

ANNEX 1

Affordable Medicines Facility – malaria

RBM AMFm Taskforce

**Interim report on progress against
outstanding AMFm implementation
challenges**

17 February 2008

Executive Summary

Background

In November 2007, the Roll Back Malaria Partnership (RBM) Board declared its support for the creation of an Affordable Medicines Facility – malaria (AMFm) to be implemented in accordance with the agreed technical design, noting that a launch is contingent upon resolution of five implementation challenges in the following areas:

- i) pharmaceutical standards and treatment guidelines,
- ii) supporting interventions,
- iii) developing and agreeing a business plan for managing the AMFm,
- iv) supplier sourcing and forecasting,
- v) resource mobilization.

It also invited The Global Fund to Fight AIDS, Tuberculosis and Malaria (Global Fund) to consider taking responsibility for managing the AMFm for implementation in accordance with the agreed design principles.

In December 2007 the UNITAID Board requested the UNITAID Secretariat to explore the potential role and added value of UNITAID's involvement in the AMFm, taking into consideration the alignment between the objectives of UNITAID and AMFm.

The RBM AMFm Task Force conducted intensive further work on the five implementation challenges, starting in early December 2007, and met in person in London on February 1, 2008 for a full day conference hosted by the UK Department for International Development where it discussed its recommendations.

This Interim Progress Report with the preliminary conclusions from these discussions aims at updating the RBM Executive Committee on the work undertaken to address the outstanding issues flagged at the 13th RBM Board meeting.

It is also an opportunity to inform the Global Fund Board on the challenges and ongoing work to shape solutions.

The requested endorsement by the RBM Executive Committee of this progress report will be an encouragement to the many RBM Partners to remain mobilized around the AMFm, a confirmation of RBM Board ownership of the further development and ultimately launch and in turn a significant safeguard for success to the future manager of the AMFm.

With its expected effect on the affordability of ACT treatment across all sectors, the AMFm represents an important component among others in the comprehensive response to the global problem of malaria. And it is crucial to its success that it be tightly integrated with and reinforce existing efforts.

RBM AMFm Task Force Recommendations

1. Pharmaceutical standards and treatment guidelines

Harmonized quality assurance standards

Recommendations:

Based on the consideration of the risk and benefits of the criteria adopted by UNICEF/WHO and the Global Fund, and the evaluation of new mechanisms to be established, the following agreed criteria are proposed as the basis for harmonized selection criteria of artemisinin-based antimalarial medicines.

ONE of the two following clinical selection criteria:

- Inclusion in the current WHO Guidelines for Treatment of Malaria and in the national treatment guidelines, or
- Inclusion in the national treatment guidelines, but not in the WHO Guidelines for Treatment of Malaria, after the "ad hoc" clinical review committee¹ (convened by WHO to evaluate the evidence on safety and efficacy of the product requested) approves the selection of the product.

PLUS the following quality selection criteria:

- WHO Prequalified products or products registered² by a Stringent Drug Regulatory Authority should be selected in priority.
- In case there are less than two or three³ WHO prequalified or SDRA registered products, or if the products that meet these standards are unavailable⁴, then products complying with all the following quality criteria can be selected:
 - GMP compliance certified after inspection by WHO or by a Stringent Drug Regulatory Authority for the dosage form concerned;
 - Submission of the "Product Dossier" to the WHO PQ Programme⁵ and acceptance by WHO PQ Programme to review the dossier;
 - Acceptance of the product by after technical review of the documentation submitted by the supplier by an "ad hoc" quality review committee⁶ convened by WHO on the following:
 - registration information;
 - regulatory (licensing) situation of the finished product;
 - pharmaceutical product and the manufacturing facility;
 - finished product specifications and compliance with international pharmacopoeia standards, if available;
 - stability testing data (both accelerated and real time studies in Zone IV) as per ICH and/or WHO Guidelines;
 - labeling information;

¹ The composition of the committee, procedure and the timeframe of an ad hoc review process need to be discussed further

² Registration/license for export only will not fulfil this criterion

³ The minimal threshold level for selection of two **or** three prequalified products require further discussion

⁴ Unavailable: when the manufacturer of such product is unable to supply a sufficient quantity of the finished product within 90 days of the date of the order

⁵ Manufacturers are expected to meet the prequalification criteria for a product within a period of two years after dossier submission.

⁶ The composition of the committee, procedure and the timeframe of review need further discussion.

- active pharmaceutical ingredient (API) characteristics and certification;
- safety and efficacy data.

Further work needed:

Additional work by WHO (QSM and GSM) and USPML is under preparation to develop terms of reference for the clinical and quality ad hoc review committee (a sort of "malaria green light committee"), its convening mechanism by WHO, links with the WHO Treatment Guidelines review committee, the WHO Prequalification Programme, technical contributions from multiple agencies, the procedures, composition, and timeframe for establishment, review and dissemination of the results, and modus operandi under complex emergencies requiring expeditious review and response. A proposal will be shared for inputs with all other Agencies participating in the work on harmonization of quality assurance criteria for product selection, i.e. Global Fund, MMV, UNICEF, UNITAID and the World Bank.

AMFm requirements of countries with regard to WHO treatment guidelines

Product and treatment classes that will be eligible for AMFm copayment

- AMFm will only co-pay for the treatment classes of ACTs that are part of WHO recommendations and guidelines
- WHO treatment guidelines include protocols for the under-fives and pregnant and lactating women
- Any differences between WHO guidelines and National Treatment Policies will be resolved through the ad-hoc panel as described in the Quality Assurance harmonization proposal

Assessment of national treatment policies in light of country preparedness and access to AMFm funding

- No submission or assessment of National Treatment Guidelines by the AMFm Secretariat is needed
- Countries are advised to include plans (where relevant) to phase-out monotherapies as part of overall roll-out plan
- Outside the scope of AMFm – there are ongoing WHO efforts to support countries on appropriate National Treatment Guidelines and harmonization between WHO guidelines and National Treatment Guidelines where desired

Country requirements for maximizing points of access

The Task Force agreed that scheduling of ACTs is a country responsibility but that countries take decisions in partnership with WHO and manufacturers.

Recommendations:

To strike the balance between maximum access to ACTs and responsible risk management the Task Force recommends that:

- ACTs be dispensed without prescription through licensed pharmacies, but also through community level stores/vendors/providers who benefited from a light training course and accept supervision by local health professionals
- WHO Global Malaria Program determine the appropriate guidance to give to countries on rescheduling ACTs

- Ministries of Health make the case to the National Drug Regulatory Authorities in their countries in order to start the change process

Further work needed:

The Task Force sub-group will host three regional meetings to develop a road map for rescheduling to maximize points of access. Country follow-up with technical support is needed to facilitate the rescheduling process.

Particular attention will be paid to ensuring access for the vulnerable: children under-five and pregnant women, and the poorest.

Pharmacovigilance, drug safety and resistance monitoring

Pharmacovigilance

Recommendations:

- As a minimum requirement, countries that wish to access AMFm should identify a national focal point for pharmacovigilance. This focal point does not have to be malaria-specific, and ideally should be someone in the pharmacovigilance department of the National Drug Regulatory Authority (if there is one)..
- The AMFm should also establish a 'Supra-national Network' of the focal points to ensure coordination and collaboration of pharmacovigilance efforts
- Technical and financial support to bring countries in a position to establish pregnancy exposure registries and conduct active surveillance in sentinel sites to collect adverse drug reaction / adverse effect rates, but not as a prerequisite.

Further work needed:

- *Global:* A gap analysis (Gates Foundation-supported planning grant), Two meetings are planned for April 2008: (i) on development of pregnancy exposure registries for antimalarials and (ii) on global pharmacovigilance strategy.
- *National:* mapping which countries already have a national focal point, pregnancy register and active surveillance in sentinel sites.

Resistance monitoring

Recommendations:

- WHO recommends that national malaria control programs establish sentinel sites (between 4 and 8 per country) to monitor efficacy of first and second line antimalarial drugs, with assessments to be conducted at least once every 24 months. This recommendation applies to malaria surveillance overall and is reinforced by the AMFm.

Further work needed:

- An implementation plan to identify costs and funding sources.

Approach to local manufacturing

Determine an approach to increase the number of prequalified ACT manufacturers, including manufacturers in endemic countries where possible, without any concession on the quality.

Recommendations

- 1) It is important to disseminate widely and pro-actively all relevant information with regards to the upcoming implementation of the AMFm and its requirements for stringent quality criteria for the manufacturing of medicines.
- 2) This information should clearly emphasize that it requires considerable resources to produce drugs of acceptable quality at a competitive cost and more in particular:
 - Substantial and sustained funding
 - Substantial and comprehensive technological know-how
 - Prospect of significant production volume, i.e. access to markets
- 3) Most manufacturers in the industrialized world and many in emerging economies would have the resources to viably engage in ACT manufacturing. Some may benefit from technical guidance for upgrading processes to GMP and for completing the dossiers for SDRA registration or WHO prequalification. If requested technical assistance (TA) should be made available to them, in most cases a relatively light and short to medium term TA.
- 4) For manufacturers in low income countries it may be more difficult to mobilize the required resources. A joint venture with a resourced partner providing investment, technology transfer, including TA, and access to markets offers probably the best chances for success.
- 5) Manufacturers of (nearly) SDRA registered or (nearly) WHO Prequalified ACTs from the industrialized world or emerging economies should be invited and encouraged to engage in such joint ventures, if need be as part of PPPs.
- 6) Manufacturers who have submitted a dossier for, and are near to obtaining SDRA registration or WHO Prequalification, should be invited to all relevant quality assurance meetings set up by WHO and/or UNICEF for a better understanding of the environment in which tenders take place and accelerating access.

Recommendation with regards to funding the TA to local manufacturers

Needs assessment, allocation of funding and implementation planning could benefit from more consultation and coordination within a global coordination mechanism that includes partners with experience in the pharmaceutical industry. Existing projects (e.g. UNITAID support of the prequalification program, RBM PSM WG building on RBM Secretariat experience, UNIDO) should be leveraged where possible.

