

## Fake Antimalarials Found in Yunnan Province, China

### Background

The widespread availability of substandard and counterfeit drugs in Asia has been a well documented public health problem in recent years. In 2002, the U. S. Pharmacopeia Drug Quality and Information program (USP DQI), through a cooperative agreement with USAID, began monitoring the quality of antimalarials in the Mekong region. The monitoring sites included the Yunnan Province of China, which is responsible for about one-half of officially reported malaria cases in China. Two sentinel sites in Yunnan Province were selected for drug quality monitoring: Mengla and Ruili counties.

### Round 1 Test Results

Early in 2004, 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). A total of 39 samples were tested, 17 from Mengla and 22 from Ruili. Basic test results indicated that 35 of 39 samples were authentic, while two samples “failed” and two were considered “doubtful.” Overall, about five percent of all samples (based on unique lot/batch number) failed the tests; more than half (53%) of samples did not identify the manufacturing or expiration date, important quality indicators.

### Fake Artesunates

Based on established criteria, five samples (including all “failed” samples) were taken for verification testing at the National Institute of Drug Quality Control of Vietnam (NIDQC). The completed verification testing of these samples indicate that **two artesunate lots contained NO active ingredient**. The NIDQC tested these samples using TLC and a highly sensitive technique, High Performance Liquid Chromatography (HPLC), which confirmed the sentinel site results: **No artesunate**. Other samples proved to be authentic and conformed to pharmacopeial standards. The test results are summarized in Table 1.

### Actions Taken

In light of the verification test results, actions were taken to alert relevant parties that fake artesunates were circulating in the region, so that they could swiftly be removed from all drug outlets. This action was especially important, given that artesunate remains one of the few antimalarials which have not succumbed to resistance.

- USP DQI has notified our regional WHO partner of the presence of specific fake artesunate lots.
- USP DQI and WHO have notified our colleagues in China at the Yunnan Institute of Parasitic Diseases (in charge of coordinating sentinel site activities) and the Yunnan Quality Control Laboratory of the presence of fake artesunates.
- The Yunnan Institute of Parasitic Diseases has informed the Yunnan Health Bureau and, subsequently, the regulatory body, and State Drug Administration (SDA) in Yunnan to take possible legal actions.

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**Table I:** Verification Test Results from National Institute of Drug Quality Control, Vietnam

Name and strength of drug sample	Lot No.	Date of Manufacture	Expiration date	Manufacturer	Sample location	Verification test by TLC and HPLC
Artesunate tablet 50mg blister pack	030801	08/2003	08/2006	Guilin Pharmaceutical Co. Ltd	Zhaoyinglan's clinic, Nongdao township, Ruili	Failed ID test: No active ingredient
Artesunate tablet 50mg blister pack	030101	01/2003	01/2006	Guilin Pharmaceutical Co. Ltd	Liaomingfeng's clinic, Ruili	Failed ID test: No active ingredient
Artesunate tablet 50mg blister pack	030301	03/2003	03/2006	Guilin Pharmaceutical Co. Ltd	Ruili CDC	Passed ID test; and content test of 93.2% (ref: 90-110%)
Artesunate tablet 50mg blister pack	021001	10/2002	10/2005	Guilin Pharmaceutical Co. Ltd	People's Hospital in Mengla County	Passed ID test; and content test of 96.0% (ref: 90-110%)
Chloroquine tablet 250mg	730941	None	None	The 11 <sup>th</sup> Pharmaceutical Factory of Shanghai	Ruili CDC	Passed ID test; and content test of 99.2% (ref. 92.5-107.5%)