¬ Affordable Medicines Facility - malaria

Antimalarial Treatment Strategies Conference

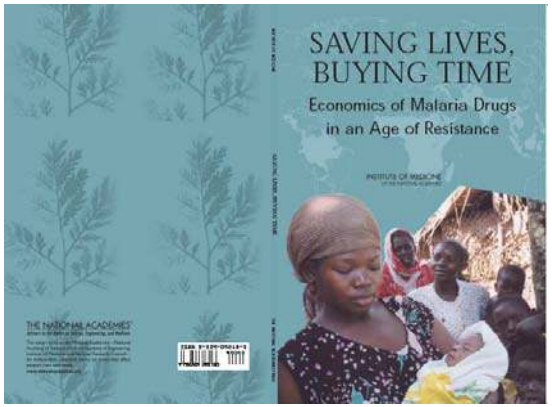
31 March – 3 April 2008

Dalberg Global Development Advisors

CDDEP THE CENTER FOR Disease Dynamics, Economics & Policy
WASHINGTON DC • NEW DELHI

History of the Affordable Medicines Facility – malaria project

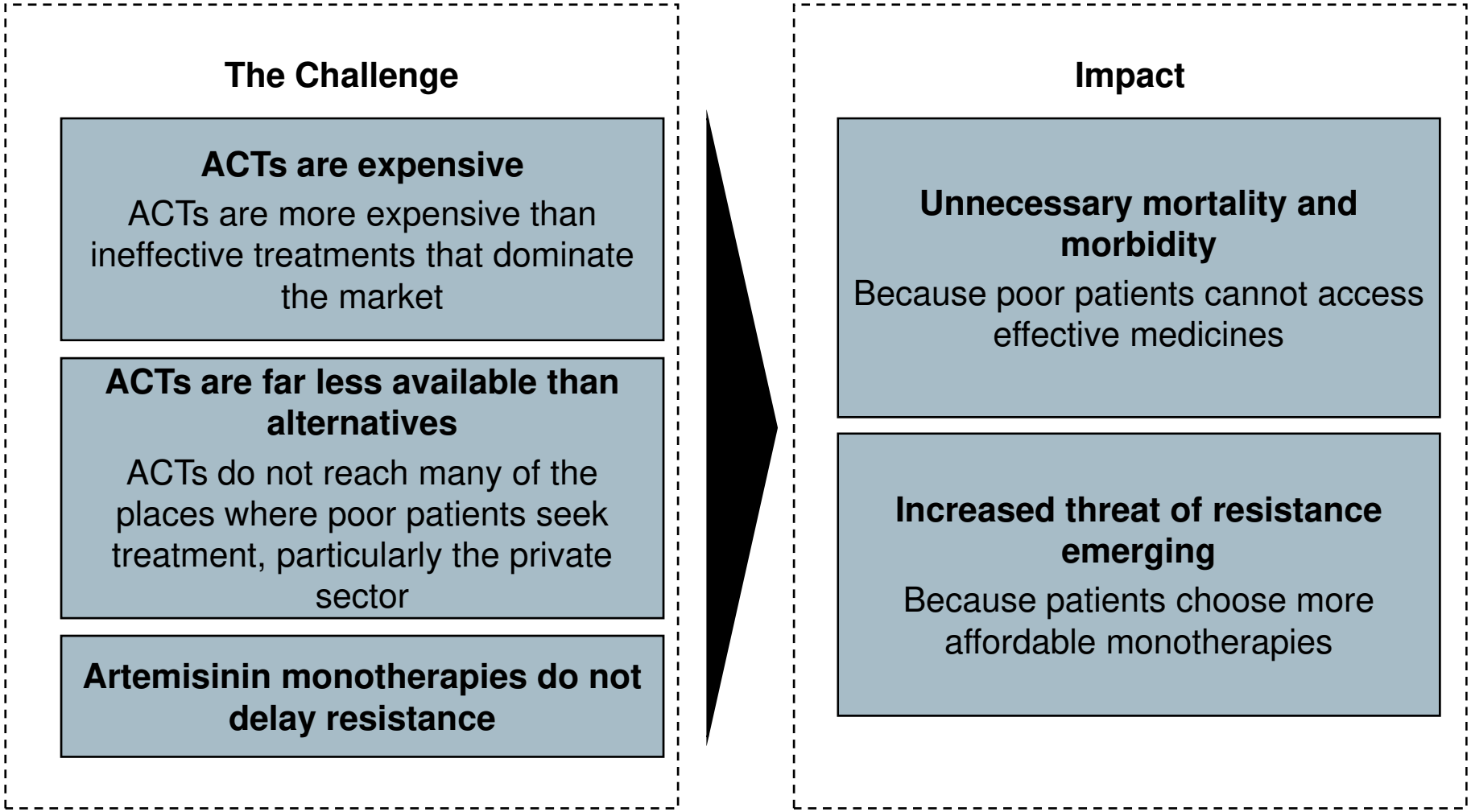
2004 — 2007 — 2008 –



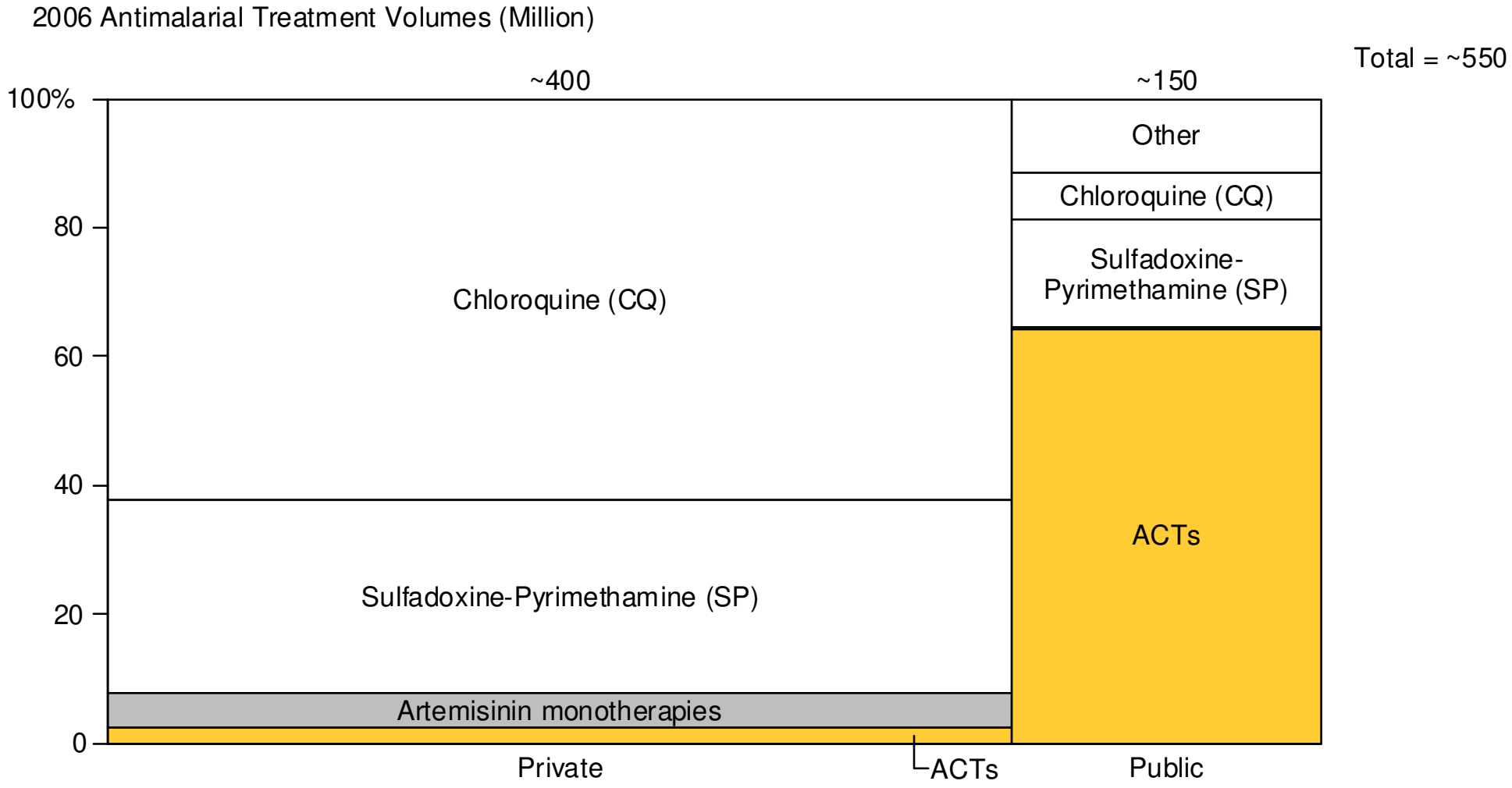
- IOM Report
- RBM and Gates Foundation initiate process
- World Bank contracts Dalberg

