GF/B16/6
Attachment 1

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Section 1: AMFm – Letter of the Roll Back Malaria Partnership to the Global Fund.

ROLL BACK MALARIA PARTNERSHIP

Professor Kazatchkine
Executive Director
The Global Fund to Fight
AIDS, Tuberculosis and Malaria
Chemin de Blandonnet 8
1214 Vernier
Geneva
Switzerland

16 August 2007

Dear Professor Kazatchkine,

On behalf of the Roll Back Malaria Partnership Secretariat, the RBM Executive Committee, and the RBM Global ACT Subsidy Task Force, I wanted to thank you and your management team for meeting with members of the Task Force and the Dalberg project team. We understand this initial meeting was very fruitful. We especially appreciate your positive comments, the constructive discussion and the mutual desire to see how best to move forward.

One important consideration which was discussed informally with you was the possibility of the Global Fund "hosting" the Global ACT Subsidy Facility. The Global Fund's role as the largest current funder of ACTs links strongly to the Global ACT Subsidy objective of increasing the overall use of ACTs. While we all recognize there is still considerable work to be done before the Global Fund Board can consider and approve such an arrangement, I wish to confirm that we would like the Global Fund to pursue initial discussions with your Board's Policy and Strategy Committee to explore the possibility of hosting the Global ACT Subsidy within the Global Fund and determine what the steps in setting up such an arrangement would be.

The RBM Global ACT Subsidy Task Force is in the process of finalizing a technical proposal for the Subsidy that will provide a detailed description of how the objectives and principles approved by the RBM Board would be implemented. We will share this technical proposal with you as input to your process. The Task Force will also be pleased to work with your team to ensure there is clear understanding of the RBM approved principles under which the subsidy would operate its objectives, design, and key performance indicators.

In the mean time we are continuing to work with other potential hosting institutions to ensure we capture all interest in this important initiative.

I look forward to further discussing with you these and related aspects of the proposed Buyer Subsidy.

ED'S OFFICE	
TO DEAL DIRECT	
17 AUG 2007	
TO DRAFT REPLY	
TO COMMENT	
FOR INFO	SL/MK/ML
FILE	RBM

Yours Sincerely,

Professor Awa-Marie Coll-Seck
Executive Director
Roll Back Malaria Partnership

RBM Board Members
May 2007

Chairperson
Ethiopia
Vice Chair
UNICEF

Constituencies

Malaria Endemic Countries
Cambodia
Cameroon (alternate Angola)
India
Lesotho
Mali (alternate Niger)
Nigeria (alternate Liberia)
Uganda
Venezuela

OECD Donor Countries
France/Italy
Netherlands/United Kingdom
United States of America

Multilateral Development Partners
UNDP
UNICEF
WHO
The World Bank

Research & Academia
MMV (Interim)

Northern NGO
JHUCCP (interim)

Southern NGO
AMREF
(alt. Zambia Malaria Foundation)

Private Sector
GSK (alternate Novartis)
ExxonMobil (alternate BASF)

Foundations
Bill & Melinda Gates Foundation
(alternate to be confirmed)

Ex-officio Members

Executive Director
The Global Fund

Executive Director
Roll Back Malaria Partnership

Executive Director, Roll Back Malaria Partnership • Partnership Secretariat hosted by WHO, 20 Av Appia, CH-1211 Geneva 27, Switzerland
Tel +41 (0)22 791 3920 • Fax +41 (0)22 791 1587 • inforbm@who.int • http://www.rollbackmalaria.org

Section 2: AMFm – Summary of the Roll Back Malaria technical draft

AMFm: Affordable Medicines Facility - malaria
[Formerly called the Global ACT Subsidy]

1. Introduction

Malaria treatment faces a dual challenge: extending the use of effective drugs for uncomplicated malaria to prevent as much suffering and death as possible, and at the same time preserving the effectiveness of antimalarials for as long as possible by reducing the chance for drug resistance to emerge and spread. Global low prices and use of drugs only in combination, respectively, have been identified as the best means available to meet these challenges. The reality is that most people who need malaria treatment cannot afford the currently recommended drugs, coformulations (i.e., two or more drugs in one pill) that include an artemisinin derivative, because they are 10-40 times as expensive as older, increasingly ineffective drugs. Those who can afford an artemisinin-based drugthey are more likely to buy it as "monotherapy," the use of which anywhere jeopardizes its viability everywhere, even where the recommended artemisinin-combination drugs (ACTs) are standard.

