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

Affordable Medicines Facility – malaria (AMFm)

Todd Summers, Chair, AMFm Ad Hoc Committee

Eyitayo Lambo, Vice-Chair, AMFm Ad Hoc Committee

IMPORTANT INFORMATION
Decisions in this presentation may have been amended after the presentation was given. For the final approved decision please refer to the final decisions document on the Global Fund website:
http://www.theglobalfund.org/en/board/meetings/nineteenth/

Agenda

1. **Overview of AMFm**
2. Previous decision point
3. Update on workstreams and preparation for launch
4. Decision point

AMFm goals

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

AMFm design and implementation

- **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 – Approximately $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

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Previous decision point

- **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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Updated timeline

Event	Previous timeline	New timeline
Applications due	15 March 2009	1 July 2009
Board approval	May 2009	November 2009
Grant signature (target)	July 2009	January 2010
Baseline data collection for independent evaluation	June-August 2009	November 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?)

Country access and applications

Application Form

- AMFm application form released 20 March
- Simpler than usual, and rigorous
  - Focused on essential information
  - Robust enough for TRP to make funding recommendation
- Developed through broad, consultative process
  - Input from eligible countries, technical partners, Ad Hoc Committee

Co-payment strategy

- Secretariat constituted and sought advice from Co-payment Technical Advisory Group (CTAG), and from key stakeholders through former RBM Task Force on AMFm
- 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
  - Secretariat to monitor and take corrective actions, if needed
- Strategy informs negotiations with manufacturers

Fixed-dose combination or co-blistered ACTs

- Recent discussion and debate regarding fixed-dose combination (FDC) and co-blistered ACTs within the Ad Hoc Committee and among external partners
- WHO currently endorses both FDC and co-blistered ACTs
- Under policy framework and implementation plan approved at 18th 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 FDC
- Multiple technical issues to be considered:
  - Not all ACTs currently available in FDC (eg. AS+MQ), with impact on country choice
  - Risks of supply disruption
  - Inadvertent creation of monopolies for certain formulations
  - Inadvertent biases towards products of lower quality

Monitoring and evaluation

Monitoring and Evaluation Framework

- Draft M&E Framework developed
  - Sets out approach to monitoring, operational research and independent evaluation of AMFm Phase 1

Independent Evaluation

- Ad Hoc Committee will oversee independent evaluation of Phase 1 and report to the Board on its conclusions
  - Committee will seek guidance from TERG on evaluation
- Secretariat will commission independent evaluation
  - Independent Expert Advisory Group to advise Secretariat on evaluation design and technical quality of products from evaluation
  - RFP for evaluator being prepared (target contract award September 2009)
  - The Committee expressed concern that establishing another advisory group on evaluation may lead to confusion, but has left to the Secretariat the decision on whether and how to seek its own counsel in this area as commissioner of the evaluation

Resources available for co-payment

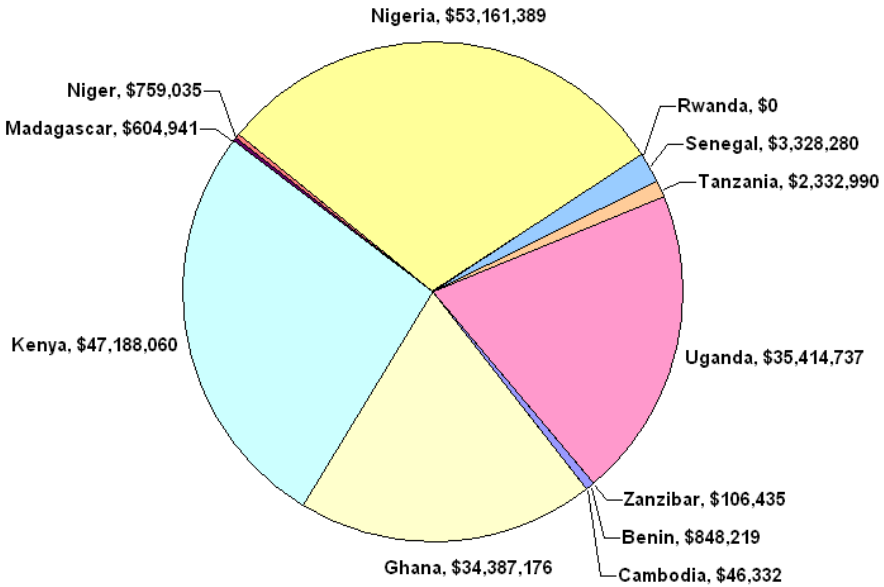
- Resources required for ACT co-payments estimated at US$225-233 million
- UK pledged GBP £40 million
- UNITAID pledged up to US$130 million
- The Netherlands considering a financial contribution of €10 million
- Secretariat undertaking additional resource mobilization
  - Requesting $20 million from 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
  - Set out in GF/B18/7 (the 'AMFm Report'), approved under Decision Point GF/B18/DP7
  - Also set out in GF/PSC9/03 (the AMFm 'business plan'), approved under Decision Point GF/B17/DP16

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
- Chart shows 95% of total = Approx $178.2 million



