

**GiveWell's summary of the key points discussed in a phone conversation regarding the 'Artemisinin Monotherapy Replacement Project' in Myanmar on May 31, 2012**

Participants:

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**The need**

Artemisinin combination therapy (ACT) is by far the best antimalarial drug combination currently available. ACT, a combination of a plant-derived antimalarial--artemisinin--with another class of drug that works in a different way, is much more effective than either drug would be if used alone. The World Health Organization (WHO) recommends the use of quality assured ACTs for the treatment of malaria caused by *P. falciparum*, a type of malaria that can be fatal if left untreated or if treated with ineffective drug therapy. Children under age five are especially vulnerable.

Resistance to artemisinin emerged in 2006/2007 along the Thai-Cambodia border in an area around the Western Cambodian Province of Pailin. Artemisinin resistance has been more recently reported to have emerged in Western Thailand/Eastern Myanmar and a small foci in South Western Vietnam. Twice before, antimalarial resistance for other classes of drugs (e.g. chloroquine and sulfadoxine/pythimethamine) has emerged in this region and spread through Myanmar to India and Africa, ultimately making those drugs ineffective in most parts of the world. Previous episodes of drug-resistant malaria that could not be effectively treated have caused the loss of many thousands of lives and negatively affected efforts to control and eliminate the disease.

In 2005, the World Health Organization called for a ban on artemisinin monotherapies (AMT) and replacement with artemisinin combination therapies (ACTs), which are less likely to lead to the emergence of drug resistance. Until recently, Myanmar had not banned monotherapies, but, following a recent political transition, the Ministry of Health has decided to institute an importation and marketing ban by the end of 2012. In order to make the ban effective and to speed up the process of AMT replacement with ACT, the government has agreed to work with partners such as PSI that have expertise in making private sector markets work for poor communities.

The eastern part of the country is heavily forested, hilly, and malaria endemic. The

area is remote, hard to access (particularly in the peak transmission season, at the end of the monsoon) and home to many ethnic minorities who are highly mobile and often migrate through forested areas and across borders to obtain work or escape geopolitical unrest. Proximity to forest and forest fringe habitat is the single most important risk factor for malaria infection in the Greater Mekong sub-region (rather than age or gender). The existing public health infrastructure in the area is limited, but there is a dynamic informal private sector that has the capacity to deliver certain health-related services regardless of the geopolitical situation and mobility of the population. Also, a number of cross border health groups exist (although their operational reach is limited).

In 2007, the Bill & Melinda Gates Foundation funded WHO to coordinate and implement a program in Thailand and Cambodia to contain and eliminate artemisinin resistance (AR). Since this initial investment, the foundation has funded a number of grantees to implement programs designed to prevent and contain AR, as well as to determine where exactly it is. Since the foundation's initial investment, a number of development partners, including Australia (AusAID); The United Kingdom (DFID); the United States (USAID and the President's Malaria Initiative); and the 3 Diseases Fund have contributed funding for surveillance, prevention, and elimination of artemisinin resistance in the Greater Mekong sub-region and globally. However, WHO recognizes that more needs to be done and the organization is in the process of developing, with partners, a Greater Mekong sub-regional plan to prevent and eliminate AR.

### **How the project works**

The goal of the project is to replace AMT with ACT throughout Myanmar (targeting the eastern region of the country with more intense communications activity due to the location of already identified drug resistance foci). PSI has received funding from the Gates Foundation and DFID for the project, which is part of a larger national effort, The Myanmar Artemisinin Resistance Containment Framework-MARC, that has been underway for about a year to stop the spread of resistance. An estimated 17 million people live in the region, and the project aims to reach at least 10 million through the private sector.

In Myanmar, there is a dominant supplier that provides 70-80% of the antimalarial drugs to the private sector. This supplier has agreed to supply ACTs in place of the current dominant artemisinin monotherapy (Artesunate). PSI will purchase ACTs and sell them to the distributor at a subsidized price. The price structure (mark-ups along the supply chain) is designed in such a way as to ensure that consumers pay what they can afford for a full course of ACT (i.e. the current cost of a partial course of Artesunate monotherapy). Drug replacement will begin later in 2012.

PSI is also targeting drug retailers and consumers with intensive behavior change communication as part of the project. It will seek to educate these groups in order to (a) increase demand for ACTs, keeping prices affordable and (b) ensure that

patients receive and take the recommended dosages and know where to access them.

### **Monitoring and evaluation of the project**

Accurate demographic and health data for Myanmar is largely absent (the last population census was completed in 1942 by the colonial British authorities and has since been destroyed and, to date, no Demographic Health Surveys have been conducted). As a result, numerous assumptions have been made when designing this project (mostly by modeling known epidemiological parameters and using the limited data that is available through PSI's own MIS or from other agencies and published papers). PSI therefore believes that it is critical that it collect robust data for continuous project monitoring and eventual evaluation purposes. In this regard, PSI will conduct population-based household surveys, drug outlet audits, supply chain assessments, mystery client exit interviews and a variety of routine monitoring tools to assess market penetration, the robustness of the supply chain and effectiveness of deployed field staff.

To date in year one, PSI has conducted a large, nationally representative survey of private drug outlets (approx. 1,000) to collect information on antimalarial prices, sales volumes and availability. The preliminary results from this first annual outlet survey will be available at the end of June 2012. A household survey has also been completed and will be repeated in August 2012 to document knowledge, perceptions, and treatment-seeking behavior among consumers. In late June PSI will also complete a thorough Supply Chain Assessment. Routine monitoring activity will commence in August when ACT enters the top of the supply chain.

Project success will be measured by decreases in malaria transmission (through WHO sentinel sites) and through regular PSI household and outlet surveys (as described above) that will provide evidence of changes in the availability and price of quality assured ACT versus AMT in the private sector (where the majority of the population seeks care). PSI has developed a logframe with the metrics that will be followed over the course of the project.

### **Risk factors**

The Gates Foundation and PSI have identified factors that could affect the success of the program. Factors include: potential government restrictions on NGO movement in the area and on project activities (less of a concern in the new political climate), inability to stem the flow of monotherapies coming over the border from China, difficulty reaching isolated populations living in the forest, lack of acceptance of the new drugs by patients, and market factors leading to high pricing of ACTs in the country. All risk factors are tracked continually as a result of the dynamic changes underway in Myanmar at present with contingency plans drafted as and when necessary. The primary donors are kept informed of any significant issues that arise.

## **Funding needs**

The budget for the program is \$35 million over three years. To date, PSI has raised \$27.5 million from the Gates Foundation and DFID.

At current levels of funding, PSI will conduct the planned surveys, run social mobilization campaigns, and purchase some commodities. The additional \$7.5 million would allow for the purchase of additional ACTs and malaria diagnostic tests, and therefore scale up the replacement program more quickly.

The specifics of how additional funding would be spent may change once results of the baseline surveys are available.

The overall funding gap for responding to drug resistance in the region is over \$350 million, and PSI and the Gates Foundation believe that it is hard to see how the funding gap can be filled without the contributions of new donors.

PSI and the Gates Foundation would welcome new donors in this space and are looking to bring a major donor onto the project within six months.