In 2004, an Institute of Medicine (IOM) Committee, led by Professor Kenneth Arrow, published a report recommending a global buyer co-payment for effective, coformulated antimalarials for uncomplicated malaria as the most economically and bio-medically sound means to meet the dual challenge[1]. The proposed buyer co-payment would be available to both the public and private sectors. In addition to saving lives, the innovation could delay the onset of resistance to artemisinins, creating a benefit for all – a "global public good." Better access to these drugs is an essential part of the comprehensive package of interventions required to fight malaria that includes prevention (insecticide-treated nets, indoor residual spraying, other vector control techniques and in-development vaccines) and treatments for severe malaria. Subsequent analyses published in both the Development Economics Working Paper Series and a peer reviewed journal[2], reconfirmed the principles laid out by the IOM committee. Immediate action is called for.

The Finance and Resources Working Group of the Roll Back Malaria Partnership initiated a work program in 2006 to translate the IOM proposal into reality. The work program is financed by a grant from the Bill and Melinda Gates Foundation, managed by the World Bank and guided by the RBM Affordable Medicines Facility - malaria (AMFm) Task Force[3]. The Netherlands and Tanzania co-chair the Task Force. Dalberg Global Development Advisors are facilitating the process of designing the co-payment system. Since a consultation among key stakeholders in Amsterdam in January 2007, this process has achieved several milestones and received strong support from endemic countries. In May 2007 the Roll Back Malaria (RBM) Partnership Board endorsed the key design principles of the co-payment. The AMFm Task Force members have provided inputs (which will be reflected in the final version) to a draft technical proposal and agreed on the co-payment design and requirements for implementation[4].

[1] Arrow, K., C. Panosian, and H. Gelband (eds.). 2004. Saving Lives, Buying Time: Economics of Malaria Drugs in an Age of Resistance. Washington, DC: The National Academies Press.
2 Laxminarayan, R., Over M, Smith D. Will a global subsidy of new antimalarials delay the emergence of resistance and save lives? Health Affairs. 25(2). Pp 325-336.
[3] Originally called the RBM Global ACT Subsidy Task Force.
4 The Task Force met on 11 September 2007.

2. Objectives and design principles

The immediate purpose of this summary is to facilitate a decision by the Executive Committee of RBM to endorse the design of the AMFm, which would pave the way for consideration by the full RBM Board during its meeting in November 2007. The draft technical proposal which complements this document has been prepared to describe the detailed design of the AMFm to meet the objectives and design principles endorsed by the RBM Board in May 2007.

Objective: Increase overall use of ACTs and other effective antimalarial coformulations
AMFm will promote the use of eligible antimalarials and help to drive monotherapies and ineffective drugs from the market. Initially, the only class of eligible antimalarials will be ACTs but this should change in the future as novel antimalarials emerge from ongoing R&D. It will achieve this by:

- Reducing end-user prices to an affordable level through a properly supported global buyer co-payment of ex-manufacturer prices (CIF[5] basis), in line with IOM recommendation by Professor Kenneth Arrow's committee;
- Introducing supporting interventions, including those for the proper use of effective antimalarials.

Summary of design principles

1. The success of AMFm will be measured by the degree to which it lowers the consumer price of effective antimalarials to the affordable level of CQ and SP, increases access to these drugs in all market sectors (public and private) -- particularly among the lower income quintiles-- drives monotherapies, sub-standard drugs and counterfeits out of the market and ensures that the effective lifespan of effective antimalarials is maximized through responsible introduction and use;
2. The antimalarials eligible for co-payment will be available to first-line buyers in the public, private, and NGO sectors in all malaria-endemic countries at a price competitive with CQ and SP;
3. The AMFm will be managed by a small Secretariat, hosted by an existing organization or organizations;
4. Product, supplier, and buyer eligibility will be guided by clear quality and price standards, with the concomitant aim of being as inclusive as possible;
5. In-country activities, essential to ensure the success of the AMFm, will be identified, facilitated and encouraged;
6. The co-payment roll-out under AMFm will be informed and monitored on a learning-by-doing basis. The modalities will include concomitant operational research and monitoring and evaluation of retailer prices, access, drugs quality, drug resistance and market dynamics. These can be either specific to or co-paid by AMFm.

