

AFFORDABLE MEDICINES FACILITY – MALARIA

WHAT IS THE PROBLEM?

Malaria is one of the greatest threats to human life in the developing world. Each year, between 300 and 500 million people contract malaria and of those, one to three million die. Most of those who lose their lives to this disease are children.

Malaria parasites are becoming increasingly resistant to the older, less expensive medicines, currently used for treating the disease. These treatments include chloroquine (CQ) and sulfadoxine-pyrimethamine (SP). The most effective forms of treatment for malaria are artemisinin-based combination therapies (ACTs), which combine artemisinin with another antimalarial drug. The World Health Organisation (WHO) specifically recommends ACTs for the treatment of uncomplicated falciparum malaria.

Today, ACTs represent only one in five antimalarial treatments taken to treat malaria. ACTs are not more widely used because they are more expensive than the less effective alternatives. Malaria needs to be treated within 24 hours and many patients in endemic countries are not able to access outlets where free medicines are distributed in this timeframe. In the private sector, ACTs are too expensive so many people who purchase their own drugs rely on cheaper, less effective drugs. As a result, many more people die from malaria than would if ACTs were more affordable.

To ensure equitable access to treatment, ACTs must be made available at affordable prices through the public, non-profits and private sectors. Of the approximately 550 million antimalarial treatments administered per year globally, only 110 million or 20% are ACTs – and these are provided almost entirely by the public sector. Currently, ACTs make up approximately 5% of total antimalarial treatments provided by the private sector, where 60-80% of patients purchase drugs.

WHAT IS THE AFFORDABLE MEDICINES FACILITY - MALARIA?

The Affordable Medicines Facility – malaria (AMFm) was developed as a financing mechanism to make ACTs more available and affordable and to delay resistance to the artemisinin active ingredient. It is a proposed solution to one of the specific challenges facing malaria treatment: effective treatment is too expensive or simply unavailable to the 60% of patients who buy antimalarial medicines in the private sector. The AMFm is an innovative financing intervention that seeks to make affordable ACTs available to patients in the malaria endemic world who use facilities run by the public or NGO sectors or who purchase drugs themselves.

HOW WOULD THE AMFM MECHANISM WORK?

The objective of the AMFm is to ensure that people suffering from malaria have access to inexpensive, effective antimalarial treatment, in the form of ACTs.

The AMFm will promote the use of effective antimalarials and drive out ineffective medicines from the market by 1) reducing consumer prices to an affordable level through price negotiations and a co-payment and 2) ensuring the reduced price benefits those suffering from malaria by introducing in-country supporting interventions.

First, the AMFm will negotiate with ACT manufacturers to reduce the price of ACTs for all first-line buyers to US \$1 – equivalent to the current price available to the public sector. Second, the AMFm will provide a co-payment to buyers of approximately US \$0.95 to lower the price of ACTs to a level comparable with less effective alternatives. The co-payment would enable providers in the public sector to purchase drugs at greatly reduced prices (US \$0.05, instead of US \$1) and retailers in the private sector would be able to provide ACTs to patients at significantly reduced prices.

In addition to the co-payment the AMFm will fund in-country supporting interventions. These interventions will improve malaria case management in countries that access ACTs through AMFm. Countries would identify the needed interventions and include them as part of their plan for rolling out AMFm, which is required in order to access the AMFm for the first time.

WHAT CAN THE AMFM ACHIEVE?

The AMFm has the potential to reduce the cost of effective antimalarials to US \$0.20-0.50 for most patients. It is expected that the AMFm will reach a significant 60% of patients accessing treatment through the private sector within five years, up from less than 5% today.

This price reduction is expected to more than triple ACT usage to a projected 360 million treatment courses per year. In turn, this will reduce purchases of less effective treatments. The expected result is that up to 300,000 lives will be saved per year.

HOW DOES THE AMFM COMPLEMENT EXISTING APPROACHES TO THE GLOBAL PROBLEM OF MALARIA?

The AMFm seeks to strengthen the overall campaign against malaria by complementing existing interventions to prevent and treat malaria in both the public and private sectors. Progress continues on malaria control and treatment through expanding the coverage of long-lasting insecticide treated nets and indoor residual spraying, increasing the distribution of ACTs and diagnostics, and accelerating research and development for a malaria vaccine and new drugs to treat malaria. By increasing access to ACTs, the AMFm

represents one component of a comprehensive response to the global problem of malaria.

