

Mekong Region Takes Action Against Fake Antimalarials

Background

The widespread availability of substandard and counterfeit drugs in Asia has been a well-documented public health problem in recent years. In early 2003, the U. S. Pharmacopeia Drug Quality and Information (USP DQI) Program embarked in an effort to assist the countries in the Mekong Region strengthen their drug quality assurance program and, ultimately, improve the quality of their pharmaceuticals. Through a cooperative agreement with the U.S. Agency for International Development (USAID), USP DQI, in collaboration with national and local authorities and World Health Organization Regional and Country Offices, began monitoring the quality of antimalarials in Cambodia, Laos, Thailand, Vietnam, and Yunnan Province of China and teaching drug testing skills to sentinel site field staff.

In the first year, the sentinel site staff completed Round 1 testing of antimalarials (artesunate, quinine, chloroquine, and sulfadoxine-pyramethamine) using basic tests — visual inspection, dissolution, and thin layer chromatography (TLC). Over 25% of the drugs collected from four counties in Cambodia were either substandard or fake, that is, they contain either a sub-optimal amount of active pharmaceutical ingredient or none at all. The preliminary data also disclosed a problem with the drug supply in at least two countries, where one-half of the drug samples collected had no manufacturing or expiration date.

Making Progress

The countries involved have made impressive progress implementing the antimalarial drug quality monitoring project. During Rounds 1 and 2 of the monitoring project, fake artesunates (no active ingredient(s)) were found in 6 of 17 sites in four Mekong Region countries:

- Quang Tri, Vietnam;
- Champasak, Laos;
- Pursat, Battambang, and Preah Vihear, Cambodia;
- Rui Li County, Yunnan, China.

Fake quinine sulfate tablets were found in four sites in Cambodia, while substandard quinine sulfate tablets were identified in Quang Tri, Vietnam; Champasak, Laos; and Chanthaburi/Trat, Thailand. Drug regulatory authorities in these countries have taken aggressive action to address the problem of fake and substandard antimalarials:

- **Vietnam:** The Drug Administration of Vietnam issued an investigation notice to all 64 Provincial health and drug authorities to inspect targeted pharmacies for the specific lot number of fake artesunate tablets the monitoring project reported. The Provincial authorities have ordered a recall of this product from the market.

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- **Laos:** The Food and Drug Department issued a recall notice to all 17 Provincial health and drug authorities for four lots of artesunate tablets after receiving a negative verification test report from the Food and Drug Quality Control Center.

The Provincial authorities, in turn, conducted inspections along their distribution chains and confiscated all artesunate tablets found in pharmacies and drug retail shops. Legal action is underway against all of those who sold these fake drugs.

- **Cambodia:** The Food and Drug Department (FDD) produced information and education and communication materials (TV spots, calendars, T-shirts, and posters) to raise awareness among health care professionals and the general public on the danger of using fake drugs (including artesunate, quinine, and tetracycline). In collaboration with other law enforcement agencies, e.g., police and customs, the FDD also organized a workshop, inviting manufacturers, wholesalers, retailers, and health care professionals to discuss the issues of counterfeit drugs in Cambodia.
- **Thailand:** The Food and Drug Administration is investigating substandard quinine, artesunate, and chloroquine with local manufacturers and distributors to find the root cause of the problem.
- **China:** The State Food and Drug Authority asked the Yunnan DRA to further investigate substandard quinine dihydrochloride injections, chloroquine phosphate tablets, and fake artesunate tablets. All these substandard and fake products were confiscated, and the drug outlets and clinics where the products found were fined and had their licenses revoked. The Yunnan DRA is investigating further to find the main source(s) of these fake artesunates.

Making it Work

The improved communications of the regional monitoring system provided swift notification to local as well as national drug regulatory authorities that fake artesunates were circulating in the region, enabling them to remove the counterfeit products from all drug outlets. This action was especially important, given that artesunate remains one of the few antimalarials that has not succumbed to drug resistance. Collaborative and persistent actions like these are required by responsible authorities at local, national, and regional levels and between countries in order to advance the use of safe, effective medicines for the Mekong population.