The design of the AMFm, following these objectives and design principles, emphasises a responsible introduction of the co-payments. Standards and requirements for suppliers, buyers and countries as well as supporting interventions, will result in a gradual phase-in of demand over the first three to four years of AMFm operation. During this initial period, extensive operational research and monitoring will facilitate learning and adjustments to the mechanism.

[5] Cost, insurance and freight included, i.e. the landed cost.

3. Mechanism

A core activity of AMFm, which serves both the public and private sectors, is the co-payment towards purchases of eligible antimalarials by first-line buyers at a level that allows these drugs to arrive in countries at a price of USD 0.05 CIF per treatment course. The AMFm Secretariat will manage orders and process co-payments on an on-demand basis.

To be eligible for co-payments by AMFm, orders must meet the following standards and requirements which will be managed and validated by the AMFm Secretariat and its technical partners:

Antimalarials will be co-paid only if they belong to WHO recommended drug classes.
WHO treatment guidelines, as the internationally recognized standard for malaria treatment, define the eligible classes of drugs. Currently, these encompass four classes of ACTs[6]. As WHO treatment guidelines evolve and new products become available, eligible antimalarial drugs will be added to the portfolio of products offered by the Facility, in line with WHO recommendations. WHO, in collaboration with national authorities, will develop a list of approved antimalarials that is country specific, considering drug efficacy and parasite resistance patterns. Studies should be conducted as part of country support packages to maintain up-to-date information on these patterns.

Eligible antimalarials will be co-paid only if they belong to the list of pharmaceutical preparations meeting approved quality standards.
A transparent and internationally recognized quality standard is required to ensure delivery of high-quality pharmaceutical preparations while encouraging competition among suppliers in all treatment classes. The final quality standard will be WHO pre-qualification or registration by a stringent regulatory authority.[7] Pharmaceutical preparations submitted for such approval, but not yet approved, may be eligible for a period of two years, provided that they meet interim criteria along the lines of those currently applied to the WHO/UNICEF tender list and the Global Fund (ci) compliance list. The RBM Board has asked WHO to work with other relevant agencies to harmonize the criteria underlying these lists[8]. It is envisioned that these harmonized criteria will have been established prior to AMFm launch and will apply to AMFm.

Eligible antimalarials will be co-paid only if they are from suppliers with whom the AMFm Secretariat has an arrangement for terms and prices.
Given the limited competition in the current market for eligible antimalarials, price-setting will initially be based on negotiations with manufacturers. It is expected that the manufacturer's sales price (MSP) for private sector buyers will be negotiated down from the current level of USD 4-5 to USD 1-2 (the current price offered to public sector buyers), with a further 30-40% reduction in MSPs within the following three to five years. As markets become more competitive, alternative rule-based mechanisms with low transaction costs, such as competitive auctions, may be considered.

Eligible antimalarials will be co-paid only if their international freight and insurance are provided in line with terms and prices defined by AMFm.
The international distribution component (insurance and freight) will make up a significant share of AMFm co-payments. It is expected that the unit cost of international freight and insurance will be

[6] Those four combinations are artemether-lumefantrine, artesunate-amodiaquine, artesunate-mefloquine and artesunate-sulfadoxine-pyrimethamine.
[7] Stringent regulatory authority is defined as a national drug regulatory authority (NDRA) participating in The International Conference on Harmonization of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH) or the Pharmaceutical Inspection Co-operation Scheme (PIC/S).
[8] At their meeting on 11 September, Task Force members agreed to speed up this task.

reduced over time as the volume of low-cost eligible antimalarials increases and distribution practices improve. AMFm will negotiate insurance and freight prices and terms directly with international freight forwarding agents through a competitive process. To ensure minimal disruption to existing distribution networks, manufacturers may elect to use their own distribution arrangements (offering prices on a CIF basis). In this situation, an order with a manufacturer will be co-paid if the CIF price offered for eligible antimalarials and its insurance and freight does not exceed the prices negotiated by AMFm for a similar order (terms, destination, and volume). Manufacturers may alternatively elect to leverage the arrangement negotiated by AMFm (offering prices without freight and insurance on an FOB[9] basis).