Grants from the Global Fund, the World Bank Booster Program for Malaria Control and donor government programs, as well as funding from endemic-country governments, have been essential in enabling many countries to switch to ACTs as recommended first-line treatment. Due to these grants, 60% of antimalarials distributed through the public sector are ACTs. While efforts to make ACTs available via the public sector have been successful, current malaria interventions are still not reaching the 60% of patients who purchase drugs in the private sector. Currently, ACTs account for less than 5% of total antimalarial treatments delivered through private sector channels. The AMFm can bridge this gap.

As a financial mechanism, the AMFm will serve as a platform for low-cost ACTs that can be accessed by public, private and non-profit buyers. The AMFm will therefore facilitate public and non-profit sector interventions to distribute ACTs free of charge to vulnerable populations, including children and the poorest. The Global Fund and other funding mechanisms support free distribution through their grant programs and countries should be encouraged to incorporate these interventions into their national malaria plans.

WHAT WORK HAS BEEN DONE TO DATE ON THE AMFm?

In 2001, it was becoming clear that resistance to CQ was a global crisis and that ACTs, at 10-40 times the cost of CQ, were too expensive for most consumers. The U.S. Agency for International Development approached the Institute of Medicine (IOM) to study the situation and recommend a course of action. The IOM committee deliberated on how effective drugs could be made more affordable to all people affected by malaria and, at the same time, protect effective drugs for as long as possible from drug resistance. In its 2004 report, "Saving Lives, Buying Time," the IOM called for a global subsidy of ACTs to reduce malaria mortality and delay resistance to artemisinin.

Following the publication of "Saving Lives, Buying Time," the Roll Back Malaria (RBM) Partnership decided to further consider the AMFm. An Expert Workshop and Consultative Forum took place in Amsterdam in January 2007 during which the malaria community endorsed the creation of an RBM Task Force to steer the AMFm project. In November 2007, the RBM Board endorsed the work of the Task Force, invited the Global Fund to manage the AMFm as a business line and highlighted five challenges for the AMFm Task Force to address before the implementation of the AMFm.

In November 2007, the Global Fund Board agreed to investigate the appropriateness of managing the AMFm as a business line, considering the complementarities and synergies of the Global Fund's objectives and business model with many design elements of the AMFm. The Global Fund Board will consider the technical guidance of the AMFm Task Force and a proposed business plan to manage the AMFm at its meeting in April 2008.

HOW MUCH WOULD THE AMFm MECHANISM COST?

It is estimated that US \$1.1 billion-1.4 billion would be needed to finance co-payments made by the AMFm over the first five years of operation. An additional estimated US \$365-500 million would be required for supporting interventions to roll out the AMFm over five years, of which an estimated US\$145-180 million could be covered by reprogramming resources freed up in ACT budgets in existing Global Fund grants. The remaining US \$220-355 million needed for supporting interventions would be funded through regular Global Fund grant resources.

Economic appraisal demonstrates that the AMFm is a cost-effective health intervention, based on World Bank terms, and is in the range of other cost-effective malaria interventions, with an estimated cost per disability-adjusted life year of US \$33-56.

WILL VULNERABLE POPULATIONS BENEFIT FROM THE AMFm?

The AMFm will make ACTs available in the public, non-profit and private sectors at prices equivalent to CQ and SP. This will improve access to effective drugs for patients who might otherwise have bought less effective drugs. Nevertheless, many people cannot afford even inexpensive drugs. The AMFm will support efforts to reach the most vulnerable populations by providing to all sectors a platform of inexpensive, highly effective drugs on which interventions to reach the most vulnerable can be based.

Reaching vulnerable populations is a key global health priority. More work is needed to better understand the interventions that are effective at reaching the vulnerable at scale. The Global Fund and other funding mechanisms are open to qualified applications for interventions to reach the most vulnerable, and countries should be encouraged to incorporate these interventions into their grant applications.

IS THE AMFm A SUBSIDY TO MANUFACTURERS?