- RBM leads a Partnership meeting on AMFm in Amsterdam (2007)
- RBM Executive Committee creates a Global ACT Subsidy Task Force to forge consensus (2007) - renamed RBM AMFm Task Force
- RBM AMFm Task Force prepares technical design (2007)
- RBM Board endorses technical design and invites the Global Fund to manage the AMFm (2007)
- Global Fund Board considers managing the AMFm (2008)

Challenges for treatment of malaria



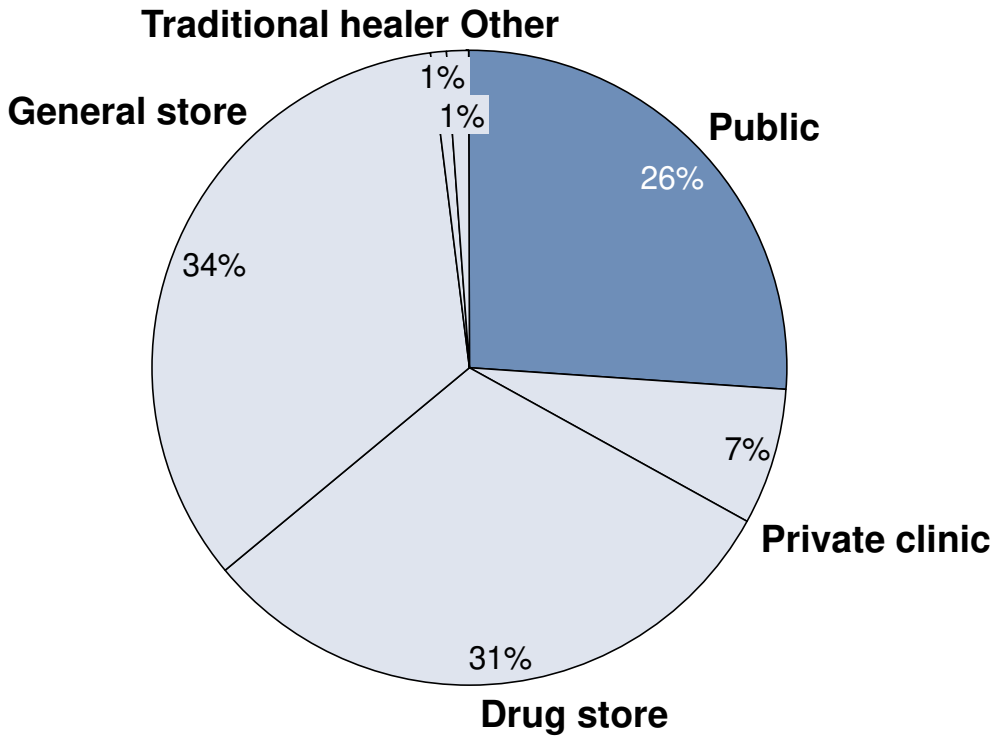
Rationale for the AMFm: to increase the availability of ACTs and substitute artemisinin monotherapies across all sectors



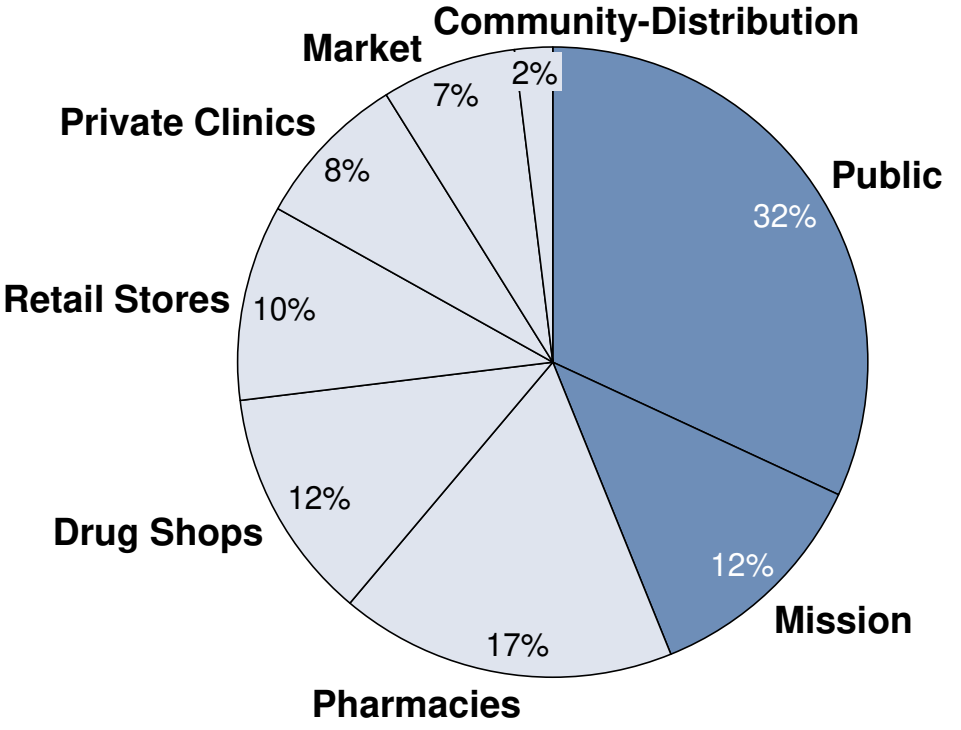
Note: Other category includes Mefloquine, Amodiaquine and others. ACT data based on WHO estimates and manufacturer interviews.
Source: Biosynthetic Artemisinin Roll-Out Strategy, BCG/Institute for OneWorld Health, WHO, Dalberg.