Further work needed

- Further mapping and assessment of local manufacturers and detailing of technical assistance needs (RBM PSM Working Group)
- Further definition of mechanisms to promote quality manufacturing of ACTs in endemic countries such as joint ventures and technical assistance modalities
- Definition of roles and responsibilities in funding and implementation of technical assistance to finished product and API manufacturers

2. Supporting interventions

Country preparedness criteria and evaluation mechanism

Naturally the implementation of AMFm is most likely to occur step wise, as only few countries fulfil readiness criteria at present. Learning by doing in those countries will generate the initial evidence base that will inform the scale up of AMFm.

Recommendations:

- 1) To be considered prepared to roll-out co-paid ACTs, countries need to nominate an in-country coordination body to oversee the AMFm. It should encourage representation of private sector stakeholders and additional donors, and will work in line with national oversight and regulation mechanisms.
- 2) Countries will have to submit a costed and financed plan for rolling out the AMFm with the following components:
 - An identified national pharmacovigilance focal point⁷
 - Approach country is taking to increase access to ACTs beyond health facilities, such as through home based management of malaria and private sector outlets
 - List of eligible first line buyers⁸
 - Approaches to strengthen national M&E frameworks to track impact of AMFm
 - Supporting interventions plan for roll-out of the AMFm. This should include the following items:
 - Public education and awareness to increase awareness of availability of cheap ACTs and to improve treatment seeking behavior
 - Provider training in the appropriate use of ACTs
 - The plan could further include (and does not have to be limited to) the following items, depending on country circumstances:
 - The use of pre-packaging of ACTs for high risk groups, such as children, to improve adherence
 - Actions to ensure price and margin control along the private sector supply chain (e.g. wholesaler incentives, margin control mechanisms)
 - Actions to strengthen private sector supply chains
 - Scaling up the use of diagnosis in the treatment of malaria
 - Strengthening regulatory capacity for enforcement consumer protection
 - Plans for phasing out of monotherapy treatment of uncomplicated malaria
- 3) The roll-out plan will be validated by an existing technical body in the malaria community (not the AMFm Secretariat), based on criteria to be determined in the implementation phase

Further work needed:

- There is a need to define how the stewardship capacity of the public sector will be developed/ strengthened to manage access to medicines and consumer protection associated with the legitimate provision of treatment through community agents and the private sector. While increased access, particularly in

⁷ As per recommendation of the work stream on pharmacovigilance

⁸ As per recommendation of the work stream on buyer eligibility

the private sector, is most welcome, the burden on public sector monies to assist in some functions could be substantial

- Investigate how many countries are willing and near to preparedness status

Establishing and managing buyer eligibility

Establishing buyer eligibility: Recommendations:

The working group recommends that all first-line buyers to be deemed eligible for AMFm, must as a minimum standard:

- Meet national legal requirements relating to the importation and distribution of pharmaceutical products.
- Sign a short, standard AMFm first-line buyer contract committing to:
 - Sell ACTs only to destination countries that meet preparedness requirements
 - Allow AMFm access to staff, facilities, and records to conduct reviews of buyer compliance with requirements

Additionally procurement agencies such as WHO and UNICEF or other international agencies, if requested to support public procurement, will do so in accordance with their normal procedures.

Assessing buyer eligibility: Recommendations:

The working group recommends that approved AMFm suppliers be required to conduct the primary assessment of buyer eligibility by (a) confirming that the first-line buyer is registered with the national regulatory authorities and (b) collecting and submitting to AMFm a standard AMFm contract signed by the first-line buyer. The manufacturer will submit this proof of registration and signed contract to AMFm ahead of the buyer's first order to AMFm, and periodically thereafter.

The working group recommends that the AMFm Secretariat verify and enforce this assessment of buyer eligibility by conducting periodic spot audits of the buyer to check compliance with its commitments in the AMFm contract and NDRA registration status. The AMFm is tasked with exploring the best method for conducting these periodic spot audits, considering as options working in partnership with local authorities, manufacturers, or other designated local entities. The AMFm Secretariat will also maintain and publish a list of all eligible buyers making transparent relevant buyer order information.⁹

Further work needed

Conduct further assessment to determine the preferred option. Questions that need to be answered include:

- Understand what impact the number of first-line buyers have on the availability and retail price (affordability) of ACTs in the downstream supply chain

⁹ The Task Force discussed the optimal number of first-line buyers needed to balance competition and coverage in the country with the complexity for the AMFm Secretariat of managing multiple buyers. If the number of first-line buyers is significantly higher than expected the AMFm Secretariat could consider streamlining the assessment process. If on the other hand M&E or OR indicate insufficient ACT coverage within the country, the AMFm Secretariat may choose to work with suppliers or first-line buyers to resolve the issue.

- To what extent does horizontal distribution (importers selling to other importers) occur? And if there is horizontal distribution, what is the impact on the wholesale price / percentage mark up?
- Consider the implications of requiring manufacturers to work with a minimum number of first-line buyers and the willingness of the manufacturers to do so?
- The ability of manufacturers to effectively screen and manage multiple first line buyers (more than what they normally do).
- What impact would the preferred option on operating costs of buyers, manufacturers and AMFm secretariat?
- Would the preferred option be applicable to buyers in all countries? What about fragile states, etc.)

Overall architecture for financing and implementing supporting activities

The approach to financing supporting interventions is based on the principles of building on existing mechanisms and ensuring country ownership. The Global Fund is likely to be the primary funder of supporting interventions. From the Global Fund perspective, supporting interventions can be financed either by releasing approved budget due to reduced ACT costs (reprogramming) or by new grants. The process for reprogramming will be light and is under development. There are two channels for funding supporting interventions:

Recommendations:

- 1) Processes for countries to obtain funding for supporting interventions should be kept as light and short as possible
- 2) Countries will define their supporting intervention programming needs and business plans to address them, which are then submitted for funding to the Global Fund and other donors in the form of either new grants or reprogramming existing grants.
 - Countries without existing Global Fund malaria grants:
 - Apply for supporting intervention finance through the Global Fund Round system.
 - Apply for new grants or reprogramming of existing grants from other donors.
 - Countries with Global Fund malaria grants:
 - Integrate reprogramming into the Phase 2 request for incremental funding.
 - Complete a short reprogramming application outlining which supporting interventions the freed up resources will fund, how the additional supporting interventions integrate into ongoing efforts, how they will be rolled out and how progress will be measured.

Further work needed:

Ongoing Resource Mobilization efforts must be scaled up:

- for cross-cutting Technical Assistance that applies to multiple countries as funds would not be channelled through the Global Fund
- for supporting interventions in countries without Global Fund malaria grants (or without an ACT component in their malaria grants)

M&E requirements and approach

Recommendations.

Three core indicators are recommended for demonstrating progress against AMFm objectives in all AMFm recipient countries:

1. Cumulative percentage mark up between retail median unit price and manufacturers unit price for full course of ACTs
2. Median cost to patient of full course of ACT relative to daily minimum wage for a government unskilled worker
3. Proportion of providers reporting no disruption of stock of ACTs for more than one week during the previous three months

Implementation

- The implementation of AMFm M&E will be coordinated by the AMFm Secretariat and will aim to minimize the burden on countries and to leverage the use of existing M&E initiatives
- It is also recommended that the AMFm Secretariat coordinate with RBM MERG to ensure access to relevant data and outcome measures and to avoid duplication
- Dialogue with WHO/HAI (and others) is recommended to promote and support the application and possible adaptation of the Medicines Prices Survey methodology.

Further work needed:

A number of technical issues need further consideration and are recommended to be included in discussions during the finalization of the M&E framework:

- To what extent the AMFm reaches those in need of malaria treatment (i.e. proportion to individuals with a fever and receiving ACTs who have malaria)¹⁰
 - Proportion of children under five years of age with a fever who received ACTs within 24 hours of onset of fever
 - Proportion of children under five years of age receiving antimalarial treatment for a fever who received ACTs, AMTs and non-artemisinin derivative antimalarials
- Monitoring of drug quality
- Inclusion of upstream indicators for monitoring of flows, volumes and prices of ACTs along the supply chain
- Data collection and reporting on the distribution of co-paid ACTs (a) in the commercial sector as a fraction of country-wide ACT consumption and commercial sector anti-malarial consumption to show AMFm contribution to improved access and (b) by socio-economic status and geographically through disaggregation of data for the core indicators to assess equity.

Operational Research (OR) requirements and approach

Recommendations:

- Synthesize and analyze results from existing initiatives to inform the selection and design of further OR on the AMFm¹¹

¹⁰ Indicators presented here differ slightly from indicators currently collected by RBM –the RBM indicator set is being reviewed by the MERG and changes to indicators may be made

- Conduct OR in 2-4 additional countries¹² to create a set of 4-6 representative sentinel countries that include different market conditions and cultures
 - Conduct OR during the preparation phase to help inform the rollout of the AMFm
 - Continue OR throughout the AMFm implementation and in particular during the first 1 to 2 years of the AMFm's launch to mitigate risks of rolling out the global copayment system and inform country selection of supporting interventions
- OR activities should where possible be planned and implemented in consultation with Monitoring & Evaluation activities, and should thus be shared with the MERG as the coordinating body for M&E tool development and the Global Fund as the likely implementer of the AMFm. Close coordination with existing implementers of OR should be sought to inform planned activities as far as possible.