Eligible antimalarials will be co-paid only if they are ordered by eligible first line buyers.
Eligibility criteria will ensure that only legal and legitimate first-line buyers of drugs have access to the AMFm and that national regulations are respected. Criteria include:

- Registration with national authorities;
- Acceptance of buyer terms of purchase;
- Record of responsible purchasing;
- Confirmation that destination country meets preparedness requirements.

Eligible antimalarials ordered by international procurement agents pooling orders on a voluntary basis will also be co-paid if those agents comply with similar eligibility criteria. These criteria will include:

- Record of respecting national regulations;
- Acceptance of buyer terms of purchase;
- Record of responsible purchasing;
- Acceptance of accountability for ensuring that co-paid eligible antimalarials will be sold on only to buyers who meet the eligibility criteria applied to first-line buyers.

Eligible antimalarials will be co-paid only if the ordered quantities are within upper limits.[10]
Upper limits will guard against unwarranted spikes in ordering volumes. These ceiling values will be set on a country-by-country basis and in consultation with national stakeholders.

Eligible antimalarials will be co-paid only if they are for distribution in a country meeting a set of minimal preparedness requirements.
Country preparedness requirements will help ensure responsible introduction of eligible antimalarials in a given country. These will be kept both technically sound and with minimal bureaucracy, in order to minimize delays in the roll-out of the AMFm. It is expected that all malaria-endemic countries will meet these requirements in a short time.

Requirements will include:

- Acceptance of WHO treatment guidelines (or guidelines of equivalent quality developed by the country);
- Provision of a list of eligible first-line buyers;
- Commitment to implement supporting interventions, including a basic monitoring framework;
- Any additional preparedness requirements, to be defined, provided that the expected benefits from these requirements appear to exceed the risks of delays potentially caused be these additional requirements.

[9] FOB stands for "Free On Board". Indicating "FOB" means that the seller pays for transportation of the goods to the port of shipment, plus loading costs. The buyer pays freight, insurance, unloading costs and transportation from the port of destination.
[10] The operationalization of these limits is still under discussion in the AMFm Task Force. It is emphasized that limits must not interfere with normal buying behavior.

A sub-group of the AMFm Task Force consisting of representatives from WHO, Global Fund, DfID, CHAI, MMV, endemic countries, and the RBM Secretariat and RBM PSM working group will convene to refine minimum preparedness requirements and propose a mechanism to assess these requirements before the end of October 2007.

4. In-country supporting interventions

The co-payment of eligible antimalarials meeting the above standards and requirements will ensure an affordable, high-quality drug supply at the point of arrival in endemic countries. Ensuring that the price reduction is transmitted to the patients at the point of purchase and that patients have access to diagnosis (where appropriate) and effective malaria treatment will require supporting interventions at country level. A core package of in-country interventions will allow countries to manage the increased volume of eligible antimalarials, particularly in the private sector, and promote the desired outcome of improved access to affordable eligible antimalarials. The core package of supporting interventions will include six areas:

- National policy and regulatory preparedness;
- Wholesaler incentives and pricing / margin control mechanisms;
- Public education and awareness campaigns;
- Provider training and supervision;
- National monitoring and quality preparedness (resistance monitoring, pharmacovigilance and quality surveillance);
- Monitoring and evaluation.

Countries will be in the lead in developing roll-out plans tailored to their specific situation and needs, drawing on but not limited to these interventions. The abovementioned sub-group, in cooperation with the RBM Harmonization Working Group, will propose mechanisms for planning and coordination of supporting interventions at country level. It will also propose international coordination mechanisms to identify funding gaps and to mobilize technical support at the global level. Such mechanisms will have minimal bureaucratic footprints. They will include but not be limited to those within the purview of RBM partners with emphasis on enabling rather than controlling innovations at the country level.