Where do patients access antimalarial treatments? Two country examples indicate importance of multi-sectoral strategy

Tanzania (rural areas)

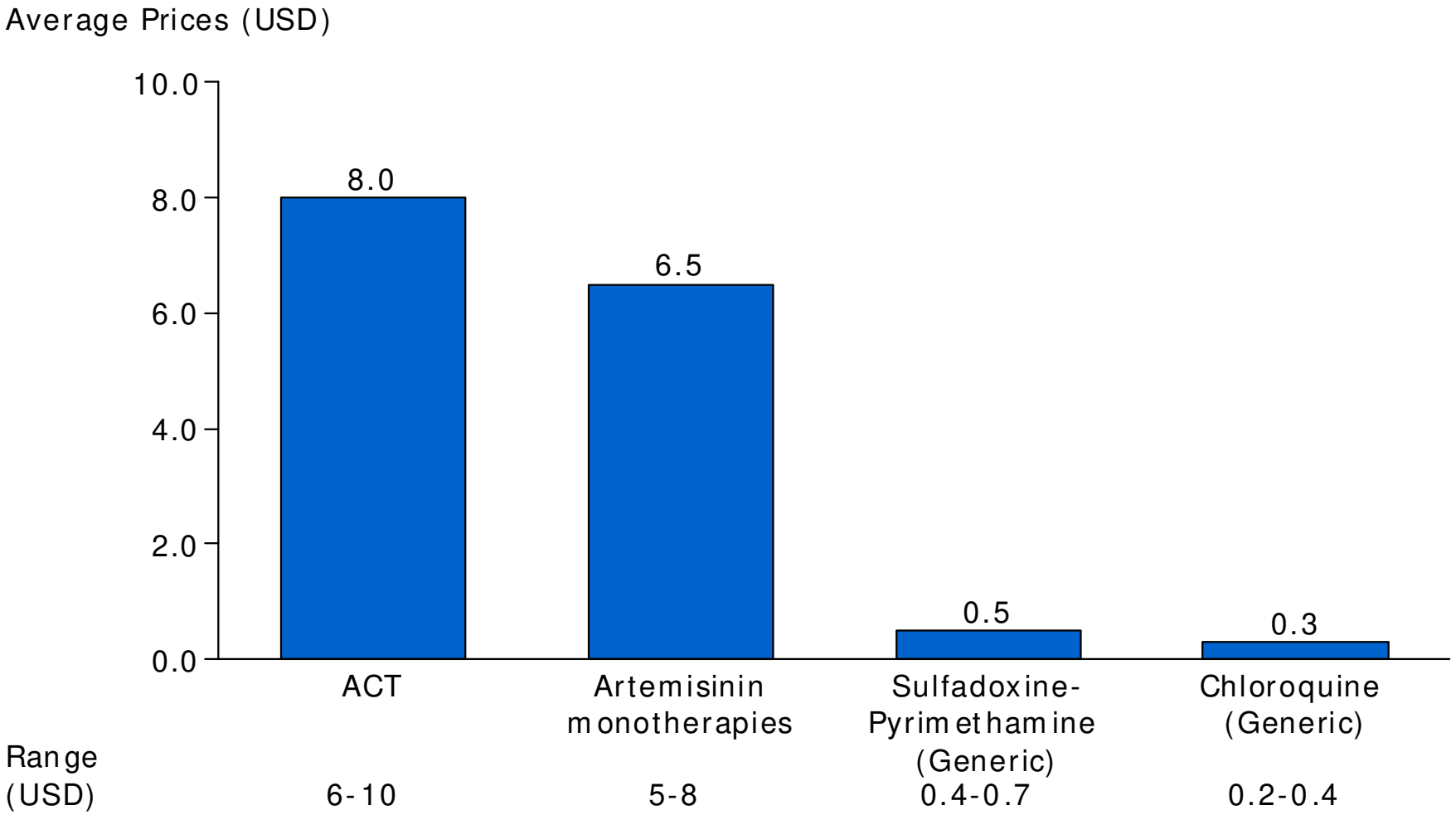


Uganda



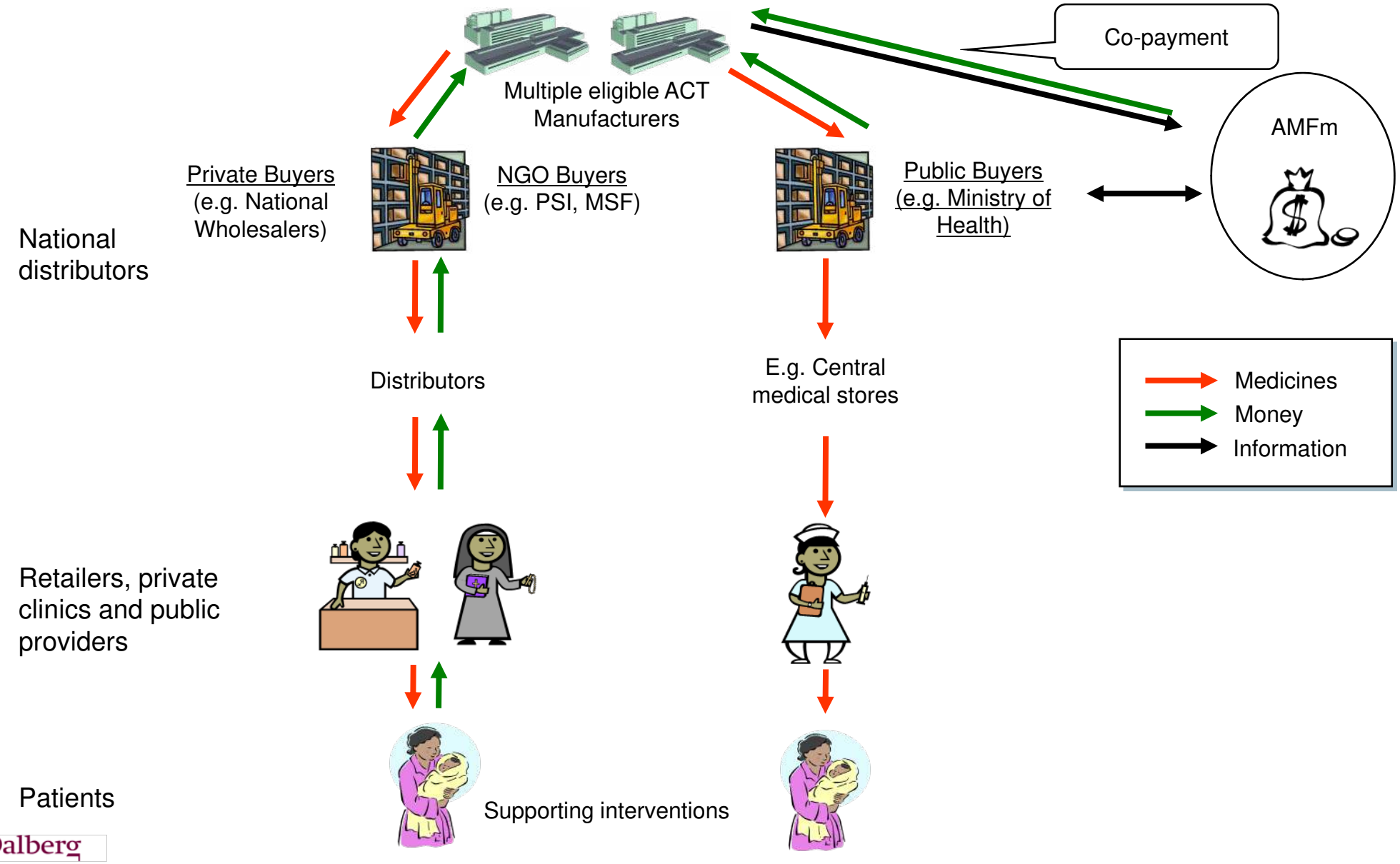
Note: Graphs shows provider visits (Tanzania) and reported number of customers (Uganda)
Source: Catherine Goodman thesis (2001), based on studies in three rural areas, MMV – Supply Side Findings – Uganda, Sep 2007

Rationale for the AMFm: ACT prices are relatively high and affordable to only few in the private sector - major barrier to usage