Operational Research Already Underway

Country	Current	Coverage	Supporting interventions	Availability of results
Cambodia (PSI)	Yes	<ul style="list-style-type: none"> • 17 provinces • Pharmacies, drug shops • All age groups 	<ul style="list-style-type: none"> • Training • IEC • MVU 	HH survey data from 2006 is available. Follow up survey mid 2008.
Cameroon (govt / GF)	Yes	<ul style="list-style-type: none"> • Nationwide • Pharmacies • All age groups 	<ul style="list-style-type: none"> • TBD 	Forthcoming (Malaria Consortium)
Madagascar (PSI)	Yes	<ul style="list-style-type: none"> • Nationwide • Children under 5 only • Through pharmacies, private sector health providers and community agents 	<ul style="list-style-type: none"> • Training • BCC • Pre-packaged products, RRP • IPT 	Late 2008
Nigeria (PSI)	Yes	<ul style="list-style-type: none"> • Limited by funding • Children under 5 only • OTC • Aiming for \$0.26-\$0.35 to the consumer 	<ul style="list-style-type: none"> • Training • Pharmacovigilance • Campaign against oral artemisinin monotherapy • IPC 	May 2008
Rwanda (PSI)	Yes	<ul style="list-style-type: none"> • HMM districts • OTC in HMM districts only • Children under 5 only 	<ul style="list-style-type: none"> • PPT packaging • Integrated A&P and BCC campaigns • Training • BCC • IPC • IPT 	Outlet survey: February 2008 HH survey: May 2008
Tanzania (to be conf. if 2 projects)	Yes	<ul style="list-style-type: none"> • 2 district operational study • OTC in research sites only • All age groups 	<ul style="list-style-type: none"> • IEC • RRP in one district 	Interim report Nov 2007 / next results Apr / May 2008
Myanmar (PSI)	Yes	<ul style="list-style-type: none"> • Small scale • Use of clinic franchises • All age groups 	<ul style="list-style-type: none"> • Product insert information • IEC • TV spots • IPC and MVU 	HH and outlet surveys planned for 2008
Senegal (Govt / GF)	Yes	<ul style="list-style-type: none"> • Nationwide • Private sector pharmacies • All age groups 	<ul style="list-style-type: none"> • TBD 	November 2007
Uganda	In launch	<ul style="list-style-type: none"> • 6 intervention districts • Sectors TBD 	<ul style="list-style-type: none"> • Training • BCC/IEC 	Mid 2008

¹¹ Issues to be considered should be developed based on the synthesis of existing work and could include, for example price transmission along the supply chain, incentives along the supply chain to displace monotherapies, equity of access, the impact of supporting interventions and the reach of the intervention

¹² In addition to existing operational research activities in Uganda and Tanzania

		<ul style="list-style-type: none"> All age groups 	<ul style="list-style-type: none"> OTC rescheduling Repackaging, RRP Umbrella branding 	
Zambia (DFID)	In prep.	<ul style="list-style-type: none"> Nationwide Private sector beyond existing channels All age groups 	<ul style="list-style-type: none"> Repackaging RRP Volume & coverage incentive to wholesalers Training Subsidized RDT Case management training 	TBD – end 2008?
DRC	On hold	<ul style="list-style-type: none"> Small scale Children under 5 only Delivered through pharmacy only 	<ul style="list-style-type: none"> TBD 	TBD
Angola	No	<ul style="list-style-type: none"> Pilot study, leading to nationwide Pharmacies and drug shops Distribution via community agents considered Children Under 5 Only 	<ul style="list-style-type: none"> TBD 	TBD - end 2008?
Malawi	No	Similar to Uganda proposal – to be confirmed	<ul style="list-style-type: none"> TBD 	Mid/end 2009
Mozambique	No	As above	<ul style="list-style-type: none"> TBD 	Mid/end 2009

Economic appraisal

In addition to providing low-cost ACTs through the private sector, AMFm will act as a platform for the public and non-profit sectors to distribute ACTs free of charge to reach vulnerable populations, including children under five and pregnant women, and the poorest. Reaching these populations is a key global health priority and the primary responsibility of public sector malaria programs and a high priority for most actors in the non-profit sector.

An independent economic appraisal of the AMFm commissioned by DFID and conducted in December and January concluded that the AMFm offers good value for money.

Recommendations:

- Countries are encouraged to incorporate interventions to reach the poor and the vulnerable populations into their national malaria plans, roll-out plans and normal Global Fund and other donor grant applications.
- Lessons from country studies need to be taken on board in refining how the AMFm works

Further work needed:

- To identify which interventions are most effective to reach the poorest and the vulnerable
- The authors of the DFID study suggested that further analysis would help to confirm the good value for money, and that a number of targeted approaches (e.g. paediatric doses only, sub Saharan Africa only) or alternative approaches such as a partial subsidy should be investigated for their cost-effectiveness.

3. Developing and agreeing a business plan for managing AMFm

The business plan for managing the AMFm within Global Fund is being prepared by the Global Fund Secretariat and will be submitted to the Global Fund Board's Policy and Strategy Committee on 14 March 2008. It outlines the implications for the Global Fund of the technical design agreed by the RBM Board in November 2007. The business plan will cover the following topics:

- Co-payment mechanism and approach
- Supporting interventions: financing and management
- Resource mobilization
- Monitoring and evaluation
- Governance and organization
- AMFm Team: Organizational structure, systems, staffing and budget

Further work needed

- AMFm Taskforce to follow up with the EC

4. Supplier sourcing and forecasting

Copayment setting and supplier arrangements

Recommendations:

Determination of initial price:

- Given that currently ACT markets are non-competitive (limited supplier) markets, a direct negotiation is recommended, taking into account the cost structures where possible (e.g. through a cost plus approach).
- A move to an auction mechanism could be made if product markets become more competitive.

Determination of copayment:

- Copayment levels should be set for each supplier of each product.
- Where possible the copayment should not be greater than the supplier's cost of production, but in line with the RBM Board approved key principle that the AMFm is to replace cheap and increasingly ineffective CQ and SP with ACTs, the copayment should be set so that the remaining cost to the first-line buyers is comparable to the price they pay for CQ today.

International Distribution:

- Ceiling prices should be set for international distribution in a manner that enables flexibility by suppliers and buyers, but which does not incentivize price increases or inefficient purchasing behavior (e.g., shipping of very small orders).

Price to First-Line Buyer:

- AMFm should set a price range that manufacturers can charge first-line buyers based on the initial price and level of copayment, but not exceeding the price they pay for CQ.

Non-Price Factors:

- AMFm should require suppliers to meet certain minimum packaging standards and to play a role in enforcing buyer eligibility requirements.

Assessment of packaging options*Recommendations:*

- The AMFm manager should require suppliers to meet certain minimum packaging standards. The initial recommendation is weight/age-specific packs with minimal global illustrations.
- An AMFm brand identity would provide a seal of approval for quality and affordability which would be needed for information and education campaigns.
- All packaging and labeling should be to WHO Good Manufacturing Practice standards of quality.

Further work needed:

- To investigate the feasibility of a general recommendation of weight/age specific packs

Demand forecasting

A number of organizations have ACT forecasting initiatives underway and have committed to share data, assumptions and methodologies within the Forecasting Taskforce (FTF) of the RBM PSM working group. The objective of the PSM WG is to rapidly come to grip with ACT forecasting recognizing the challenge in this particularly immature market with an upcoming unprecedented global copayment to the private sector buyers.

Recommendations:

In order for RBM to rapidly come to grips with ACT forecasting and to enable convergence to an acceptable range of forecasts in a foreseeable future

- the PSM WG is requested to provide a first range of forecasts as soon as possible
- the PSM WG is requested to include UNITAID and other interested partners.
- forecasts should be created by each group separately and shared for comparison together with the methodologies and assumptions used and relevant data collected.
- The AMFm manager should provide transaction and monitoring data in real time to forecasters to facilitate timely forecasts, but is not expected to conduct its own forecasts..
- The AMFm manager should publish all available forecasts.

Further work needed:

The FTF workplan includes several workstreams aiming at improving and refining data and info collection. A particular effort aims at data and info to be gathered from the private sector distribution channels in countries. To this purpose MIT-Zaragoza kindly accepted to join and support the Forecasting Taskforce of the PSM WG. The FTF will also explore a possible role and contribution of the ACT suppliers in refining the private sector demand forecast.

5. Resource mobilization

Updated Resource Requirements

There is an advocacy and resource mobilization sub-group including the Bill & Melinda Gates Foundation, the Global Fund, Malaria No More, the RBM Secretariat, the UK Department for International Development, UNITAID, the William Clinton Foundation and the World Bank.

The AMFm co-payment fund requires USD 1.1-1.4B for the first 5 years. The UNITAID Board in December 2007 requested the UNITAID Secretariat to further explore the potential role and added value of UNITAID's involvement in the AMFm, taking into consideration the alignment between the objectives of UNITAID and AMFm.

Supporting interventions require approximately USD 400M – 500M for the first 5 years. Supporting interventions will be funded

- out of regular Global Fund grant resources through the reprogramming and new grant process described above
- by other donors including foundations, bilateral donor agencies and multilaterals.

Further work needed:

Organize donor consultations and meeting to secure funding additional to possible UNITAID funding for the co-payments and to Global Fund funding for supporting interventions

Requested action from the RBM Executive Committee:

1. Recalls the RBM Board decision to endorse the design of the AMFm as outlined in the executive summary of the technical design submitted by the AMFm Task Force and support the AMFm as a mechanism for making effective anti-malarials available to countries that need them at an affordable price.
2. Recalls the five areas that the RBM Board requested be addressed prior to the launch of the AMFm:
 - i) pharmaceutical standards and treatment guidelines,
 - ii) supporting interventions,
 - iii) developing and agreeing a business plan for managing the AMFm,
 - iv) supplier sourcing and forecasting,
 - v) resource mobilization
3. Acknowledges the commitment and contributions of RBM partners to the design, objectives and principles, and ongoing development of the AMFm;
4. Commends the AMFm taskforce for the substantial progress made in addressing outstanding issues highlighted by the RBM Board in November 2007, and notes the report and annexes on the design of the AMFm produced following the taskforce meeting of 1 February;
5. Recognizes the consensus reached on key challenges, and acknowledges the work planned on identified issues prior to Global Fund, UNITAID and RBM Board meetings in April and May
6. Asks the AMFm Task Force to continue to contribute to the resolution of outstanding issues related to the AMFm implementation subsequent to the decision by the Global Fund Board on managing the AMFm and prior to launch;
7. Endorses the report of the 1 February taskforce meeting, subject to the changes requested at the RBM Executive Committee meeting, as the basis for its recommendation to the Global Fund PSC and Board to favourably consider that the Global Fund manage the AMFm.

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1A: Harmonization of Quality Assurance Standards

WHO: A. Bellah, A. Bosman, R. Kiivet, S. Schwarte; *UNICEF*: F. Blanco, B. Kamps, A. Ojoo; *Global Fund*: J. Daviaud, S. Logez, S. Stottrup; *UNITAID*: P. Duneton, L. Witherspoon; *World Bank*: A. Imasheva, J. Qamruddin, A. Seiter; *Malaria Consortium*: S. Meek; *PMI*: J. Murphy; *MMV*: T. Wells

Objective

To establish quality assurance standards that ensure drug safety and efficacy, while building on existing progress, minimizing administrative burden and ensuring patients have access to the most effective medicines.

