

POLICY *Brief*

“Saving Lives and Buying Time”: Lessons in good subsidy design from the Affordable Medicines Facility – malaria (AMFm)

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INTRODUCTION

Malaria is one of the world’s leading health problems. In 2008, an estimated 243 million people fell sick, and nearly 900,000 people died from the disease—85 per cent of them children under five years of age (World Health Organisation, 2009). In response, over the last 15 years the global health community has ramped up its fight against malaria. But the arsenal of options to treat malaria has declined over time, as old treatments have become increasingly ineffective due to growing resistance by malaria parasites.

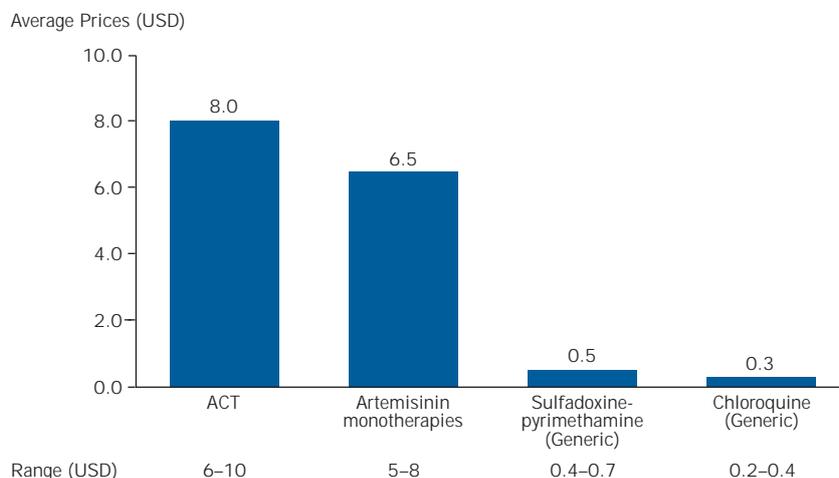
The most commonly used anti-malarial medicines—chloroquine and sulfadoxine-pyrimethamine (SP)—are cheap but increasingly ineffective. One malaria treatment—artemisinin-based combination therapy (ACT)—remains effective, but faces two obstacles. First, the cost of producing and distributing ACTs is too high to be affordable by people who need the medicine in malaria-endemic countries. Especially in the private sector where over 60 per cent of patients purchase anti-malarial medicines (Global Fund to Fight AIDS, Tuberculosis and Malaria, 2010), the artemisinin-based combination treatments can cost as much as \$8 (all dollar amounts are in U.S. dollars) per adult treatment dose, if they can be found at all (Dalberg Global Development Advisors, 2007). Second, as with any medicine, there is a high probability that the malaria parasite could quickly develop resistance to artemisinin. The risk is significantly heightened by the use of artemisinin monotherapies,² which are available for a lower price than the ACTs.

A number of global health experts have known that these two problems needed to be addressed in order to win the fight against malaria. In 2004 the Institute of Medicine published a report that called for subsidization of ACTs to reduce malaria mortality and delay resistance to artemisinin (Arrow, Panosian & Gelband, 2004). This report provided the intellectual underpinning for what became the Affordable Medicines Facility – malaria (AMFm) program.

¹ Dalberg has worked closely with the World Bank and the Global Fund for AIDS, Tuberculosis and Malaria on the design and implementation of AMFm.

² Artemisinin-based combination treatment, as the name suggests, combines the artemisinin with other anti-malarial drugs, for example lumefantrine (LU) or amodiaquine (AQ). Resistance against combination therapies only occurs if the malaria parasite adapts to both components. The chance of this occurring is many times lower than adaptation against just one component (e.g. the artemisinin monotherapy).

Figure 1. Prices per adult treatment doses of anti-malarial medicines in 2007



Note: Ranges indicate variance across countries and products excluding outliers; N (observations): (ACT, 222); (AMT, 227); (C, 37); (SP, 118).

Source: Dalberg field research (Kenya, Uganda, BF, Cameroon), Observations by World Bank and Research International (Nigeria). Smaller pricing observations were also performed in Ghana, Rwanda, Burundi, Niger and Zambia, but due to low N not included. Sulfadoxine-pyrimethamine and Chloroquine data complemented HAI and IOM observations.