Note: Ranges indicate variance across countries and products excluding outliers; N (observations): (ACT, 222); (AMT, 227) ; (CQ, 37) ; (SP, 118).
Source: Dalberg field research (Kenya, Uganda, BF, Cameroon), Observations by World Bank and Research International (Nigeria). Smaller pricing observations were also performed in Ghana, Rwanda, Burundi, Niger and Zambia), but due to low n not included. Sulfadoxine-Pyrimethamine and Chloroquine data complemented with HAI and IOM observations

The AMFm will offer ACTs to first-line buyers at a similar price range as CQ and SP through existing channels (illustrative)



Impact of AMFm on prices in supply chain

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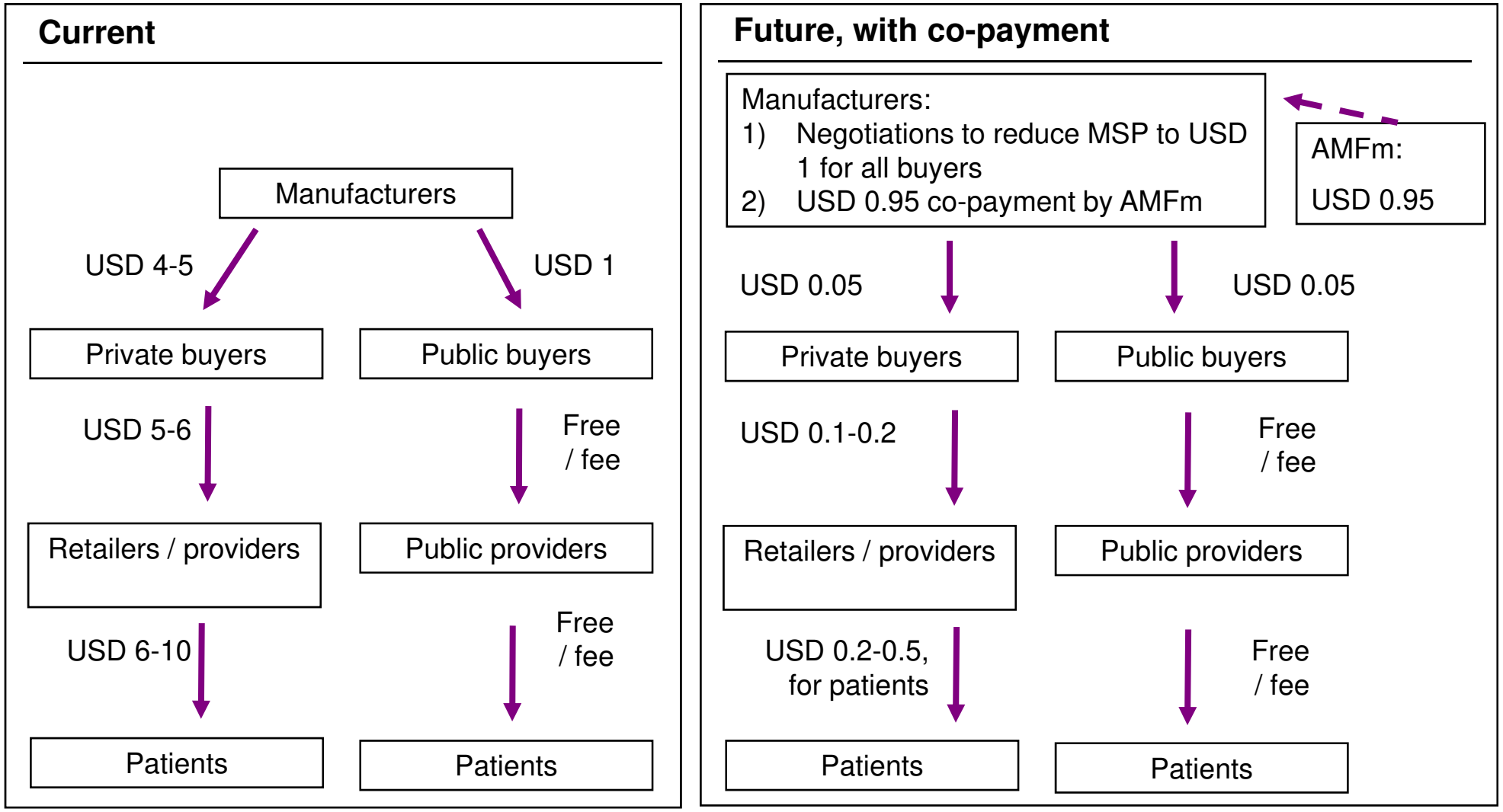