Context

Differences in product quality selection criteria for procurement of artemisinin-based antimalarial medicines by international agencies are confusing for both national health authorities and manufacturers of artemisinin-based medicines. The two major lists used to procure artemisinin-based antimalarial medicines are the UNICEF/WHO procurement list and the Global Fund list of antimalarial pharmaceutical products classified according to Global Fund Quality Assurance Policy (QA Policy). The UNICEF/WHO and Global Fund lists rely on different criteria and have different processes for updating. Only 9 of 20 (45%) of the products overlap.

Three options were considered to guide selection going forward: 1) Adoption of the "UNICEF/WHO procurement list"; 2) Adoption of the Global Fund QA criteria for procurement; 3) Adoption of a new set of selection criteria based upon the clinical and quality assessment of the medicines, based on harmonization of existing systems.

Technical Recommendations

There is broad consensus within the AMFm Task Force that Option 3 should be the QA criteria for the selection of artemisinin-based antimalarial medicines:

ONE of the two following clinical selection criteria:

- Inclusion in the current WHO Guidelines for Treatment of Malaria and in the national treatment guidelines, or
- Inclusion in the national treatment guidelines, but not in the WHO Guidelines for Treatment of Malaria, after the "ad hoc" clinical review committee¹³ (convened by WHO to evaluate the evidence on safety and efficacy of the product requested) approves the selection of the product.

PLUS the following quality selection criteria:

- WHO Prequalified products or products registered¹⁴ by a Stringent Drug Regulatory Authority should be selected in priority.

¹³ The composition of the committee, procedure and the timeframe of an ad hoc review process need to be discussed further

¹⁴ Registration/license for export only will not fulfil this criterion

- In case there are less than two or three¹⁵ WHO prequalified or SDRA registered products, or if the products that meet these standards are unavailable¹⁶, then products complying with all the following quality criteria can be selected:
 - GMP compliance certified after inspection by WHO or by a Stringent Drug Regulatory Authority for the dosage form concerned;
 - Submission of the “Product Dossier” to the WHO PQ Programme¹⁷ and acceptance by WHO PQ Programme to review the dossier;
 - Acceptance of the product by after technical review of the documentation submitted by the supplier by an “ad hoc” quality review committee¹⁸ convened by WHO on the following:
 - registration information;
 - regulatory (licensing) situation of the finished product;
 - pharmaceutical product and the manufacturing facility;
 - finished product specifications and compliance with international pharmacopoeia standards, if available;
 - stability testing data (both accelerated and real time studies in Zone IV) as per ICH and/or WHO Guidelines;
 - labeling information;
 - active pharmaceutical ingredient (API) characteristics and certification;
 - safety and efficacy data.

Next Steps

More work is required to establish an ad-hoc clinical and quality review committee and to analyze the potential impact of the QA criteria on the domestic manufacturers involved in the production of artemisinin-based products in developing countries. The Global Fund is currently in the process of reviewing its current QA Policy with a view to updating its common criteria across all three diseases. The review process will end in August 2008 to be ready for the Portfolio Committee meeting in September 2008, and the final decision of the Global Fund Board will be available in November 2008. This is also where the harmonized QA criteria would be finalized.

Reference Documents

“Harmonization of criteria for the selection of artemisinin-based antimalarial medicines,” 11 pages.

¹⁵ The minimal threshold level for selection of two or three prequalified products require further discussion

¹⁶ Unavailable: when the manufacturer of such product is unable to supply a sufficient quantity of the finished product within 90 days of the date of the order

¹⁷ Manufacturers are expected to meet the prequalification criteria for a product within a period of two years after dossier submission.

¹⁸ The composition of the committee, procedure and the timeframe of review need further discussion.

1B&C: Requirements with Regard to WHO and National Treatment Guidelines

WHO: P. Olumese (focal point); MMV; P. Grewal; PSI: R. Orford

Objective

Determine AMFm requirements with regard to WHO and National Treatment Policies and Guidelines.

Context

The question of alignment between WHO and National Treatment Policies (NTP) and National Standard Treatment Guidelines (NSTG)¹⁹ is relevant in two contexts:

- Alignment of product and treatment classes that will be eligible for AMFm copayment
- Potential assessment of appropriate national treatment policies in light of country preparedness and access to AMFm funding.

Technical Recommendations

- 1) Product and treatment classes that will be eligible for AMFm copayment
 - AMFm will only copay for the treatment classes of ACTs that are part of WHO recommendations and guidelines²⁰.
 - WHO treatment guidelines include protocols for the under-fives and pregnant and lactating women
 - Any differences between WHO guidelines and NTPs will be resolved through the ad-hoc panel as described in the QA harmonization proposal (see table below).

Scenarios for misalignment between WHO and National product classes

Categories	Example	Recommendation
1) National product classes are wider than WHO treatment classes	E.g. DHA-PIP part of country X's national treatment classes	<ul style="list-style-type: none"> • Ad-hoc panel (as described in QA paper) will determine whether treatment class in question would be supported through AMFm classes
2) National product classes are stricter than WHO treatment classes	E.g. AS+MQ not part of country X's national treatment classes (due to partner-drug resistance)	<ul style="list-style-type: none"> • Overall – adherence of first-line buyers with national product guidelines is national responsibility • However – countries can voluntarily notify AMFm of potential restrictions – which would be incorporated in transactions assessment (buyer eligibility)

¹⁹ Please note the difference between National Malaria Treatment Policy (NMTP) and National Standard Treatment Guidelines (NSTG) is an adaptation of the WHO recommendations and Guidelines based on the local malaria epidemiology and therapeutic efficacy profile of antimalarial medicines. This National policy is translated into National Standard Treatment Guidelines (STGs), which is a basic requirement to provide the expected standard of care in malaria case management. In most countries, the malaria STGs provide recommendation on a few select antimalarial medicines based on their public health applicability and value within the local context in-country based on the therapeutic efficacy profile of the medicines. They do not necessarily feature all antimalarials registered or available for use in-country.

²⁰ Currently AR+LU, AS+SP, AS+MQ and AS+AQ

2) Assessment of national treatment policies in light of country preparedness and access to AMFm funding

- No submission or assessment of NSTGs by AMFm secretariat is needed
- Countries must include plans (where relevant) to phase-out monotherapies as part of overall roll-out plan
- Outside the scope of AMFm – there are ongoing WHO efforts to support countries on appropriate NSTGs and harmonization between WHO guidelines and NSTGs where desired

Reference Documents

“Pharmaceuticals, quality assurance, production, and treatment guidelines,” 7 pages.
“AMFm requirements of countries with regards to WHO treatment guidelines and national treatment guidelines” 7 pages.

1D: Country Requirements for Maximizing Points of Access

MMV: P. Grewal (Focal point); *PSI*: R. Orford; *TDR*: F. Pagnoni; *CHA*: O. Sabot, L. Ward, M. Gordon; *WHO*: P. Olumese, S. Spinaci, A. Bosman; *Bill & Melinda Gates Foundation*: T. Kanyok; *Malaria Consortium*: S. Meek; *Global Fund*: M. Grabowsky; *Private sector*: I. Boulton, H. Rietveld

Objective

Provide technical guidance on regulatory approaches for countries that they can use to maximize points of access to ACTs.

Context

ACTs are prescription only in most countries. A notable exception is Nigeria, where they may be sold over-the-counter (OTC). Several countries, including Tanzania, Ghana, Uganda and Zambia, are studying alternative approaches in specific districts.

To successfully increase access, countries may consider moving ACTs to a different drug regulatory status (“schedule”) within the confines of the national regulatory framework. The rescheduling must be combination specific as the safety and therapeutic margins of ACTs differ in relation to the active ingredients of the combination compound. The process can be time consuming and varies between countries. Countries are likely to start by rescheduling their first-line drug of choice because frequent use has allowed for accumulation of sufficient in-country experience and safety data.

ACT scheduling must be addressed within the context of the national regulatory framework. Countries should learn from other countries’ experiences and AMFm must make sure that technical support through the most appropriate partner, complemented with a resource bank, is available to facilitate this process. The Task Force agreed that scheduling of ACTs is a country responsibility but that countries take decisions in partnership with WHO and manufacturers.

Options for ACT scheduling with regards to prescription status and minimum dispenser qualifications:

- Prescription Only Status / Licensed Dispensers
 - ACTs must be prescribed by medical professional, nurses or other trained health staff, including in some cases trained community health workers (task shifting)
 - Dispensed on a prescription basis through licensed pharmacies, drug sellers and clinics
- Over The Counter Status / Dispensers with light training and supervision
 - ACTs can be dispensed without prescription through licensed pharmacies as well as through stores/vendors/community level providers after light training and with light supervision by local health professionals
- Unrestricted Access
 - No prescription
 - Free sale through all types of stores/vendors and community level providers

Technical Recommendations

The Task Force agreed that scheduling of ACTs is a country responsibility but that countries take decisions in partnership with WHO and manufacturers.

Recommendations:

To strike the balance between maximum access to ACTs and responsible risk management the Task Force recommends that:

- ACTs be dispensed without prescription through licensed pharmacies, but also through community level stores/vendors/providers who benefited from a light training course and accept supervision by local health professionals
- WHO Global Malaria Program determine the appropriate guidance to give to countries on rescheduling ACTs
- Ministries of Health make the case to the National Drug Regulatory Authorities in their countries in order to start the change process

Further work needed:

The Task Force sub-group will host three regional meetings to develop a road map for rescheduling to maximize points of access. Country follow-up with technical support is needed to facilitate the rescheduling process.

Particular attention will be paid to ensuring access for the vulnerable: children under-five and pregnant women, and the poorest.

Reference Documents

“Challenge 2D: Country requirements for maximizing points of access,” 4 pages.

1E: Pharmacovigilance, Drug Safety and Resistance Monitoring

MMV: S. Duparc (Focal point); *WHO*: M. Couper, S. Pal; *Bill & Melinda Gates Foundation*: T. Kanyok; *University of Washington*: A. Stergachis; *RaPID*: P. Lalvani

Objective

Determine the most effective approach for ensuring drug safety and efficacy.