Use of ‘excess’ savings

- 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

AMFm Phase 1 Governance

- Three Decision Points

1. PSC recommends continuation of AMFm Ad Hoc Committee (AHC) for Phase 1 period (and AHC agrees)
2. AHC recommends committee TORs (with possibility for revising TORs)
3. Board Chair and Vice Chair recommend:
   - AHC membership and leadership will be renewed at same time as other committees
     - Membership is 10 voting members + WHO, RBM, UNITAID
   - Professor Lambo to fill AHC Chair vacancy as acting chair until membership renewed
   - UNITAID Board invited to hold AHC Vice Chair role
     - Appointment of UNITAID representative subject to approval of new Board Chair and Vice Chair and new AHC Chair

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Ad Hoc Committee Decision Point (1/4)

[Marked changes represent the proposed amendment by the Board Chair and Vice Chair, following consultation with the current leadership of the AMFm Committee.]

The Board recalls its decision regarding the Affordable Medicine Facility – malaria ("AMFM") (GF/B18/DP7).

The Board notes that it will vote on the AMFm proposals at its Twentieth meeting. The Board understands that the independent evaluation of AMFm Phase 1 is now estimated to be completed in the second half of 2011.

The Board decides to maintain the AMFm Ad Hoc Committee as a separate committee of the Board for the duration of the AMFm Phase 1 period with the terms of reference set out in Annex 1 to the Report of the AMFm Committee (GF/B19/7).

Ad Hoc Committee Decision Point (2/4)

~~*The Board approves the appointment of Professor Eyitayo Lambo as Chairof the AMFm Committee requests the Board Chair to invite the UNITAID Board to nominate a suitable representative to serve as Vice-Chair of the AMFm Committee. The appointment of the UNITAID Board representative shall be subject to the approval of the Board Chair and the AMFm Committee Chair.*~~

~~*The Board also approves the inclusion of the Private Foundations delegation as additional member of the AMFm Committee, and approves the inclusion of representatives of Roll Back Malaria and the World Health Organization as non-voting members of the Committee.*~~

The Board confirms that the Technical Evaluation Reference Group (TERG) will provide guidance with regard to the technical parameters of the design of the independent evaluation of the AMFm, under the oversight of the AMFm Ad Hoc Committee. Consistent with its previous decisions, the Board confirms that the Secretariat will continue to have responsibility for commissioning of the independent evaluation, under the oversight of the AMFm Ad Hoc Committee.

Ad Hoc Committee Decision Point (3/4)

The Board notes pending WHO guidance that fixed-dosed co-formulations (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. The Board urges that WHO expedite finalization of this guidance on FDCs and co-blistered ACTs.

The Board requests its Chair to delegate to the relevant committee(s) the task 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 ACTs, and to report back to the Board at its Twentieth meeting.

<u>This decision does not have material budgetary implications.</u>

Ad Hoc Committee Decision Point (3/3)

Annex 1 – Revision 1

AMFm AD HOC COMMITTEE – TERMS OF REFERENCE

The AMFm Ad Hoc Committee is an ad hoc committee of the Board established for the sole purpose of overseeing and advising the Board on the development, launch, implementation and evaluation of the first phase of the Affordable Medicine Facility for Malaria (AMFm).

Terms of Reference

The committee shall be composed of 10 voting members + WHO + RBM + UNITAID.

The committee shall have the following responsibilities:

- Oversee the preparations for launch of the AMFm Phase 1, review reports provided by the Secretariat and provide guidance to the Secretariat
- Advise the Board on critical strategic and policy matters related to AMFm Phase 1
- Provide regular updates to the Board on progress
- Oversee the independent evaluation of AMFm Phase 1 and report the findings to the Board
- Based on the results of the independent evaluation, make recommendations to the Board on whether to expand, accelerate, terminate or suspend the AMFm business line

In fulfilling these responsibilities the committee will have regard to the Principles for AMFm Policy Framework, Implementation and Business Plan set out in the Board's decision at the Seventeenth Board Meeting (GF/B17/DP16).

The committee shall report directly to the Board and shall consult with other committees as appropriate in developing its recommendations and advice to the Board.

Board Chair's Decision point

1. On the recommendation of the Board Chair and Vice Chair, the Board makes the following decisions with respect to the AMFm Ad Hoc Committee leadership and membership.

2. The Board decides that, in order to enable the new Board leadership to ensure appropriate balance, the leadership and membership of the AMFm Committee shall be renewed at the same time as all the other committees of the Board. The Board clarifies that the membership of the AMFm Committee is 10 voting members, plus representation by WHO, RBM and UNITAID.

3. The Board notes that the AMFm Committee Chair is resigning and approves the appointment of Professor Eyitayo Lambo as acting Chair of the AMFm Committee pending renewal of committee leadership and membership.

4. The Board notes that UNITAID has requested a role in the governance of AMFm. Recognizing UNITAID as a key partner in support of AMFm, the Board decides, as a one-time exception to the Committee Rules and Procedures and without setting a precedent, to requests the Board Chair to invite the UNITAID Board to nominate a suitable representative to serve as Vice-Chair of the AMFm Committee. The appointment of the UNITAID Board representative shall be subject to the approval of the Board Chair and Vice Chair and the AMFm Committee Chair.

This decision does not have material budgetary implications.