AMFm technical design – three layers of functions

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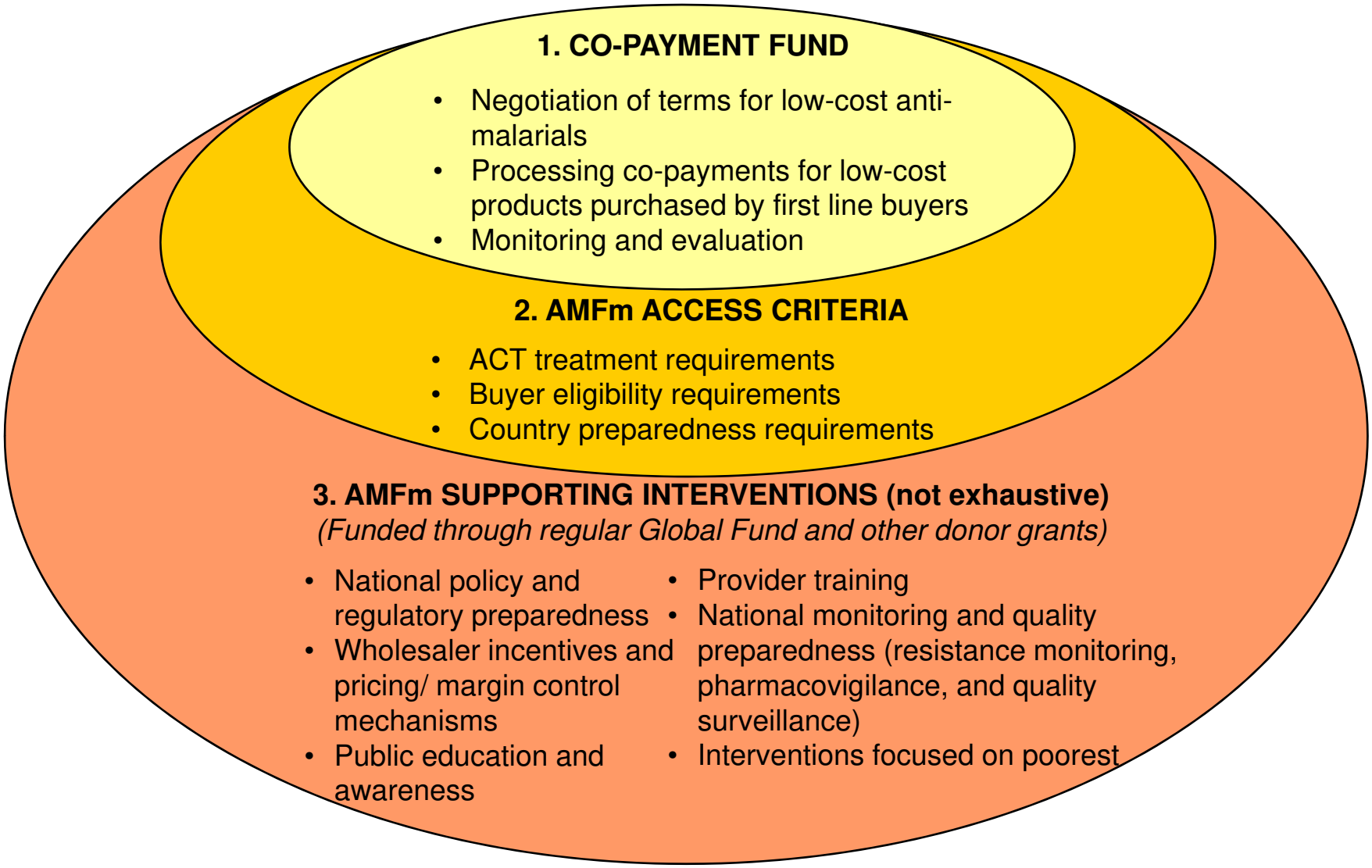
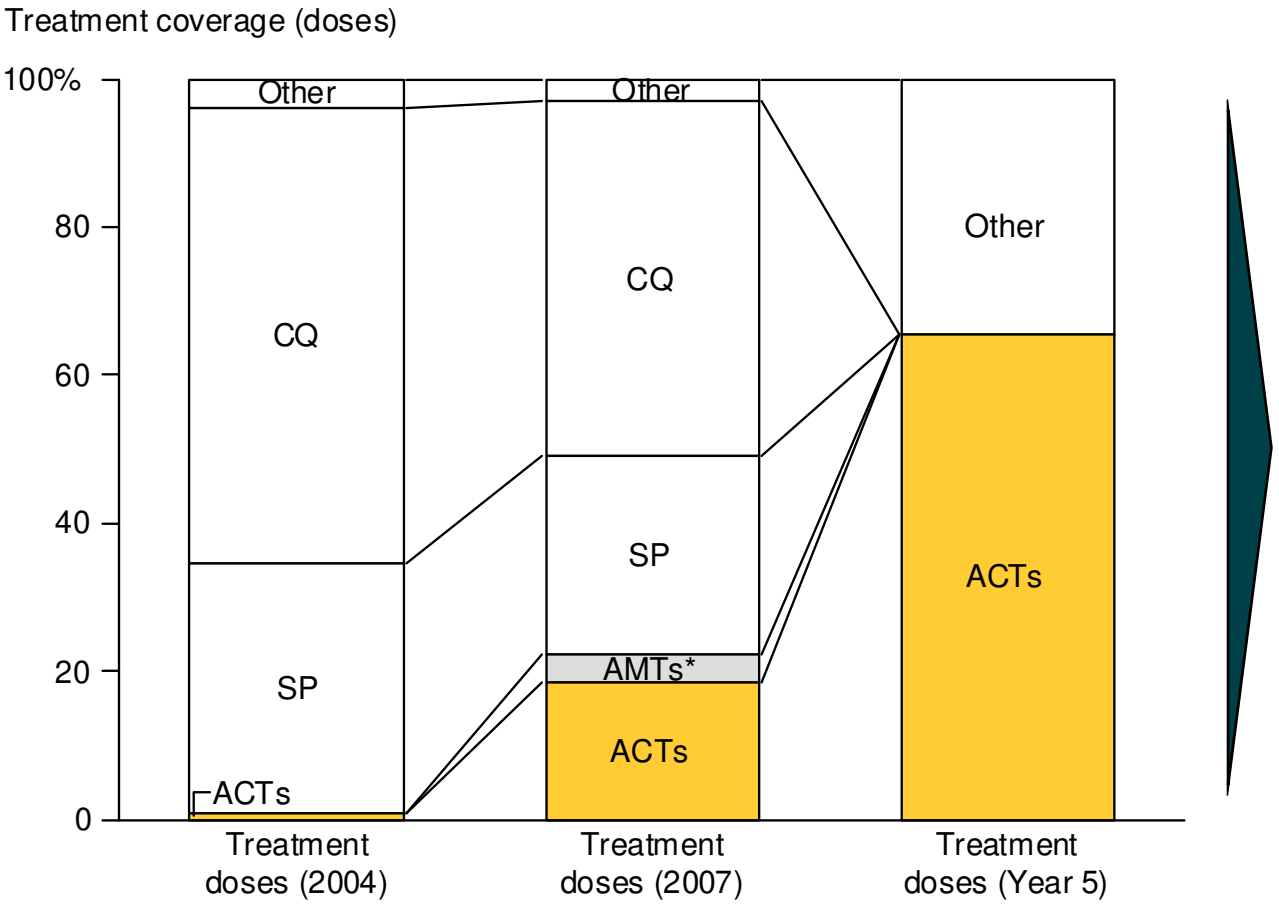


Impact of AMFm on uptake in ACT treatments



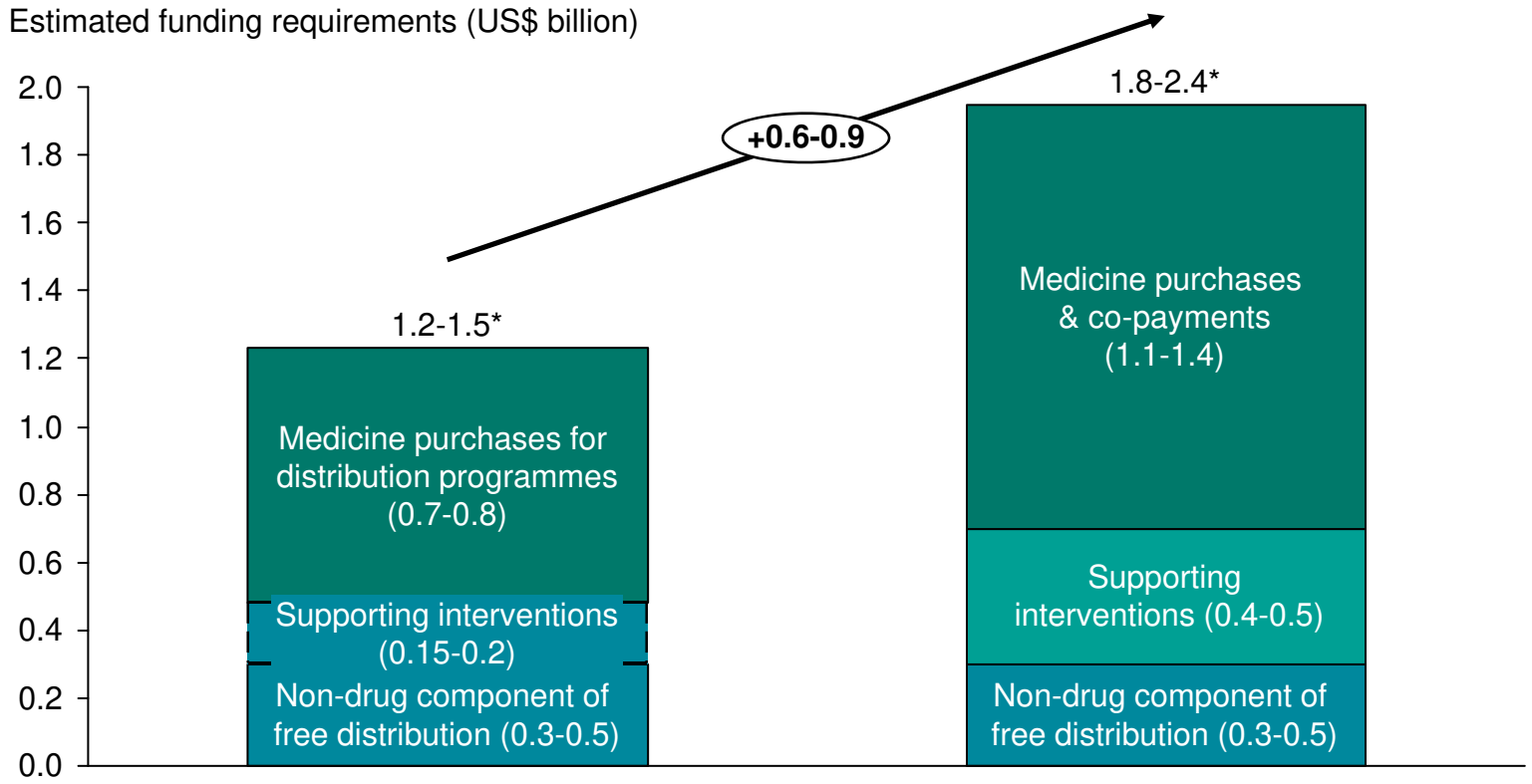
- Penetration of overall antimalarial treatment volumes is estimated at over 65% driven by ~60% penetration of the private sector and ~90% penetration of the public sector

* Artemisinin monotherapies.