Context

Pharmacovigilance is important to assess the use and safety of marketed medicines, particularly for detecting serious, rare or unexpected adverse events; chronic toxicity; effects in understudied populations, such as children and pregnant women.

Resistance monitoring provides essential information for monitoring the therapeutic efficacy of a range of antimalarial drugs and ensures a minimal evidence base from which ministries of health can develop informed treatment policies and guidelines.

Technical Recommendations: Pharmacovigilance

As a minimum requirement, countries that wish to access AMFm should identify a national focal point for pharmacovigilance. This focal point does not have to be malaria-specific, and ideally should be someone in the pharmacovigilance department of the National Drug Regulatory Authority (if there is one). The AMFm should also establish a 'Supra-national Network' of the focal points to ensure coordination and collaboration of pharmacovigilance efforts

Countries accessing ACTs co-financed by AMFm must be in a position to establish pregnancy exposure registries for ACTs to assess medication safety; and conduct active surveillance studies that collect adverse drug reaction / adverse event rates by ensuring the collection of 'denominator' data.

To support the implementation of these studies, countries will need technical and financial assistance (this topic must be included in the 'Supporting Interventions Working Group.').

Technical Recommendations: Resistance Monitoring

WHO recommends that malaria control programs establish sentinel sites surveillance to monitor antimalarial drug efficacy. Between four and eight sites should be sufficient to achieve a balance between representativeness and practicality. It is recommended that assessments of the efficacy of first and second line drugs be conducted at least once every 24 months at all the sites.

Next Steps

Pharmacovigilance:

- *Global*: A gap analysis will be conducted between now and April 2008 via the Gates Foundation-supported planning grant, "Development of a Global Strategy for the Conduct and Use of Pharmacovigilance." Two meetings are planned for April 2008 to identify and prioritize challenges in global pharmacovigilance: One on a funding proposal development for pregnancy exposure registries for antimalarials and the second on global pharmacovigilance strategy.

- *National:* The April meetings will be an opportunity to map which countries already have a national focal point, pregnancy register and active surveillance in sentinel sites.

Resistance monitoring: An implementation plan will be developed to identify costs and funding sources.

Reference Documents

“Pharmacovigilance and drug safety” 13 pages and “Monitoring antimalarial drug resistance – a summary,” 2 pages.

1F: Local Manufacturing

RBM Procurement and Supply Chain Management Working Group: IDA Solutions: H. den Besten; WHO: A. Bosman; FSC: M. Cutler; RBM Secretariat: J. van Erps; OTECI: J. Pilloy, MSH: R. Shretta, CHAI: I. Singh, Dalberg: N. Theopold; RBM consultants: E-M. Dupuy, P. Lalvani

Context

The launch of AMFm will create significant demand increase for ACTs. Very likely many manufacturers of ACTs, particularly in Africa, will be unable to meet the proposed harmonized QA standard²¹ and therefore face the prospect of diminished revenues. Given the predictable impact on manufacturers in Africa and some Asian and Latin American countries (“local manufacturing”), this is an important and politically sensitive question to prepare for.

Objective

Determine an approach to increase the number of prequalified ACT manufacturers, including manufacturers in endemic countries where possible, without any concession on the quality.

Recommendations

- 1) It is important to disseminate widely and pro-actively all relevant information with regards to the upcoming implementation of the AMFm and its requirements for stringent quality criteria for the manufacturing of medicines.
- 2) This information should clearly emphasize that it requires considerable resources to produce drugs of acceptable quality at a competitive cost and more in particular:
 - Substantial and sustained funding
 - Substantial and comprehensive technological know-how
 - Prospect of significant production volume, i.e. access to markets
- 3) Most manufacturers in the industrialized world and many in emerging economies would have the resources to viably engage in ACT manufacturing. Some may benefit from technical guidance for upgrading processes to GMP and for completing the dossiers for SDRA registration or WHO prequalification. If requested technical assistance (TA) should be made available to them, in most cases a relatively light and short to medium term TA.
- 4) For manufacturers in low income countries it may be more difficult to mobilize the required resources. A joint venture with a resourced partner providing investment, technology transfer, including TA, and access to markets offers probably the best chances for success.

²¹ These recommendations assume that the harmonized criteria (clinical and quality criteria) for the selection of artemisinin-based antimalarial medicines, as submitted in response to Challenge 1A, will be adopted

5) Manufacturers of (nearly) SDRA registered or (nearly) WHO Prequalified ACTs from the industrialized world or emerging economies should be invited and encouraged to engage in such joint ventures, if need be as part of PPPs.

6) Manufacturers who have submitted a dossier for, and are near to obtaining SDRA registration or WHO Prequalification, should be invited to all relevant quality assurance meetings set up by WHO and/or UNICEF for a better understanding of the environment in which tenders take place and accelerating access.

Recommendation with regards to funding the TA to local manufacturers

Needs assessment, allocation of funding and implementation planning could benefit from more consultation and coordination within a global coordination mechanism that includes partners with experience in the pharmaceutical industry. Existing projects (e.g. UNITAID support of the prequalification program, RBM PSM WG building on RBM Secretariat experience, UNIDO) should be leveraged where possible.

Further work needed

- Further mapping and assessment of local manufacturers and detailing of technical assistance needs (RBM PSM Working Group)
- Further definition of mechanisms to promote quality manufacturing of ACTs in endemic countries such as joint ventures and technical assistance modalities
- Definition of roles and responsibilities in funding and implementation of technical assistance to finished product and API manufacturers

Reference Documents

“Local Production of ACTs,” 4 pages.

2Ai: Country Preparedness Criteria

PSI: R. Orford; *WHO*: R. Carr, G. Ki-Zerbo, P. Olumese, S. Spinaci; *WHO Consultant*: E.M. Depuy, P. Lalvani; *UNICEF*: M. Renshaw, A. Spiers; *CHAI*: B. Mooneri, O. Sabot; *Malaria No More*: S. Basu; *World Bank*: J.P. Clark; *Global Fund*: M. Grabowsky, S. Lazzari, C. Schrade; *MSH*: R. Shretta; *IDA Solutions*: H. den Besten; *RBM*: J. Banda, J. Van Erps, N. Lasri, B. Udom Rhona; *Columbia University*: A.. Teklehaimanot; *World Bank Booster Program*: A-M. Pierre-Louis

Objective

Develop criteria to ensure that the largest number of countries can access the AMFm, while ensuring that risks involved in introducing co-paid ACTs are mitigated and that resources committed to the AMFm are used effectively, quickly and safely.

Context

Country preparedness criteria have been developed as part of a set of rules that determine the AMFm. Broad criteria were defined in the technical design phase and refined during technical consultations of the working group.

Naturally the implementation of AMFm is most likely to occur step wise, as only few countries fulfil readiness criteria at present. Learning by doing in those countries will generate the initial evidence base that will inform the scale up of AMFm.

Technical Recommendations

To be considered prepared to roll-out co-paid ACTs, countries need to nominate an in-country coordination body to oversee the AMFm. To be considered prepared, countries will have to submit a costed and financed plan for rolling out the AMFm. The following components are preliminarily recommended:²²

- An identified national pharmacovigilance focal point²³
- Approach country is taking to increase access to ACTs beyond health facilities, through home based management of malaria and private sector outlets
- List of eligible first line buyers²⁴
- Approaches to strengthen national M&E frameworks to track impact of AMFm
- Supporting interventions plan for roll-out of the AMFm. This should include the following items:
 - Public education and awareness to increase awareness of availability of cheap ACTs and to improve treatment seeking behavior
 - Provider training in the appropriate use of ACTs
- The plan could further include (and does not have to be limited to) the following items, depending on country circumstances:
 - The use of pre-packaging of ACTs for high risk groups, such as children, to improve adherence
 - Actions to ensure price and margin control along the private sector supply chain (e.g. wholesaler incentives, margin control mechanisms)
 - Actions to strengthen private sector supply chains
 - Scaling up the use of diagnosis in the treatment of malaria

²² To be finalized in consultation with countries, technical partners and the Global Fund

²³ As per recommendation of the work stream on pharmacovigilance

²⁴ As per recommendation of the work stream on buyer eligibility

- Strengthening regulatory capacity for enforcement consumer protection
- Plans for phasing out of monotherapy treatment of uncomplicated malaria

It is proposed that the roll-out plan will be validated by RBM-MIST, based on criteria to be determined in the implementation phase.

To be considered prepared to roll-out co-paid ACTs, countries also need to identify a local coordination body that leverages existing structures to oversee the AMFm. It should encourage representation of private sector stakeholders and additional donors, and will work in line with national oversight and regulation mechanisms.

There is a need to define how the stewardship capacity of the public sector will be developed/ strengthened to manage access to medicines and consumer protection associated with the legitimate provision of treatment through community agents and the private sector. While increased access, particularly in the private sector, is most welcome, the burden on public sector monies to assist in some functions could be substantial.

Next Steps

Prior to launch the subgroup needs to complete the following steps:

- Engage in country consultations
- Determine, for each criterion, the minimum requirements for approval
- Develop a process for validating country roll-out plans

Reference Documents

“Country Preparedness Criteria: Task Force Recommendation”, 4 pages.

2Aii: Buyer Eligibility Requirements

Members

RBM Consultant: P. Lalvani (Focal point); *LSHTM:* L. Mangham; *Global Fund:* L. Dann, A. Freeman, C. Schrade, S. Stottrup (Input from *CHAI:* O. Sabot; *RBM Secretariat:* J. Van Erps)

Subgroup Objective

Buyer eligibility requirements ensure that only first-line buyers with the necessary qualifications and capabilities access the AMFm. This requirement will help ensure that co-paid ACTs are introduced responsibly and efficiently. Buyer-eligibility requirements will be designed to be transparent and light, still covering all important buyer aspects of responsible introduction of ACTs.

Context

The working group used as its starting point two documents: the AMFm Technical Design and the Background Paper 6 section on buyer eligibility requirements. In forming and refining its recommendations, the working group consulted with a selection of manufacturers, first-line buyers, and other stakeholders. However, given the short deadlines, the group was not able to 'field-test' the recommendations to determine the validity in multiple country settings--it is highly recommended that this is done before agreeing on the final recommendations.