WHAT ARE THE OBJECTIVES OF THE AMFm?

The AMFm serves the dual goals of reducing mortality (“saving lives”) and staving off resistance to the artemisinin active ingredient (“buying time”) until a new active ingredient can be developed.

The AMFm aims to achieve the following objectives (Global Fund to Fight AIDS, Tuberculosis and Malaria, 2010):

- Reduce the cost of ACTs to between \$0.20 and \$0.50 per dose for adult treatment
- Increase availability of ACTs
- Increase use of ACTs
- Displace artemisinin monotherapies from the market.

The development of the AMFm technical design by the Roll Back Malaria Partnership was funded by the World Bank and the Bill & Melinda Gates Foundation, and supported by Dalberg Global Development Advisors. The

Global Fund for AIDS, Tuberculosis and Malaria was asked to host and manage the AMFm. The Global Fund is currently finalizing preparations, including price negotiations with manufacturers, and phase one of the AMFm will be launched in the first nine countries in 2010.³

HOW WILL THE AMFm WORK?

The principle of the AMFm program is simple: it provides a co-payment to manufacturers covering a majority of the sales price for every ACT they sell to wholesalers. The wholesalers will thus pay a lower price for ACTs and prices will fall throughout the supply chain, increasing affordability for the final consumer, while at the same time undercutting the price of resistance-inducing artemisinin monotherapies and competing with the prices for chloroquine and SP.

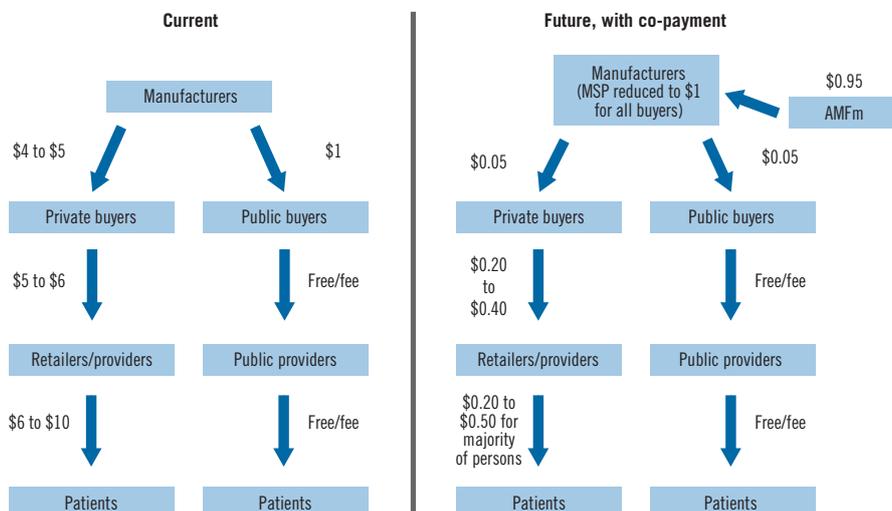
Currently there is a discrepancy between the wholesale price for anti-malarial medicines to the public and private sectors. For example, a manufacturer will sell ACT to public-sector wholesalers for \$1 and to private-sector wholesalers for \$4.⁴ On the basis that the AMFm will result in significantly increased sales volumes, the Global Fund to fight AIDS, Tuberculosis and Malaria will negotiate a new price for both the private and public sectors, for example \$1. The Global Fund will then commit to paying a fixed amount, for example \$0.95, of the new price on behalf of all first-line buyers (public and private), allowing first-line buyers to buy a medicine worth \$1 for only \$0.05. The reduced price at the beginning of the supply chain will, after the regular mark-ups across the chain to allow for safe distribution and storage, bring the price to consumers from approximately \$6 to \$10 down to \$0.20 to \$0.50 per dose for adult treatment. This type of financial support is called a “co-payment” because consumers are still required to bear part of the cost. The process is illustrated in Figure 2.

³ Cambodia, Ghana, Kenya, Madagascar, Niger, Nigeria, Rwanda, Tanzania (mainland and Zanzibar) and Uganda

⁴ This differentiated pricing was a result of significant pressure by multilateral organizations and activists to make medicines available to the public sector on a “no-profit, no-loss” basis.