Note: Split between CQ/SP in 2004 assumed to be equal to today. Increase in ACT usage to 360M doses (from 100M today) assumed, with 235M in the private sector (55% penetration) and 125M in the public sector (90%).

Source: Dalberg analysis, BCG/Institute for One World Health Institute.

5-year global malaria treatment scenarios with and without AMFm. An additional US$ 0.6 – 0.9B buys a doubling of treatments delivered



Scenarios

Without AMFm: 750-900M treatments over 5 years

- Grant-driven distribution programmes continue at current level of 100-120M per year
- Further expansion by up to 50% through public sector, social marketing and community-based programmes

With AMFm: 1450-2000 M treatments over 5 years

- Continuation (and potential futher expansion) of public and non-profit sector distribution programmes
- Expansion of private sector distribution by up to 240M courses per year
- Additional expenditure proportional to growth in treatments delivered

Source: Dalberg analysis

Key challenges in implementation of AMFm

RBM Work streams	Key questions
Maximizing points of access	• What are the most effective approaches to balancing access, safety and prevention of resistance? • How will guidelines for diagnosis and re-scheduling evolve? • What is the required provider training package?
Roll-out approach and technical assistance	• What is the appropriate "phasing" of country access to AMFm that balances rapid access with the opportunity to learn?
Reaching the poor and the poorest	• What are the most effective approaches to reaching vulnerable populations, including the poorest of the poor?
Operational Research	• How should AMFm Operations Research be organized to facilitate timely learning and adjustment?
Demand Forecasting	• What are the latest forecasts for AMFm demand, production and artemisinin cultivation?
Local manufacturing	• What is the required support to allow local manufacturers to adhere to the AMFm quality standard?

Next steps

Coming up…

- Global Fund Board 28-29 April
- RBM Task Force workstreams between May – November
- Global Fund Board 4-5 November
- Potential launch of AMFm - Q2 2009

Back-up

RBM Board recommendations (Nov 2007)

The RBM Board declared its support for the creation of AMFm to be implemented in accordance with the agreed technical design

The RBM AMFm Task Force was asked to work on a number of **outstanding implementation challenges** including:

- pharmaceutical standards and treatment guidelines
- country access and supporting interventions
- supplier sourcing and forecasting
- reaching the poor
- resource mobilization

The next 5 slides address each of these challenges at a high level

Quality standard, pharmacovigilance and M&E

Key questions	Consensus recommendations
Which quality standard will be applied?	• Harmonized Quality Assurance criteria for ACTs agreed (to be finalized in the context of overall Global Fund QA Policy review process for Board decision November 08)
What is the approach for pharmacovigilance, resistance monitoring, M&E and OR?	• Identification of a national focal point for pharmacovigilance requirement for access to AMFm • National malaria programs to establish sentinel sites to monitor efficacy of ACTs • Three core indicators related to availability and affordability of ACTs recommended for M&E • Ongoing operations research to be expanded to inform AMFm implementation

AMFm access & supporting interventions

Key questions	Consensus recommendations
Which buyers will be eligible?	• Buyers meeting national legal requirements and signing contract committing to 1) sell ACTs only to destination countries that meet preparedness requirements and 2) allow AMFm access to staff, facilities and records • International procurement agencies e.g. UNICEF, WHO
When is a country considered prepared to access AMFm?	• Countries need to nominate an in-country coordination body and submit a budgeted and financed plan for rolling out AMFm which includes list of eligible buyers, national pharmacovigilance focal point, approach to increasing access and M&E and supporting interventions plan
How will supporting interventions be financed?	• Countries define their supporting intervention needs and plans to address them • Countries apply for funding from Global Fund / other donors - new grants or reprogramming existing grants • Process should be light and quick

Manufacturer negotiations

Key questions	Consensus recommendations
What is the approach to negotiating with manufacturers?	• Negotiate directly with manufacturers (taking into account their cost structures) to lower private sector manufacturer sales price to that of public sector • Set ceilings for international distribution costs • Set co-payment level to lower purchase price for first line buyers to ~US$0.05 for each product

How AMFm will reach the poor

Key questions	Consensus recommendations
Will the poor have access to affordable ACTs?	• AMFm provides a **platform** for access to low cost ACTs **through all sectors and to all socio-economic segments**, including free distribution programmes to reach the poorest • Supporting interventions, such as **programs targeting the poor, are critical to ensuring broad access**, and will benefit from affordable ACTs financed by the AMFm • Global Fund and other agencies **will continue to finance these programs**, including facility and community based free distribution through the public and NGO sectors • **Malaria operations research** (not only for AMFm) needs a special focus on **determining the most effective approaches to increase access by the poor**

Resource Mobilization Update

- Updated financial estimates
  - **AMFm co-payments :** USD 1.1-1.4 billion over five years for both public and private sector (or USD 220-280 million per annum) – **separate, additional funding required**
  - **Supporting interventions:** USD 400-500 million over 5 years **– financed from regular grant resources and reprogramming,** using savings from reduced ACT prices. Bridge funding may be required from other donors
- Indications to RBM Partnership that a number of donors are strongly interested in **providing additional finance for co-payments and supporting interventions**
- **UNITAID** to propose potential role and added value of involvement in AMFm (including financial support)
- **Donor consultations** and conference to secure funding to be organized following the Global Fund Board decision in April
- To be set in context of **overall malaria response** efforts (RBM Partnership, Global Malaria Business Plan, MNM, MDG Call to Action, G8, UNGASS)