Buyer eligibility requirements will apply to all first-line buyers, defined as buyers purchasing AMFm co-financed ACTs directly from manufacturers. First-line buyers will include international, regional or national buyers from the private, public or NGO sector, or procurement agents buying ACTs on their behalf.

Technical Recommendations: Assessing Buyer Eligibility Requirements

The working group recommends that all first-line buyers to be deemed eligible for AMFm, must as a minimum standard:

- Be legally registered with the national drug regulatory authority (NDRA) for the importation and distribution of pharmaceutical products
- Sign a short, standard AMFm first-line buyer contract committing to:
 - Sell ACTs only to destination countries that meet preparedness requirements.
 - Adhere to the AMFm principles of good practice and ethical behavior²⁵
 - Allow AMFm access to staff, facilities, and records to conduct reviews of buyer compliance with requirements

Additionally procurement agencies such as WHO and UNICEF or other international agencies, if requested to support public procurement, will do so in accordance with their normal procedures.

²⁵ Specific principles of good practice and ethical behavior to be determined by the AMFm Secretariat

Although there was general agreement with the above criteria and that it should be used as a minimum standard, the working group in London did not reach consensus on what **additional** criteria to include. The three options explored by the group were:

Option 1: to work with buyers that have a commercial relationship with AMFm eligible suppliers

Option 2: to work with buyers that have a commercial relationship with AMFm eligible suppliers (option 1) plus some number of additional buyers

Option 3: to work with all eligible buyers as per the minimum criteria indicated above.(no additional requirement)

While each option has its advantages and disadvantages, the group was 'leaning towards' Option 2, which would minimize the high transactions costs of including all eligible buyers (option 3) and would also reduce the concern that relying on too few buyers and existing commercial relationships only (option 1) would reduce access..

However, there was no consensus on how many buyers would be appropriate, nor was there consensus on how to select these buyers. In order to respond to these questions, additional research would be required in different country settings, e.g. in high burden and low-burden countries; Anglophone and Francophone countries; African and Asian countries, etc. (refer to end of this section for additional research)

Technical Recommendations: Assessing Buyer Eligibility Requirements

The working group recommends that approved AMFm suppliers be required to conduct the primary assessment of buyer eligibility by (a) confirming that the first line buyer is registered with the national regulatory authorities and (b) collecting and submitting to AMFm a signed AMFm first-line buyer contract. The manufacturer will submit this proof of registration and signed contract to AMFm along with the buyers' first order to AMFm, and periodically thereafter. The manufacturer will enter this information in the same AMFm order system as the one capturing order details and forecasts for future purchases.

The above recommendation has to be 'field-tested' with manufacturers—and although they are likely to agree with options 1 and 2, they may not be able to effectively implement this recommendation for Option 3, especially if 'too many' eligible buyers apply to purchase these medicines. This section of how to implement buyer eligibility will need to be revisited after a preferred option has been agreed upon.

Whichever approach is selected, the working group recommends that the AMFm Secretariat verify and enforce this assessment of buyer eligibility by conducting periodic spot audits to determine compliance with requirements. The AMFm or PSM Working Group is tasked with exploring the best method for conducting these periodic reviews, and the best partners to work with in implementing these assessments, including working with local authorities, manufacturers, or other designated local entities. The AMFm Secretariat will also maintain and publish a list of all eligible buyers making transparent all buyer order information.

Next Steps

Conduct further assessment to determine the preferred option. Questions that need to be answered include:

- Understand what impact the number of first-line buyers have on the availability and retail price (affordability) of ACTs in the downstream supply chain
- To what extent does horizontal distribution (importers selling to other importers) occur? And if there is horizontal distribution, what is the impact on the wholesale price / percentage mark up?
- Consider the implications of requiring manufacturers to work with a minimum number of first-line buyers and the willingness of the manufacturers to do so?
- The ability of manufacturers to effectively screen and manage multiple first line buyers (more than what they normally do).
- What impact would the preferred option have on operating costs of buyers, manufacturers and AMFm secretariat?
- Would the preferred option be applicable to buyers in all countries? What about fragile states, etc.)

Reference Documents

“Report from the RBM/PSM WG AMFm Buyer Eligibility Working Group Team”, 13 pages.

2B,C&D: Supporting Interventions Architecture

Global Fund: C. Schrade; RBM Harmonization Working Group: M. Renshaw (UNICEF), S. Basu (Malaria No More), R. Orford (PSI).

Objective

The objective of this workstream is to outline the high level architecture and channels for financing supporting interventions programming and technical assistance (TA).

Context

The approach to financing supporting interventions is based on the principles of building on existing mechanisms and ensuring country ownership. The Global Fund is likely to be the primary funder of supporting interventions. From the Global Fund perspective, supporting interventions can be financed either by releasing approved budget due to reduced ACT costs (reprogramming) or by new grants. The process for reprogramming will be light and is under development.

Technical Recommendations

There are two channels for funding supporting interventions:

1) Countries will define their supporting intervention programming needs and business plans to address them, which are then submitted for funding by the Global Fund and other donors. Countries could be supported by the RBM Harmonization Working Group (HWG) and the RBM Malaria Implementation Support Team (MIST) or whomever countries prefer, building on existing processes. Countries will be able to apply to the Global Fund and other existing funding entities for funding for supporting interventions in the form of either reprogramming or new grants.

- Countries without existing Global Fund malaria grants:
 - Apply for supporting intervention finance through the Round system.
 - Apply for funding (reprogramming or new grants) from other donors.
- Countries with Global Fund malaria grants:
 - Integrate reprogramming into the Phase 2 request for incremental funding.
 - Complete a short reprogramming application outlining which supporting interventions the freed up resources will fund, how the additional supporting interventions integrate into ongoing efforts, how they will be rolled out and how progress will be measured.

2) For cross-cutting TA that applies to multiple countries, there will be a separate funding stream. Resource Mobilization for TA would need to be carried out separately as funds would not be channelled through the Global Fund.

Next Steps

HWG is continuing to work on options for the provision and financing of cross-cutting TA, and clarifying the role of MIST in relation to AMFm support by November 2008.

Reference Documents

“Overall architecture for financing supporting activities,” 2 pages.

2E: Monitoring and Evaluation

MERG: R. Steketee, S. Meek, A. Kilian, E. Eckert, R. Newman, P. Mbabazi, B. Nahlen;
LSHTM: L. Mangham

Objective

Monitoring and evaluation (M&E) of the AMFm will be essential to demonstrate progress towards its objectives of increasing the affordability and availability of ACTs and crowding out of AMTs. M&E and operational research (OR) will also provide information to adjust the AMFm design as needed to fit various endemic countries, guide the use of supporting interventions, assess the effectiveness of the approach and plan an exit strategy.

Context

The M&E framework for the AMFm was developed during the technical design phase and presented in annex to the technical design. The MERG has commented on this framework as part of the effort to finalize outstanding technical questions of the AMFm. It suggested changes to the approach, including reducing the number of core indicators and limiting M&E activities to outcomes directly linked with the implementation of the AMFm. Based on these suggestions, adjustments to the framework are recommended here and next steps are presented.

Technical Recommendations

Indicators

Three core indicators are recommended for demonstrating progress against AMFm objectives in all AMFm recipient countries:

4. Cumulative percentage mark up between retail median unit price and manufacturers unit price for full course of ACTs
5. Median cost to patient of full course of ACT relative to daily minimum wage for a government unskilled worker
6. Proportion of providers reporting no disruption of stock of ACTs for more than one week during the previous three months

In addition, it is recommended that two further indicators, collected by RBM, be analyzed:²⁶

7. Proportion of children under five years of age with a fever who received ACTs within 24 hours of onset of fever
8. Proportion of children under five years of age receiving antimalarial treatment for a fever who received ACTs, AMTs and non-artemisinin derivative antimalarials

Implementation

- The implementation of AMFm M&E will be coordinated by the AMFm Secretariat and will aim to minimize the burden on countries and to leverage the use of existing M&E initiatives
- It is also recommended that the AMFm Secretariat coordinate with RBM MERG to ensure access to relevant data and outcome measures and to avoid duplication

²⁶ Indicators presented here differ slightly from indicators currently collected by RBM –the RBM indicator set is being reviewed by the MERG and changes to indicators may be made

- Dialogue with WHO/HAI (and others) is recommended to promote and support the application and possible adaptation of the Medicines Prices Survey methodology.

Technical issues for discussion

A number of technical issues that need further consideration have been identified and are recommended to be included in discussions during the finalization of the M&E framework:

- To what extent the AMFm reaches those in *need* of malaria treatment (i.e. proportion to individuals with a fever and receiving ACTs who *have* malaria)
- Monitoring of drug quality
- Inclusion of upstream indicators for monitoring of flows, volumes and prices of ACTs along the supply chain
- Data collection and reporting on the distribution of co-paid ACTs (a) in the commercial sector as a fraction of country-wide ACT consumption and commercial sector anti-malarial consumption to show AMFm contribution to improved access and (b) by socio-economic status and geographically through disaggregation of data for the core indicators to assess equity

Next Steps

The following next steps are recommended to finalize the M&E framework:

- By April 2008: finalization of indicator set – coordinated by MERG and Global Fund, with technical support by consultants in drafting of indicator set
- By July 2008: finalization of M&E tools (surveys, data collection plans) and definition of roles and responsibilities between the AMFm Secretariat, countries and MERG partners
- By Q3 2008: implementation of baseline studies in sentinel countries

Reference Documents

“Comments from the Roll Back Malaria Monitoring and Evaluation Reference Group (MERG) on the AMFm Monitoring and Evaluation (M&E) and Operations Research (OR) Plan”, 9 pages.

“AMFm Technical Design Background Paper 3: Monitoring & Evaluation and Operational Research”, 73 pages.

2F: Economic Appraisal and Access by the Poor

DFID commissioned: M. Pearson, K. Hanson, C. Goodman

Objective

Assess the ability of AMFm to reach the lowest income quintiles (equity) and its cost effectiveness.

Context

During its sixteenth meeting, the Global Fund Board emphasized the need for the intended mechanism to seek to increase broad access to ACTs especially among those at highest risk. Cost effectiveness compares AMFm to alternatives and assesses the relative benefits and costs of each.