5. Governance and management

The governance and management of AMFm will concentrate on how to meet the set objectives by making the best use of established institutions. As a basic principle, no new bureaucracy will be created for the AMFm Secretariat, whether it is located in one institution or shared among several institutions. The strategic intent is to ensure that it is fit for purpose, as lean as possible, and transparent.

The RBM Board will consider the parameters for the AMFm prior to announcement, including:

- The technical design of AMFm;
- Key performance indicators by which the success of AMFm will be measured; and
- Terms of reference of the host institution.

Once these parameters have been agreed upon, two options are open to the RBM Board to support the governance and management of AMFm:

Option 1: Within agreed parameters, RBM would hand the responsibility for governance and management over to a host institution. In matters of implementation, the host would use its own judgment on approaches to implementation. The hand-over from RBM to host institution would be based on one of two arrangements:

A. A memorandum of understanding, in which the host would accept the basic design of AMFm; it would agree not to substitute a pre-existing business model for the agreed design of AMFm; and it would commit to working collaboratively with RBM members and others in performing its duties to achieve success. A joint announcement of the AMFm would be made by RBM and the host institution.
B. An informal commitment by the host institution(s) to proceed with implementation of AMFm and a statement by the RBM Partnership, expressing commitment to the long-term success of AMFm co-payment and offering continuing technical support.

Option 2: The RBM Board could take a direct role in specific activities and the ongoing governance of AMFm. As the RBM Board is neither a legal entity nor an operational entity, the AMFm Secretariat would have to be administratively hosted in an existing institution.

In practice, it seems most appropriate to adopt Option 1, preferably with a memorandum of understanding that also commits the AMFm host to provide the RBM Board with periodic updates, perhaps at each Board meeting. In turn, the RBM Board will provide candid feedback and recommendations to ensure the success of AMFm. The RBM Board will neither manage day-to-day activities nor insist on a particular approach to tasks such as procurement or payment.

The host institution, or institutions, would be responsible for providing the following:

- Governance and resource mobilization: A legal entity within which the AMFm Secretariat is hosted, governed, and overseen. This also comprises basic strategic and general management-support functions, fiduciary responsibility as well as functions to support resource mobilization.
- AMFm mechanism: A Secretariat that sets prices and terms for eligible antimalarials, manages orders and processes co-payments to eligible first-line buyers on an on-demand basis. The Secretariat will have to respond quickly, effectively, and with low transaction costs as orders are placed, while enforcing eligibility and performance criteria.
- Responsible introduction: Coordination of a range of policy and supporting activities that facilitate the responsible introduction and operation of the Facility. National partners will have the primary responsibility for executing in-country supporting interventions. It is expected that a portion of the cost of these interventions could be funded, or are already being funded, via existing financing mechanisms. The AMFm Secretariat will be responsible for coordinating and identifying resources for these activities.

An estimated 10 to 20 staff will be required to carry out the core functions of the AMFm Secretariat. It is expected that the hosting institution and Secretariat will draw on partners to execute functions that are outside its own core expertise.

6. Expected impact

If established as described here, AMFm will contribute to the achievement of the 2015 RBM targets and to five of the eight Millennium Development Goals. AMFm has the potential, and will be measured against its ability, to reduce consumer prices of a treatment course of an effective coformulated antimalarial from the current level of USD 6-10 to a far lower level of USD 0.20-0.50

(competitive with current retail prices of CQ and SP) for the majority of patients[11]. This drop in prices is expected to more than triple current ACT usage, increasing ACT demand from the current level of 110 million treatment courses per year to a projected 360 million. In doing so, the AMFm will shift most purchases away from ineffective medicines and greatly reduce the market for artemisinin monotherapies and other substandard and ineffective antimalarial drugs. The result is an estimated 174,000 - 298,000 lives saved per year, with an estimated cost per Disability Adjusted Life Year (DALY) of USD 33-56, making AMFm a cost-effective intervention.

7. Financial requirements

The total resource requirements for AMFm will be USD 1.4 -1.9 billion for the first five years.