Components of the AMFm Business Plan

1. Co-payment mechanism and approach

2. Managing access to the AMFm and financing supporting interventions

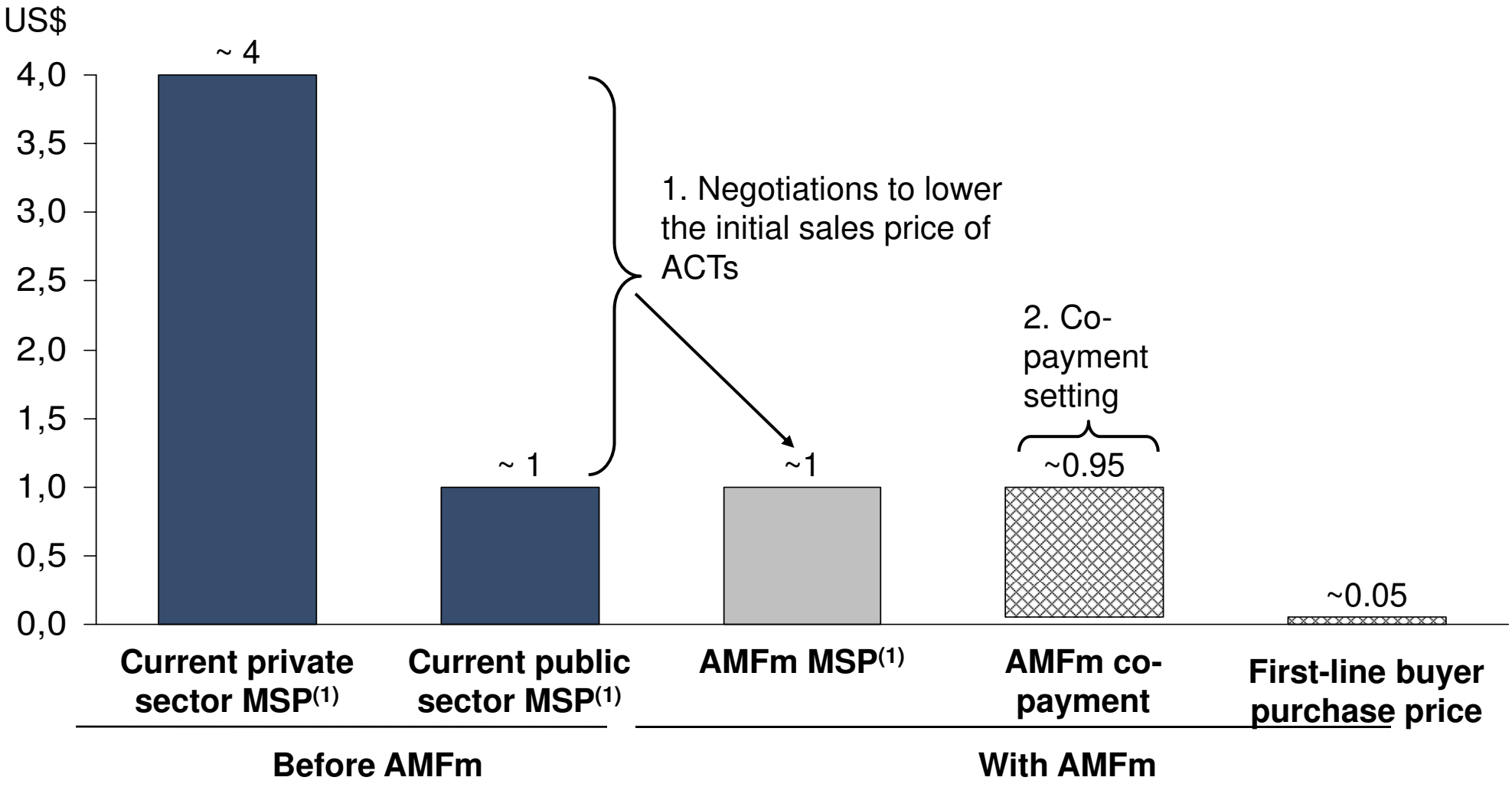
3. Resource requirements and mobilization

4. Monitoring and Evaluation

5. Governance arrangements

6. AMFm Team: Organizational structure, staffing, and budget

1. Co-payment - mechanism



(1) Manufacturer sales price

1. Co-payment - management approach

Trustee arrangement

- Establishment of sub-account for co-payments within existing World Bank trust fund

Approach to co-payments (Manufacturer negotiations)

- Step 1: Manufacturer sales price to private sector lowered to public sector level through negotiations, potentially in collaboration with a strategic partner
- Step 2: Co-payment set to ensure price paid by first-line buyers is approximately US$ 0.05 per treatment

Co-payment contract

- Global Fund would contract directly with manufacturers

Buyer eligibility verification

- Buyers must meet national legal requirements and sign a purchase contract to sell only in eligible countries; compliance verified through manufacturers and through periodic Global Fund audits

Co-payment processing

- Global Fund would verify co-payment requests from manufacturers in-house and send payment orders to the trustee

2. Managing access to AMFm

Objectives:

- Country preparedness assessment seeks to ensure ***basic requirements*** are in place for effective roll out of ACTs prior to granting access to the AMFm. Key principle is ***integration of access to AMFm co-payments and supporting interventions financing***

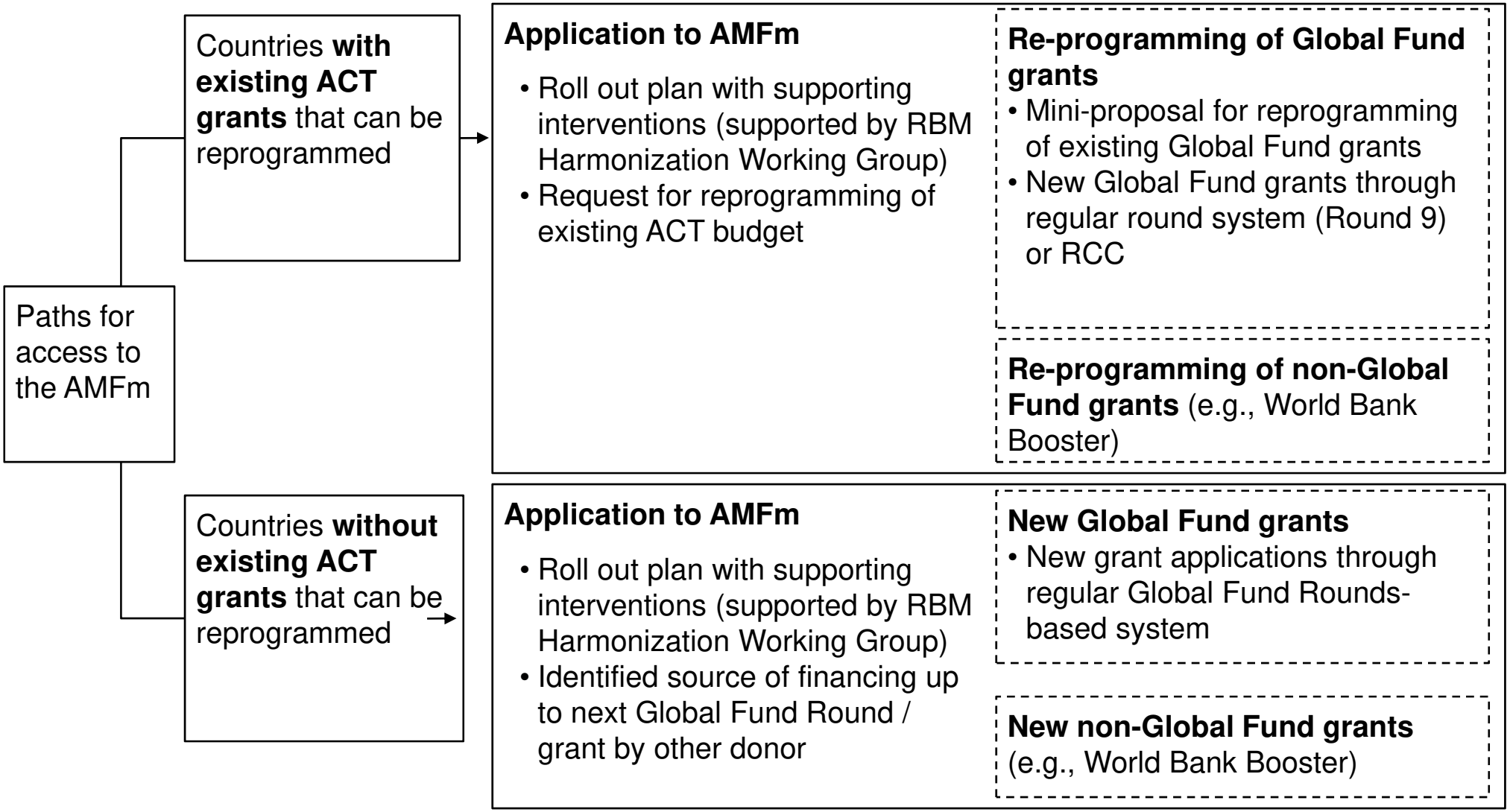
Preparedness criteria defined by RBM Task Force:

- ***Plan for roll out*** of co-paid ACTs (including supporting interventions and required policy preparations) with an ***identified source of financing;*** development supported through Harmonization Working Group
- Nomination of a **local body to coordinate** in-country AMFm related activities

Preparedness assessment

- Submission of roll out plan (by national coordinating body) to AMFm Secretariat, indicating source of financing (re-programming of existing grants, new grants or national resources)
- Access granted once the roll out plan has been received and financing for supporting interventions has been secured

2. Managing access to AMFm



Resource requirements

Background

- ***Co-payment mechanism*** would require ***new, additional funding***, whereas supporting interventions would be financed through reprogrammed and new Global Fund grants
- Revised resource estimates:
  - Copayments: ***US$ 1.1 billion -1.4 billion over first 5 years***
  - Supp. Interventions: US$ 400 - 500 million over first 5 years (of which an estimated US$ 145 -180 million could be covered through reprogramming)

Recommended approach

- Resource mobilization for the AMFm would focus on raising the additional finances required for co-payments
- AMFm launch dependent on: ***contributions received for initial 1.5 years, and firm pledges to cover remainder of first three years funding requirements***
- Contingency plans for funding shortfalls (reserves, increased resource mobilization targets and outreach)

Monitoring and Evaluation

Background

- Objective: Track the performance of the AMFm against its objectives; enable learning and adjustments
- Co-payment mechanism requires additions to M&E framework (performance of supporting interventions grants monitored through existing M&E framework)
- ***RBM MERG proposed indicators***: cost of ACTs to patients in countries compared to the price to first-line buyers; their affordability in the context of patients incomes; provider availability of ACTs)

Recommended approach

- GF would coordinate collection of three core indicators at country level (with focus on minimizing additional burden to countries) and would also leverage related malaria indicators collected by RBM
- Comprehensive evaluations of the AMFm would be held at regular intervals
- Operational research would be conducted prior to and during AMFm implementation (informed by ongoing studies in 9 countries) with specific attention to reaching the most vulnerable populations

Governance – recommended approach

Background

- Management of the AMFm as a new Global Fund business line would require appropriate governance and oversight arrangements
- Governance of the AMFm should be ***integrated into existing Global Fund governance structures*** as much as possible, while allowing for ***additional capacity and subject-specific expertise*** required for effective AMFm oversight

Recommended approach

- Global Fund Board in existing form responsible for overall governance (incl. strategic and corporate policy decisions; approval of annual funding envelope; monitoring AMFm performance)
- Establishment of a ***Transitional AMFm Committee*** (from May 07 to launch), dedicated to overseeing preparations for the launch of the AMFm
- Establishment of a standing AMFm Committee after launch to ensure appropriate expertise and sufficient capacity for the ongoing oversight of the AMFm
- Transitional Committee would ***review governance arrangements proposed in business plan and make recommendations to the Board*** for decision at its November meeting

Governance - Transitional Committee

- Oversee the ***pre-launch planning*** for the AMFm facility
- Review the ***policy framework*** for the AMFm as drafted by the Secretariat and advise the Board on this matter at the November Board meeting
- Make recommendations to the Board on ***proposed arrangements for ongoing governance of the AMFm*** (incl. ToR for potential AMFm standing committee)
- Under delegated authority of the Board (to be given in November), ***approve AMFm specific policies*** (including co-payment management, price negotiations, and AMFm access criteria for countries and buyers)
- Advise the Finance and Audit Committee on
  - 2009 funding envelope for co-payments and operating expense budget for AMFm
  - progress towards meeting minimum resources required for launch of AMFm
- Advise the PSC on any strategic implications of AMFm pre launch activities
- Advise the PC on any AMFm policies that may affect grant making policies

The transitional AMFm Committee would be active from its establishment after the April 2008 Board meeting until the launch of the AMFm

Organization – recommended approach

Background

- Management of the AMFm would require ***appropriate structures and additional resources*** to execute new functions

Recommended approach

- ***Dedicated AMFm Unit*** (reporting to Director of Finance and Pharmaceutical Procurement Cluster) to undertake core functions of the AMFm
- Other ***functions integrated into the activities of other units*** within the Global Fund Secretariat in order to leverage synergies and existing expertise
- Global Fund Secretariat would also continue to work with and rely on ***external partners*** to collaborate on key AMFm functions
- A preliminary estimated ***21 - 26 FTEs*** would be required to manage and perform AMFm related functions in the first year of operation
- ***Estimates to be further refined*** prior to November based on further operationalization of AMFm functions

OUT OF FLOW

Key AMFm questions with regards to treatment strategies - What is the appropriate “OTC” status for AMFm ACT’s?

Proposed solution – Controlled Access

- Technical partners to promote controlled access:
  - Prescription by medical professional, nurses or other trained health staff, including in some cases trained community health workers
  - Distribution (with prescription) through licensed pharmacies, drug sellers and clinics
  - In addition - ACTs are available for sale (without prescription) through licensed pharmacies as well as stores/vendors supervised by local health professionals and trained community level providers
- However – not full OTC status (unsupervised sales through regular stores)

Outstanding Questions

- Does the proposed solution strike the right balance between control and access?
- Which measures can be taken to support patient safety (e.g. teratogenicity / pregnancy)?
- Would less or more restrictive solutions yield net-benefits in terms of resistance? (e.g. stronger pressure on mono-therapies vs. less supervised usage)

Key AMFm questions with regards to treatment strategies - What is the appropriate country-phasing for AMFm?

Proposed solution – De-facto phasing

- Overall objective is to make affordable ACTs available to as many people as soon as possible
- However – countries need to plan and finance supporting interventions before getting access to AMFm
- However – perceived donor need to see prove of concept and learn lessons / adjust design during introduction phase
- Currently –de-facto phasing is proposed, as different countries will join at different times due to a) different levels of interest, b) different time-requirements to prepare supporting intervention roll-out plan

Outstanding Questions

- Should a more restrictive phasing (e.g. starter-group of 10 SSA nations) be considered?
  - Impact on resistance, access and arbitrage?
- Can other measures be taken to support a gradual phase-in that supports learning and adjustment?

Key AMFm questions with regards to treatment strategies – How can AMFm increase its reach among the poorest of the poor

Proposed solution – Supporting interventions and Challenge Fund

- Historic background that most health interventions have lower uptake with people in the lowest income quintiles
- AMFm will aim to reach these groups in a multi-faceted approach:
  - Lower prices in the private-sector, a key distribution channel for anti-malarials to all income groups
  - Integration in the regular free-distribution grants of the Global Fund, providing a platform for cheap ACTs
  - Opportunity for countries to program supporting interventions specifically for these groups
  - Specific OR to identify approaches to make health interventions reach groups with people in the lowest income quintiles (“Challenge Fund”)

Outstanding Questions

- Could other measures be taken to support uptake of anti-malarials in the lowest income-quintiles?
- How would the “Challenge Fund” be structured?

The RBM AMFm Task Force will keep working on key outstanding questions

Examples of key issues

- What is the appropriate balance between access, safety and prevention of resistance?
- How can local manufacturers be brought up to the AMFm quality standard
- What is the appropriate "phasing" of country access to AMFm that balances rapid access with the opportunity to learn and adjust?
- How should AMFm OR be structured to facilitate timely learning and adjustment?
- How can AMFm increase its reach among vulnerable populations, including the poorest of the poor?

RBM AMFm Task Force workstreams

- Country policy requirements for maximizing points of access
- Local manufacturers
- Approach to country support and TA
- Operational Research
- Options for reaching the poor and the poorest