Technical Conclusions: Equity

Access to antimalarials is currently very limited for vulnerable populations. While Chloroquine and SP penetrate relatively well into remote and urban poor populations, there are families and individuals who cannot afford the 0.20 – 0.30 USD cost of CQ today. Unfortunately, there are significant constraints for interventions to reach these populations cost-effectively and at scale. In this respect, distribution of antimalarial treatments faces similar challenges to other public health interventions. The AMFm will be a platform providing low-cost ACTs and thereby facilitating public and non-profit sector interventions to distribute ACTs free of charge to reach vulnerable populations, including children under five and pregnant women, and the poorest. Reaching these populations is a key global health priority and the primary responsibility of public sector malaria programmes and in some cases the non-profit sector. The Global Fund and other funding mechanisms are open to qualified applications for support for such free distribution and countries should be encouraged to incorporate these interventions in their national malaria plans. Operations research using the cheap drugs provided by the AMFm is needed to understand exactly which interventions are most effective to increase access for vulnerable populations. Lessons from country studies also need to be taken on board in refining how the AMFm works.

Technical Conclusions: Cost effectiveness

The proposal is judged to offer good value for money. However, further analysis would help to confirm this finding, and a number of alternative approaches (e.g. paediatric doses only, sub Saharan Africa only, partial subsidy) should be investigated further on their cost-effectiveness, or at least the reasons for not pursuing these alternatives should be clearly explained.

Recommendations

The Task Force recommends that the current design as approved by the RBM Board in November offers good value for money. It further recommends that a number of alternative approaches (e.g. paediatric doses only, sub Saharan Africa only, partial subsidy) should be investigated further on their cost-effectiveness.

Next Steps

Operations research (potentially using a “challenge fund”) could be used to understand exactly how AMFm could increase access for the poor. Countries should be encouraged

to include strategies to reach the poorest in their malaria/health plans, and the Global Fund and other grantmaking bodies have a role in funding these. Further analysis may be needed on alternative, more targeted approaches.

Reference Documents

“AMFm – Economic Appraisal and Access by the Poor,” 41 pages.

2G: Operational Research

Roll Back Malaria Monitoring and Evaluation Reference Group (MERG): R. Coghlan (MMV), L. Mangham (LSHTM), S. Khan (PSI)

Context and objective

To date, a number of countries have implemented national or sub-national subsidization schemes that lower the price of ACTs to patients. These schemes are similar at the country or district level to the planned AMFm. Interventions are known to be in place or being launched in 10 countries²⁷, and planned in 4 countries²⁸. The attached table provides a brief summary of existing and planned interventions.

In view of the rollout of the AMFm, thorough understanding of the likely functioning and impact of the AMFm at the country level is required. It is critical that there is an understanding of the dynamics of the overall antimalarial market, and not just the market for ACTs, in malaria endemic countries. This is to understand the impact of the AMFm on replacing older classes of drugs and expanding the total antimalarial market. During the technical design phase questions were raised around the likely outcomes of providing low-cost ACTs in endemic countries. The question of price transmission along the supply chain was identified as particularly important in determining the feasibility of the AMFm. These questions were in part addressed by the results of two ongoing initiatives in Senegal (through Global Fund grant funding) and Tanzania (through a study by CHAI).

In implementing and launching the AMFm, operational research (OR) will serve two distinct objectives, complementing M&E activities:

- Help mitigate risks in the rollout of the AMFm by feeding in the lessons learned from existing national or sub-national initiatives subsidizing ACTs, and through intensive M&E and operational research in sentinel countries during the first years of operation of the AMFm
- Help make the implementation of the AMFm more efficient by determining the effectiveness of supporting interventions, thereby helping endemic countries select the most appropriate interventions

Technical Recommendations

Given the two objectives for operational research and the existence of a number of initiatives that can be evaluated to inform the rollout of the AMFm, the following approach is recommended:

- Synthesize and analyze results from existing initiatives to inform the selection and design of further OR on the AMFm²⁹

²⁷ PSI reports projects in: Cambodia, Madagascar, Myanmar, Nigeria, Rwanda and Tanzania; MMV in Uganda; DFID in Zambia; Global Fund grant funded subsidization exists in Cameroon and Senegal

²⁸ Interventions are planned in Angola, Malawi and Mozambique; an intervention in DRC is currently on hold

²⁹ Issues to be considered should be developed based on the synthesis of existing work and could include, for example price transmission along the supply chain, incentives along the supply chain to displace monotherapies, equity of access, the impact of supporting interventions and the reach of the intervention

- Conduct OR in 2-4 additional countries³⁰ to create a set of 4-6 representative sentinel countries that include different market conditions and cultures
 - Conduct OR during the preparation phase to help inform the rollout of the AMFm
 - Continue OR during the first 1 to 2 years of the AMFm's launch to mitigate risks of rolling out the global copayment system and inform country selection of supporting interventions

OR activities should be planned and implemented in coordination with Monitoring & Evaluation activities, and should thus be addressed by the MERG as the coordinating body for M&E and the Global Fund as the likely implementer of the AMFm. Close coordination with existing implementers of OR should be sought to inform planned activities as far as possible.

Next Steps

To implement OR, the process for deciding on sentinel countries and the focus of research will have to be put in place. This should be informed by information about existing OR activities, which should be synthesized and shared with the community to determine OR focus. The following steps are recommended:

- By May 2008: synthesis of existing information – coordinated by MERG, with external support
- By June 2008 (conditional on endorsement of the AMFm business plan by the Global Fund board): determination of OR focus areas and approaches and choice of additional sentinel countries – guided by MERG, in close collaboration with the Global Fund and current implementers of operational research
- From June 2008: funding, planning and implementation of OR studies in sentinel countries

³⁰ In addition to existing operational research activities in Uganda and Tanzania

Operational Research Already Underway

Country	Current	Coverage	Supporting interventions	Availability of results
Cambodia (PSI)	Yes	<ul style="list-style-type: none"> 17 provinces Pharmacies, drug shops All age groups 	<ul style="list-style-type: none"> Training IEC MVU 	HH survey data from 2006 is available. Follow up survey mid 2008.
Cameroon (govt / GF)	Yes	<ul style="list-style-type: none"> Nationwide Pharmacies All age groups 	<ul style="list-style-type: none"> TBD 	Forthcoming (Malaria Consortium)
Madagascar (PSI)	Yes	<ul style="list-style-type: none"> Nationwide Children under 5 only Through pharmacies, private sector health providers and community agents 	<ul style="list-style-type: none"> Training BCC Pre-packaged products, RRP IPT 	Late 2008
Nigeria (PSI)	Yes	<ul style="list-style-type: none"> Limited by funding Children under 5 only OTC Aiming for \$0.26-\$0.35 to the consumer 	<ul style="list-style-type: none"> Training Pharmacovigilance Campaign against oral artemisinin monotherapy IPC 	May 2008
Rwanda (PSI)	Yes	<ul style="list-style-type: none"> HMM districts OTC in HMM districts only Children under 5 only 	<ul style="list-style-type: none"> PPT packaging Integrated A&P and BCC campaigns Training BCC IPC IPT 	Outlet survey: February 2008 HH survey: May 2008
Tanzania (to be conf. if 2 projects)	Yes	<ul style="list-style-type: none"> 2 district operational study OTC in research sites only All age groups 	<ul style="list-style-type: none"> IEC RRP in one district 	Interim report Nov 2007 / next results Apr / May 2008
Myanmar (PSI)	Yes	<ul style="list-style-type: none"> Small scale Use of clinic franchises All age groups 	<ul style="list-style-type: none"> Product insert information IEC TV spots IPC and MVU 	HH and outlet surveys planned for 2008
Senegal (Govt / GF)	Yes	<ul style="list-style-type: none"> Nationwide Private sector pharmacies All age groups 	<ul style="list-style-type: none"> TBD 	November 2007
Uganda	In launch	<ul style="list-style-type: none"> 6 intervention districts Sectors TBD All age groups 	<ul style="list-style-type: none"> Training BCC/IEC OTC rescheduling Repackaging, RRP Umbrella branding 	Mid 2008
Zambia (DFID)	In prep.	<ul style="list-style-type: none"> Nationwide Private sector beyond existing channels All age groups 	<ul style="list-style-type: none"> Repackaging RRP Volume & coverage incentive to wholesalers Training Subsidized RDT Case management training 	TBD – end 2008?
DRC	On hold	<ul style="list-style-type: none"> Small scale Children under 5 only Delivered through pharmacy only 	<ul style="list-style-type: none"> TBD 	TBD
Angola	No	<ul style="list-style-type: none"> Pilot study, leading to nationwide Pharmacies and drug shops Distribution via community agents considered Children Under 5 Only 	<ul style="list-style-type: none"> TBD 	TBD - end 2008?
Malawi	No	Similar to Uganda proposal – to be confirmed		Mid/end 2009
Mozambique	No	Similar to Uganda proposal – to be confirmed		Mid/end 2009

4A: Copayment Setting and Supplier Arrangements

UNITAID: J. Bermudez, P. Duneton, I. de Leon; *Global Fund:* C. Schrade, S. Stottrup;
CHAI: O. Sabot, I. Singh

Objectives

Examine options for AMFm's interactions with ACT manufacturers up until the point of delivery to the first-line buyer. The following objectives should govern those interactions:

- Maximize impact of available resources by securing lowest possible sustainable price for ACTs prior to copayment
- Maximize patient ACT access by ensuring an appropriate price to first-line buyers which makes ACTs affordable to end users
- Facilitate a healthy, competitive global ACT market with multiple quality assured suppliers of each product and strong incentives for the development of new products

Context

The proposed Affordable Medicines Facility - Malaria (AMFm) presents major opportunities and risks to the global market for ACTs. As the facility will eventually copay most ACTs purchased in the world, it will drive global demand for these products. If leveraged appropriately, this ability, unique in global health, could enable the AMFm to ensure a sustainable supply of diverse, low-cost ACTs. It is critical that the AMFm adopt a policy and operational framework for its interaction with suppliers that is focused on promoting the successes and mitigating the anticipated risks.