Figure 2. Impact of the AMFm on prices at each level of the supply chain (illustrative example)



Source: Roll Back Malaria Partnership, 2007

The co-payment mechanism is complemented by a set of supporting interventions. These interventions aim to mitigate risks and unintended consequences of the co-payment, and maximize synergies with wider malaria programs. The AMFm will make grants⁵ to national governments to finance the country-specific supporting interventions. The set of supporting interventions include, among others:

- *Wholesaler incentives* to encourage wholesalers and importers to pass through the co-payment;
- *Public education and awareness campaigns* to educate consumers about the co-payment and the changes in medicine prices;
- *Training programs for health providers* to inform them of the co-payment and the correct usage of ACTs;
- *Pharmacovigilance and resistance monitoring* to track quality, counterfeits and the onset of resistance;
- *Monitoring and evaluation* to track the impact of the co-payment and any unintended consequences.

⁵ More precisely, the hosting organization of the AMFm, the Global Fund to fight AIDS, Tuberculosis and Malaria, will integrate the financing of the supporting interventions into their regular grant-making process, which includes pre-determined criteria for successful implementation. The supporting interventions are a one-off transaction between the AMFm and national governments, whereas the co-payments are ongoing financial transactions between the AMFm and ACT manufacturers. More information can be found at www.theglobalfund.org.

The AMFm will initially be launched in nine countries during a two-year pilot phase. At the end of this pilot phase a review of the AMFm will be conducted by an independent evaluation and assessed against pre-determined indicators. Based on the results, the Global Fund Board will decide whether to expand, accelerate, modify, terminate or suspend the AMFm (Global Fund to Fight AIDS, Tuberculosis and Malaria, 2010).

WILL THE AMFm INTERFERE WITH MARKET DYNAMICS?

During the consultation process, a number of stakeholders raised concerns about potential “side effects” of such a market intervention. Three types of side effects were most often mentioned: a) potential distortions of existing market structures by the new subsidy; b) potential over-consumption of the treatment; and c) potential rent-capture by unintended stakeholders.

“Subsidies distort markets.” The introduction of a co-payment for ACTs changes the competitive interaction between ACTs and other anti-malarial medicines, and between different ACT products. Distorting the market in favour of ACTs is, of course, one of the objectives of the AMFm. It aims to drive resistance-inducing monotherapies out of the market by artificially lowering the price of resistance-delaying combination therapies.

Negotiations with manufacturers are still ongoing and the final co-payment mechanism cannot yet be made public. However, there is no perfect co-payment mechanism that will fully replicate the former competitive structure. Each co-payment mechanism will have advantages and disadvantages in terms of how it affects final consumer prices, overall costs, incentives for price-competition and incentives for innovation. The AMFm was designed to find the best trade-offs, on advice from a panel of renowned economists, and through intensive discussions with the ACT manufacturers.

“Subsidies will encourage over-consumption.” There was also concern that a co-payment could lead to over-consumption of ACTs. Subsidized prices could increase incentives for consumers to use the cheap ACTs preventively, without diagnosis, for every fever (many of them non-malarial), thereby increasing the chance of resistance occurring. However, a modelling exercise showed that a subsidy to ACTs is likely to slow the rate of resistance to artemisinin-based treatments, even if such a subsidy were to increase the use of ACTs significantly (Laxminarayan, Over & Smith, 2006). Nonetheless, countries will also be encouraged to improve the use and affordability of diagnostics as a supporting intervention alongside the AMFm.