- Co-payments to cover ACT treatment and distribution costs will require an estimated total financing of USD 1.2-1.6 billion over the first five years of AMFm operation;
- The core package of in-country supporting interventions will require financing of USD 230-330 million for the first five years of operation. This estimate principally covers financing for activities by endemic country partners but also reflects the principle that the AMFm should not create unfunded mandates for international technical assistance[12];
- In addition to co-payments and supporting interventions, the AMFm Secretariat is estimated to cost USD 25-30 million over the first five years.

Based on the AMFm design, RBM will now encourage donors who have shown interest in funding the Facility to formalize the terms of their contribution. Institutions funding existing grants for purchases of eligible antimalarials are similarly invited to work with countries and grantees to reallocate funds that may be freed up by the AMFm towards supporting interventions required for countries to absorb increased volumes of eligible antimalarials, particularly in the private sector.

8. Risk Mitigation and Implementation Planning

At each stage of the supply chain and in the implementation of the co-payment, risks must be considered and mitigated. The technical design[13] includes measures to mitigate the following risks: (a) Affordability: Failure to sustain competition and price reductions in the global market for eligible antimalarials; cost of eligible antimalarials to patients does not decline as expected due to retailer absorption of co-payment; (b) Availability: Slow consumer, wholesaler or retailer uptake of eligible antimalarials; insufficient increase in scale of manufacturer production; long production cycle and restricted growing season of Artemisia annua making it difficult to respond rapidly to changes in product demand; (c) Product Arbitrage: Failure to stop co-paid product from being transferred to markets/countries where the co-payment is not applied and so allowing high profits to middlemen; (d) Drug resistance: Failure to effectively replace monotherapies and sub-standard drugs; (e) Patient safety: Unexpected rare adverse events; (f) Product innovation: Failure to maintain innovation in the market for antimalarial treatments; (g) Funding: Insufficient funding available, or funding just short term; (h) Implementation: Failure to implement supporting interventions; project management mission creep.

A number of additional activities targeted at risk mitigation will be put in place as part of the operational planning for the AMFm by the time of launch: (a) Communication and consultation with endemic country governments and national implementation partners to facilitate preparation for

[11] It is estimated that first quartile retail price will be USD 0.25, second quartile USD 0.30, third quartile USD 0.60.
[12] Consideration will be given to a block grant to ensure that essential mandates are funded, including international technical assistance.
[13] Details are available in the main text and annexes of the technical proposal of August 10, 2007.

responsible introduction of AMFm; (b) Forecasting and specification of the burden on ACT suppliers and other private sector partners to allow preparation for scale-up in production and AMFm-specific requirements such as packaging; (c) Operational research to be launched in 4-6 countries; (d) Monitoring and evaluation in all countries, integrating into existing systems and surveys to the greatest extent possible. This operational planning will be conducted in liaison with relevant RBM working groups, including Harmonization, Procurement and Supply Chain Management, and Monitoring and Evaluation Reference Group.

Overall, the biggest risk is that of inaction or delayed action. The status quo of funding eligible antimalarials through grant-based programs alone virtually guarantees that only the relatively affluent and those effectively covered by public facilities that have sufficient drugs will get timely, lifesaving treatment. That leaves out a large part of the population who use the private sector, particularly the urban and rural poor, and those who use public sector clinics and other facilities that have no effective antimalarials. This is the scenario to which AMFm must be compared.

Subject to RBM Partnership Board approval, the AMFm will be announced in November 2007, but it will take several months before it is launched and becomes operational. The launch will be without a priori exclusion of particular endemic countries or sectors. The standards and requirements for suppliers, buyers and countries as well as the supporting interventions, will guide a gradual phase-in of demand over the first three to four years of AMFm operation. These standards ensure that an important part of risk mitigation is inherent in the design of AMFm. Findings from the initial phase of scale-up will be collected and appropriate adjustments to standards and requirements made. While the overall design is consistent with the original IOM recommendations, the final recommendations have been developed on the basis of broad consultations among RBM stakeholders to facilitate the success of the AMFm.

9. A call to action

AMFm is a major innovation that challenges current practices and requires institutions to transcend their traditional comfort zones and business models. The consequences of inaction and further delays as measured in avoidable deaths and disabilities of malaria sufferers are clear, and so is the case for decisive and rapid action.