Technical Recommendations

Determination of initial price: Given that currently ACT markets are non-competitive (limited supplier) markets, a direct negotiation is recommended, taking into account the cost structures where possible (e.g. through a cost plus approach). A move to an auction mechanism could be made if product markets become more competitive.

Determination of copayment: Copayment levels should be set for each supplier of each product in line with the following principles of AMFm: where possible the copayment should not be greater than the supplier's cost of production and the copayment should be set so that the remaining cost to the first-line buyer is lower than the price of SP since the goal of the AMFm is to replace cheap and increasingly ineffective CQ and SP with ACTs.

International Distribution: Ceiling prices should be set for international distribution in a manner that enables flexibility by suppliers and buyers, but which does not incentivize price increases or inefficient purchasing behavior (e.g., shipping of very small orders).

Price to First-Line Buyer: AMFm should set a price range that manufacturers can charge first-line buyers based on the initial price and level of copayment.

Non-Price Factors: AMFm should require suppliers to meet certain minimum packaging standards and to play a role in enforcing buyer eligibility requirements.

Next Steps

- Define roles and responsibilities in setting up supplier relationships.
- Gather expert resources on procurement and market incentive analysis to further operationalize negotiation and policy framework.
- Conduct market outreach towards manufacturers to build an information base, and engage in preparatory negotiations for copayments. Based on these pre-negotiations, the first round of determining copayments will be completed prior to the launch of the AMFm.

Reference Documents

“Initial Report of the AMFm Working Group on Supplier Sourcing,” 5 pages.

4B: Packaging

MMV: P. Grewal (Focal point); *PSI*: R. Orford; *TDR*: F. Pagnoni; *CHA*: O. Sabot, L. Ward; *WHO*: P. Olumese, S. Spinaci, A. Bosman; *Bill & Melinda Gates Foundation*: T. Kanyok; *Malaria Consortium*: S. Meek; *Global Fund*: M. Grabowsky; *Private sector*: I. Boulton, H. Rietveld

Objective

Propose an option which balances the goal of increased adherence to proper procedures for ACT dosing against the increased cost and complexity associated with customization.

Context

Options for packaging can be thought of in a range of five possibilities including:

- Standard blister packs (least customized)
- Weight specific generic packs
- Weight/age specific generic packs with minimal global instructions
- Country specific packaging with local language/illustrated instructions and age specific blisters (most customized).
- Weight/dispenser packs containing blister strips based on the lowest weight band.

The team looked at the benefits and risks of each option while considering issues of good manufacturing practices and WHO guidelines, which suggest illustrated patient instructions.

Technical Recommendations

Use AMFm buyer power to set minimum global standards to facilitate correct dispensing and adherence and guide consumer choice. In view of the large evidence base documenting the value of age-weight specific packaging on adherence, as well as the fact that these products will be provided by dispensers with limited knowledge and experience, this group recommends focusing on weight/age-specific packs with minimal global illustrations. It will also allow countries which choose to improve adherence through country specific packaging to work directly with manufacturers / partners on a project basis. The team agreed that an AMFm brand identity would provide a seal of approval for quality and affordability which would be needed for information and education campaigns. All packaging and labeling should be to WHO GMP standards of quality.

Next Steps

- March – May: Further work to address major questions on how standardized packaging facilitates dispensing, use and PSM; Investigate estimated costs and feasibility; Develop creative brief for development of AMFm brand identity
- July – September: Work with approved products to adapt to AMFm standards
- September onwards: Support registration of new product design, costs worked out by Task Force

Reference Documents

“Challenge 4B: Packaging,” 4 pages.

4C: Demand Forecasting

Forecasting Task Force of the RBM PSM Working Group includes S. Schwarte; P. Verstraete as well as *MSH*: R. Shretta; *IDA Solutions*: H. den Besten; *CHAI*: I. Singh; *MMV*: R. Coghlan; *RBM Secretariat*: J. van Erps; *WHO*: A. Bosman; *MIT-Zaragoza*: P. Yadav

Objective

Improve forecasts by harmonizing inputs and assumptions, providing feedback on methodology, reducing duplication of efforts, expanding access to data sources, identifying data needs, and reaching out to the malaria community to gather these data.

Context

Accurate forecasts are needed to stabilize the ACT market and to ensure adequate supply. Historically demand forecasting for ACTs has been difficult because of the immature status of the market and the lack of past procurement data with which to model. The following table summarizes the initiatives under way and progress to date.

Organization	Initiatives underway	Progress to date
CHAI	Estimating public and private sector demand with scenarios for AMFm. Public sector demand is estimated using a funding-based approach, considers funding from the Global Fund, PMI, World Bank and UNITAID, and accounts for time lags between the approval, disbursement and use of Global Fund funds. Private sector demand is estimated using an epidemiological approach to first estimate total antimalarial demand and then forecast ACT demand as a fraction of that total based on assumptions and scenarios about uptake, affordability and willingness to pay.	Draft forecast circulated to members of the PSM Working Group. Release is targeted for mid February and the first component of a web-based dynamic version of the model, which will allow users to change key assumptions, is expected in mid-March
MIT-Zaragoza	Estimating private sector demand through country by country forecasts of private sector consumption	The model has been developed and will be updated based on new data from Uganda, Tanzania, Zambia (possibly) and also new malaria incidence data and forecasts from RBM database. Conjoint analysis for anti-malarial purchasing will take place over the next 5-6 months.
WHO	Estimating public sector demand using procurement related data	Expect to launch GMP Supply Chain Management Global Database within the first quarter of 2008
RBM Secretariat	Estimating procurement and funding of key malaria commodities through historical funding and procurement data. Projections include planned and expected needs, as expressed by countries and partners.	Targeting the release of individual forecasts in mid-March

There is a need to take into account the timeline for the UNITAID Board decision making process as well as UNITAID role in negotiations and forecasting.

Recommendations:

In order for RBM to rapidly come to grips with ACT forecasting and to enable convergence to an acceptable range of forecasts in a foreseeable future

- the PSM WG is requested to provide a first range of forecasts as soon as possible
- the PSM WG is requested to include UNITAID and other interested partners.
- forecasts should be created by each group separately and shared for comparison together with the methodologies and assumptions used and relevant data collected.
- The AMFm manager should provide transaction and monitoring data in real time to forecasters to facilitate timely forecasts, but is not expected to conduct its own forecasts..
- The AMFm manager should publish all available forecasts.

Further work needed:

The FTF workplan includes several workstreams aiming at improving and refining data and info collection. A particular effort aims at data and info to be gathered from the private sector distribution channels in countries. To this purpose MIT-Zaragoza kindly accepted to join and support the Forecasting Taskforce of the PSM WG. The FTF will also explore a possible role and contribution of the ACT suppliers in refining the private sector demand forecast.

Next Steps

To ensure publication of first set of forecasts by October 2008 at the latest, the sub-group needs to address data gaps in forecasting initial demand under AMFm. The forecasting process requires active input from other workstreams including:

- Country preparedness and product eligibility
 - AMFm work streams on country preparedness and product eligibility should begin communicating regularly with forecast groups to ensure that forecasts reflect changes in planning for options,
- Operations & Market Research
 - Data collection should begin as soon as possible to allow estimation of initial order volumes under AMFm and ensure that suppliers can plan production appropriately.
- Historical procurement information
 - Historical data should be shared by participating manufacturers and buyers.

To address data gaps in ongoing demand under AMFm the sub-group will require:

- Transactional Information
 - Transactional data should be provided by the AMFm manager to forecasting groups on a quarterly basis.
- Monitoring Activities
 - The AMFm manager should gather data from representative sites, following AMFm launch.

Reference Documents

“Forecasting ACT Demand: Task Force Recommendations to AMFm”, 3 pages. CHAI,
“Global Forecast of ACT Demand,” 46 pages.

5A: Updated Resource Requirements for Supporting Interventions

Global Fund: C. Schrade; PSI: R. Orford; UNICEF: A. Spiers; CHAI: I. Singh

Objective

To arrive at a more accurate estimate of the funding that will need to be mobilized for AMFm supporting interventions.

Context

Estimates include new as well as existing activities that will be required for responsible and successful implementation of AMFm. The estimates for funding requirements have been derived using a “bottom-up” methodology of estimating activity levels as well as a “top-down” approach of benchmarking cost ratios. The categories of activities included in the funding estimates are:

- Public awareness, education and repackaging for vulnerable populations
- Provider training
- Monitoring and evaluation
- National monitoring and quality preparedness
- Technical assistance in support of policy and regulatory preparedness
- Wholesaler interventions and price control mechanisms

It should be noted that the assumptions and estimates used for this analysis are only for the purpose of developing a resource mobilization target. The actual supporting intervention plans themselves will be developed at the country level and subject to review through the proposed supporting intervention funding architecture.

These scenarios were updated to incorporate feedback from various stakeholders that the original country participation estimates did not fully account for the length of time that it will take countries to prepare and file applications for the AMFm. Country consultations will yield more accurate information on the level of country interest and preparedness. In the meantime various scenarios have been constructed using assumptions based on stakeholder feedback.

One of the key changes made to the model was to develop more accurate AMFm rollout scenarios. Country participation estimates have been updated to include all 107 malaria endemic countries in the base assumptions. Participation scenarios have been modified (high, medium and low) based on qualitative assumptions of varying levels of country interest and preparedness.

Technical Recommendations

There is an advocacy and resource mobilization sub-group including the Bill & Melinda Gates Foundation, the Global Fund, Malaria No More, the RBM Secretariat, the UK Department for International Development, UNITAID, the William Clinton Foundation and the World Bank.

The AMFm co-payment fund requires USD 1.1-1.4B for the first 5 years. The UNITAID Board in December 2007 requested the UNITAID Secretariat to further explore the potential role and added value of UNITAID’s involvement in the AMFm, taking into consideration the alignment between the objectives of UNITAID and AMFm.

Supporting interventions require approximately USD 400M – 500M for the first 5 years. Supporting interventions will be funded

- out of regular Global Fund grant resources through the reprogramming and new grant process described above
- by other donors including foundations, bilateral donor agencies and multilaterals.

Further work needed:

Organize donor consultations and meeting to secure funding additional to possible UNITAID funding for the co-payments and to Global Fund funding for supporting interventions

Reference Documents

“Updated resource requirements,” 3 pages.