The objective of the AMFm is to lower the price of effective malaria treatment to those who need it most – the patients. The AMFm will pay for a large portion of the cost of producing ACTs, dramatically lowering the price to consumers. The co-payment will not result in any direct profit to manufacturers who must sell the products in order to make any profit. In fact, due to price negotiations that will occur to bring down the price of ACTs to US \$1 for all buyers in the public, non-profit and private sector, suppliers will make less profit per sale than under current market conditions and, therefore, must sell higher volumes, supporting the collective goal of increasing access to ACTs.

The only opportunity for suppliers to unduly profit from the AMFm is if the co-payment is greater than their cost of production or if they are able to charge inflated prices to buyers. The AMFm Task Force recommends that systems be put in place to prevent both these risks. Suppliers will be required to

reveal some or all of their cost structure during negotiations of prices and co-payments. This approach will enable the AMFm to appropriately set co-payments that will ensure low prices to patients but not generate excess profits for manufacturers. To ensure that manufacturers do not inflate prices to buyers, during negotiations, the AMFm will set ceiling prices that suppliers can charge for each co-paid product. These transactions will be monitored and suppliers who break the ceiling will be penalized or even excluded from participation in the AMFm.

WILL AMFM CO-PAYMENTS BE AVAILABLE FOR LOCALLY PRODUCED ANTIMALARIALS?

The WHO currently recommends types of ACTs that are mostly single and limited source products. A core aim of the AMFm is to foster innovation and competition among ACT manufacturers, including manufacturers based in endemic countries. It is a priority that local industries in endemic countries participate in the manufacturing and distribution of ACTs and other essential medicines. RBM partners are working to define a harmonized quality assurance standard across the WHO, UNICEF and the Global Fund which would also apply to AMFm. (In this sense, the requirements for suppliers would be similar to those applied to grant-based purchases of ACTs.) Local manufacturing of ACTs is increasing and it is expected that some local manufacturers will be able to meet these quality assurance standards in the foreseeable future.

Several activities are underway to speed up participation of local manufacturers. For example, UNITAID is financing a pre-qualification programme, which would support quality assurance applications from all manufacturers and the RBM Procurement and Supply Chain Management Working Group is undertaking a mapping of the technical assistance needs of local manufacturers. Jointly, these and other activities will promote the participation of local manufacturers.

WILL THE AMFM INCREASE THE LIKELIHOOD THAT NON-MALARIAL FEVERS ARE TREATED AS MALARIA?

By increasing the availability and affordability of ACTs, the AMFm will allow more people who need antimalarial drugs to receive them. As happens now, people with other causes of fever will continue to take anti-malarial drugs. So while lives will be saved, overtreatment will continue.

The effects of increasing antimalarial drug availability on resistance are not straightforward and depend on several factors. More drug use does tend to increase the spread of resistance because more people have low levels in their blood after treatment. But, several factors act in the opposite direction to reduce resistance. Antimalarial drug resistance tends to arise in low transmission settings in patients with malaria who receive insufficient drug – particularly if they receive only one component of a combination treatment. Increasing the probability that people take the full treatment course of an ACT (because they can now afford to) and discouraging people from buying the

single components in the market place will decrease the chance of resistance arising. Increasing the availability of ACTs will reduce the incidence of malaria. This too reduces resistance.

HOW CAN WE ENSURE THAT THE MIDDLEMAN DOES NOT CAPTURE THE COST SAVING?

Initial data from studies of subsidized ACTs are very positive. For example, in September 2006 the Senegalese government began distributing subsidized ACTs through both public and private sector outlets. In August and September 2007, the Institut de Recherche pour le Développement conducted a pricing study in 67 facilities and found that price adherence was consistently high in all sectors.

Initial results from the Clinton HIV/AIDS Initiative's (CHAI) price transmission study in drug shops in Tanzania also suggest that a low price is maintained through to the end-consumer. On average, consumers paid US \$0.42 for co-paid ACTs, the same price as for SP. The CHAI study included behaviour change communications, provider training and recommended retail price strategies.

Consumer information and awareness-raising programs and monitoring and evaluation of consumer prices will be key to the successful transmission of low prices. Interviews with wholesalers have indicated that, assuming pricing policies of the AMFm are consistent with the distribution costs of the wholesalers, the co-payment will be passed on to the consumer. To further encourage this, the AMFm will consider volume incentives that promote sales of lower cost products by allowing higher relative margins on those products.

Updated 27 February 2008