“The benefits of subsidies are captured by unintended stakeholders.” For the AMFm, a major risk was that the cost savings would not be passed on to the consumer and would instead be captured by middle-men, such as wholesalers and retailers. The most effective way to address this risk would be to subsidize the end-consumer. However, a consumer-payment, for example through a voucher system, was impossible, as there are no reliable structures and systems to reach the hundreds of millions of malaria patients across some of the poorest



countries in the world in an effective and efficient manner. A number of steps were therefore taken to reduce the risk of co-payment capture along the supply chain:

- Analysis was undertaken to identify the environments that would be most susceptible to this risk. For example, lack of competition within the supply chain (e.g., between retailers) was identified as a risk factor.
- Pilot studies were conducted by, among others, the Clinton Foundation and Medicines for Malaria Ventures to further understand the risk. These studies showed that, overall, the final consumer prices dropped as expected, and that co-payment capture by other players in the supply chain was very limited.
- A number of the supporting interventions were designed to mitigate this risk. For example, consumer education programs could, in some countries, include the communication of recommended retail prices.
- First-line buyers are required to sign a memorandum of understanding and behave according to the spirit of the AMFm. If they are found to behave inappropriately, they will be prevented from buying affordable ACTs through the AMFm in future.
- A monitoring and evaluation framework will track prices, and make it possible to intervene where necessary.

WHEN WILL A CO-PAYMENT BE EFFECTIVE?

The co-payment mechanism seems to be most effective where there is not only a need for increased affordability, but also for elimination of a market failure in the private sector. In the case of anti-malarial treatments, under-regulated and resistance-inducing drugs were the most competitive in the marketplace. The shift in incentives and competitive balance that are inherent to a subsidy can, in those cases, be used to a positive extent. The feasibility of a co-payment is furthermore increased if there is a limited set of players to interact with. The AMFm would have been harder to implement if there were hundreds of ACT manufacturers in the world.⁶

These criteria limit, but do not exclude, other areas where a co-payment mechanism can be applied. Within the global health space, the applicability for antibiotics should be explored, as these drugs face similar challenges of resistance and indiscriminate usage in both human and agricultural settings.

⁶ A limited set of manufacturers could indicate a potential manufacturer co-payment, whereas a limited set of consumers could indicate a potential consumer co-payment (e.g., a voucher system)

POLICY RECOMMENDATIONS

The AMFm shows that good subsidy design should include:

- **Analysis and research.** The AMFm project was a very innovative design and required rigorous analysis on the impact of the subsidy, as well as pilot studies and operational research that were critical in addressing stakeholders’ concerns.
- **Stakeholder consultation.** The AMFm affects, and needs the support of, a wide set of stakeholders. These stakeholders range from national governments to manufacturers, from African retailers to donors. Extensive consultations were held over a period of nearly two years to obtain feedback and insights, discuss concerns and build a global coalition. A fine balance needed to be struck between bringing as many stakeholders as possible on board and maintaining pace and momentum.
- **Supporting interventions to mitigate risks and unintended consequences.** The supporting interventions for the AMFm are, to a large extent, focused on mitigating risks and distortions inherent to subsidies. It is crucial that policy-makers analyze and map these risks beforehand, so that effective mitigation measures can be designed as part of a coherent policy package.
- **Monitoring and evaluation.** The AMFm that will be implemented today differs markedly from the original concept, having undergone vital adjustments based on stakeholder feedback. Moreover, significant resources will be invested to monitor and evaluate the AMFm in the future, in order to be able to make further adjustments after roll-out.

FURTHER INFORMATION ABOUT THE AMFm

- Information on the AMFm can be found on the website of the Global Fund: www.theglobalfund.org/en/amfm/
- An evaluation report on the creation of the AMFm has been posted online by the World Bank: <http://siteresources.worldbank.org/INTMALARIA/Resources/AMFmProcessEvaluation.pdf>
- A teaching case on the process of developing the AMFm is available on Professor Michael R. Reich’s Harvard webpage: <http://www.hsph.harvard.edu/faculty/michael-reich/teaching-cases-in-global-health/>

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FURTHER DETAILS AND CONTACT INFORMATION

The GSI is an initiative of the International Institute for Sustainable Development (IISD). Established in 1990, the IISD is a Canadian-based not-for-profit organization with a diverse team of more than 150 people located in more than 30 countries. The GSI is headquartered in Geneva, Switzerland and works with partners located around the world. Its principal funders have included the governments of Denmark, the Netherlands, New Zealand, Norway, Sweden and the United Kingdom. The William and Flora Hewlett Foundation have also contributed to funding GSI research and communications activities.

See the GSI's *Subsidy Primer* for a plain-language guide to subsidies on www.globalsubsidies.org.

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