AMFm and PMI's Commitment to Global Efforts to Ensure Prompt Malaria Diagnosis and Treatment

The President's Malaria Initiative (PMI) is committed to ensuring that all persons with malaria are promptly diagnosed and treated with a safe and efficacious antimalarial drug. In sub-Saharan Africa, children under five in impoverished, rural areas are at the greatest risk of dying from malaria and are the focus of PMI's efforts.

Read PMI's Principles on Scaling up Malaria Case Management in the Private Sector here.

Since a large proportion of patients with malaria are treated within the private sector, improving the quality of malaria treatment through private pharmacies and drug shops is critical. PMI is committed to working with the Global Fund to Fight AIDS, Tuberculosis and Malaria (Global Fund), the World Health Organization (WHO), the Roll Back Malaria Partnership (RBM), and other partners to support evidence-based strategies to introduce malaria diagnostics, treatment, and referral support for suspected severe febrile cases in children in the private sector, when endorsed by national malaria control programs.

One approach to improving the quality of malaria case management in the private sector is the Affordable Medicines Facility – malaria (AMFm), an innovative financing mechanism designed to save lives and delay the onset of resistance to artemisinin by expanding access to affordable artemisinin-based combination therapies (ACTs) for malaria through the public, private, and NGO sectors. This is done through a factory-gate subsidy for ACTs that will reduce the price for local buyers and pass on those savings to the patient. The AMFm is hosted by the Global Fund and was launched in nine African countries in 2009. The results of an Independent Evaluation of AMFm's first phase were released in July 2012. At the upcoming November 2012 Global Fund Board meeting, members will be asked to vote on options for the next phase of the AMFm.

PMI Comment on AMFm Independent Evaluation

PMI recognizes the work done by the AMFm Independent Evaluation team in assessing the progress of this approach and adding to the body of knowledge about the feasibility of ACT scale up through the private sector. At its 20th Global Fund Board Meeting in Addis Ababa in 2009, Board members agreed that any expansion of AMFm beyond its pilot phase would have to be based on evidence showing that it was likely to achieve the following four stated objectives:

(i) increased ACT affordability,
(ii) increased ACT availability,
(iii) increased ACT use, including among vulnerable groups, and
(iv) "crowding out" of oral artemisinin monotherapies, chloroquine and sulfadoxine-pyrimethamine by gaining market share.

PMI is still evaluating the evidence available to date on the AMFm, which includes the Independent Evaluation. Our key areas of focus are as follows:

1. **The Independent Evaluation report provides no evidence on ACT use by vulnerable groups, particularly for children under five.** The information that is available on ACT procurements through AMFm indicates that most of the drugs purchased were for adults but information on the level of ACT penetration to rural, hard-to-reach areas is not yet available. Therefore, we have no evidence on whether children under five and poor rural populations at risk for malaria and greatest risk for dying were actually reached. The AMFm procurement data reveals that, on average, as of November 2011, only 35% of the treatments procured by the private sector were for child doses[1].

2. **The AMFm model also does not take into account changes in malaria epidemiology that are occurring throughout Africa.** For example, Zanzibar has seen major declines in malaria prevalence in the past five years and, while the AMFm pilot resulted in increased ACT market share, without use of a diagnostic test, many of those treatments were probably administered to patients with non-malarial illnesses, possibly causing harm through misdiagnosis of pneumonia or other serious illnesses.

[1] AMFm Monthly Analysis, July 2010-November 2011, Clinton Health Access Initiative

3. **Although the intent of AMFm was also to supply the public sector in the pilot countries with ACTs, many AMFm countries experienced severe shortages of ACTs in public health facilities.** Based on country requests to fill public sector ACT gaps, PMI procured 14. 8 million treatments for the public sector in five AMFm countries (Ghana, Kenya, Madagascar, Nigeria, and Tanzania) in 2011 and 27.2 million treatments for these countries in 2012.

4. **The findings of the Independent Evaluation do not indicate that the AMFm has played any significant role in "crowding out" artemisinin monotherapies, as was originally intended.** In fact, evidence suggests that the circulation of oral artemisinin monotherapies was not a problem in most of the AMFm pilot countries. This may have been the result of WHO's earlier efforts to encourage drug manufacturers to cease the production, marketing, and distribution of these drugs.

