for commissioning of the independent evaluation, under the oversight of the AMFm Ad Hoc Committee

## May 2009 GF Board decision point (contd.)

- Notes pending WHO guidance that FDCs are strongly preferable to co-blistered ACTs and may help to delay resistance to artemisinin. The Board also notes that multiple technical issues need to be taken into account to ensure a smooth transition to an exclusive use of FDC ACTs. Urges that WHO expedite finalization of this guidance on FDCs and co-blistered ACTs
- Requests its Chair to delegate to the relevant committee(s) the tasks of identifying and considering options for the Global Fund, within its mandate as a financing institution, to support countries in expediting the transition to FDCs, taking into consideration the implications for quality, supply, pricing and appropriate use of ACT, and to report back to the Board at its 20<sup>th</sup> meeting



## Next steps for AMFm Phase 1

Date	Milestone
1 July 2009	AMFm Phase 1 applications due
Aug/ Sept 2009	Technical Review Panel assessment
Nov 2009	Board vote on TRP recommendations
Nov 2009 – Jan 2010	Baseline data collection for independent evaluation
Jan 2010	Grant amendment for AMFm Phase 1 (target)
March 2010	Co-paid ACTs expected to arrive in country
Nov 2010 – Jan 2011	End point data collection for independent evaluation
Nov 2011 (or May 2011?)	Board decision on global roll-out



## Supplementary slides

## History of AMFm

Date	Milestone
2004	US Institute of Medicine published report 'Saving Lives, Buying Time'
Early 2007	RBM Task Force created to lead development of AMFm project
November 2007	RBM Board endorsed the AMFm design
February 2008	RBM Executive Committee endorsed Task Force report on recommendation to Global Fund to host and manage AMFm
April 2008	Global Fund Board agreed to prepare to host and manage the AMFm as a new business line
May 2008	RBM Board asked Task Force to continue to work with Global Fund on outstanding implementation challenges
November 2008	Global Fund Board approved AMFm Phase 1 policy framework and implementation plan, requested Secretariat to begin operation of Phase 1

## 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



## Grant amendment

- Funding for supporting interventions disbursed through existing Global Fund malaria grant
  - Streamline negotiations and management for countries
  - Accelerate disbursement of funds for supporting interventions
- ‘Host’ grant amended to incorporate budget and performance framework for supporting interventions
  - Amended within two months of Board approval



## Funding supporting interventions

Under Decision Point **GF/B18/DP7**, the Board approved the Policy Framework and Implementation Plan set out in the AMFm Ad Hoc Committee Report to the Board (GF/B18/7 – the “AMFm Report”).

### GF/B18/7 – the “AMFm Report”

- “Essential supporting interventions are estimated to cost in the order of USD 100-125 million. Countries can fund these interventions using their own resources, support from other donors, or by seeking assistance from the Global Fund. **To the extent that new Global Fund resources are provided for these interventions, they will be drawn from the existing Global Fund Trust Fund.**” (page 3)
- “The cost of supporting interventions for Phase 1 of the AMFm is estimated in the order of USD 100-125 million. **Essential supporting interventions included by countries in their roll-out plans for AMFm in Phase 1 may be financed through grants in line with regular Global Fund procedures** or through finance provided by other donors. It is expected that a significant portion of the finance required for supporting intervention grants would come from reprogramming grant resources which would be released as PRs get access to co-paid ACTs.” (page 18)



## Funding supporting interventions

Under Decision Point **GF/B17/DP16**, the Board agreed to have the Secretariat prepare to host and manage the AMFm as a business line within the Global Fund based on the AMFm design and business plan set out in the Secretariat Report to the Policy and Strategy Committee (GF/PSC9/03).

### GF/PSC9/03 – PSC paper on AMFm (the AMFm “business plan”)

- “Roll out plans with supporting interventions would be financed through either reprogramming of existing Global Fund grants or **through new Global Fund grants** (depending on whether countries have existing Global Fund ACT grants) and by other donors (including foundations, bilateral donor agencies and multilaterals).” (page 12)
- “**Countries without reprogrammable Global Fund grants would need either to identify funding through other resources and/or to submit new applications for supporting intervention funding to the Global Fund through its existing funding channels.**” (page 13)
- “It is estimated that US\$ 1.1 -1.4 billion would be needed to finance co-payments made by the AMFm over the first five years of operation. An additional estimated US\$ 400 - 500 million would be required for supporting interventions to roll out the AMFm over five years, of which an estimated US\$145 -180 million could be covered through reprogramming of freed up resources from ACT budgets in existing Global Fund grants as outlined above. **The remaining US\$ 220 - 355 million would come from existing resources for financing Global Fund grants.**” (page 15)



## ACT budgets in current or approved grants (at April 2009)

- Estimates as at April 2009, based on current or approved grant amounts, subject to change based on procurement activity
- Total = Approx. \$187.5 million [Not transferrable across countries]
- Chart shows 95% of total = Approx \$178.2 million [Not transferrable across countries]