5. **The AMFm design did not incorporate the WHO recommendations on universal usage of malaria diagnostic testing prior to treatment.** The overuse of ACTs within the private sector that can occur when malaria treatment is provided to patients who do not have malaria can lead to the selection of resistance parasites. The loss of ACTs as an efficacious malaria treatment would severely jeopardize efforts to control and ultimately eliminate malaria in Sub-Saharan Africa.

PMI Path Forward

The PMI is participating in the Roll Back Malaria AMFm Task Force that will make recommendations to the next Global Fund Board meeting on the future of the AMFm. The Global Fund Board will meet in November 2012 to discuss and make recommendations about the future of the AMFm. Regardless of the Global Fund Board's decision to modify or terminate the AMFm, PMI believes that there is a need for a transition plan to ensure malaria treatment needs of the most vulnerable populations are met.

PMI remains committed to working with the Global Fund, WHO, RBM, and partners to support evidence-based strategies for malaria diagnostics, treatment, and referral support for suspected severe febrile illnesses in children in the private sector, when included in the national malaria control strategy.

PMI's Principles for Scaling up Malaria Case Management in the Private Sector

Since its launch in 2005, the President's Malaria Initiative (PMI) has worked closely with ministries of health and non-governmental partners to scale up malaria case management, including both improved diagnosis and prompt, appropriate treatment. PMI is committed to evidence-based approaches and prioritizing interventions to ensure they reach the most vulnerable populations. **In sub-Saharan Africa, children under five in impoverished, rural areas are at the greatest risk of dying from malaria**.

PMI supports all essential elements of a comprehensive program to diagnose and treat patients appropriately for malaria, which entails early, accurate diagnosis and rapid treatment with a safe and efficacious antimalarial drug. Thus, PMI's strategy focuses on scaling up access to appropriate diagnostic testing with either microscopy or rapid diagnostic tests (RDTs) and treatment with artemisinin-based combination therapies (ACTs) in line with the World Health Organization's (WHO's) Treatment Guidelines, 2nd Edition http://whqlibdoc.who.int/publications/2010/9789241547925_eng.pdf.

Although ACTs are the best treatment available for the species of parasite that causes the deadliest form of malaria, resistance to ACTs has already been identified in Southeast Asia. Spread of this resistant parasite to Sub-Saharan Africa would represent a public health catastrophe. Therefore rational use of ACTs only in patients with confirmed malaria is critical.

PMI supports case management through multiple channels: public and private health facilities, community health workers, and pilot projects in private pharmacies and drug shops, when these are part of a country's national strategy. In FY 2011 alone, PMI procured 38.6 million ACTs and 14.5 million RDTs. In FY 2012, PMI's estimated procurements for ACTs are 74 million treatments and 29 million RDTs.

To strengthen case management of malaria in the private sector, PMI:

- Ensures that malaria case management in the private sector is carried out in partnership with the public sector, including malaria diagnostic testing, appropriate treatment, referral for severe cases, and treatment for non-malaria febrile illnesses, such as pneumonia.

- Ensures that the specific country context is taken into account in the design and implementation of private sector initiatives for case management. In particular, careful consideration should be

given to differences in the epidemiology of malaria between and within countries, health systems infrastructure. In particular, there should be an evaluation of the most accessible and demand driven channels, such as access to health care facilities, role of the private sector (informal vs. formal) in providing care, and availability of community-based health services.

- Believes that further country pilots are needed to determine the best models of subsidy delivery, health worker incentives for diagnosis and treatment, and referral for suspected severe malaria or non-malarial illnesses to ensure the best health outcomes for intended beneficiaries. Factory-gate subsidies, such as the AMFm, are one model, but there are other models—such as demand-side or social marketing subsidies, which may be more effective in reaching target prices and penetrating rural, hard-to-reach areas. The experience gained in implementing country-driven private sector case management in Angola, Cambodia, Nigeria, Rwanda, and Tanzania using different subsidy models can help inform these pilots.

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