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One-Third of Antimalarial Medicines Sampled in Three African Nations Found to be Substandard in Large-Scale USP-WHO Study

Inadequacies May Contribute to Drug Resistance

Rockville, Md., February 8, 2010 — The first results from a large-scale study of key antimalarial medicines in ten Sub-Saharan African countries reveal that a high percentage of medicines circulating on national markets are of substandard quality and thus may contribute to the growth of drug-resistant strains of *Plasmodium falciparum*, the most virulent form of malaria. The findings, released today by the Promoting the Quality of Medicines (PQM) Program, a USAID-funded program implemented by the U.S. Pharmacopeial Convention (USP), are for three countries surveyed in the study—Madagascar, Senegal and Uganda.

The results are part of the larger Quality of Antimalarials in Sub-Saharan Africa (QAMSA) study, a ten-country collaborative study conducted by the World Health Organization (WHO) and PQM. Within Madagascar, Senegal and Uganda, the study sampled 491 antimalarials, performed basic testing on almost all, and submitted 197 samples to full-scale quality control testing. The focus was on artemisinin-based combination therapy (ACT) products, currently the WHO's recommended form of first-line treatment for uncomplicated malaria, and sulfadoxine-pyrimethamine (SP) products, often used for preventative treatment of malaria during pregnancy. The samples were collected from the public and regulated private sectors in these countries, as well as from informal markets, as many patients obtain their medicines from these sources. Substandard and counterfeit versions of antimalarial medicines are highly problematic throughout Africa, Asia and Latin America because of the direct threat they pose to the lives of individual patients as well as their contribution to the development of drug-resistant strains of these diseases.

In total, the QAMSA study found that approximately 44 percent of sampled medicines from Senegal, 30 percent of samples from Madagascar, and 26 percent of samples from Uganda that underwent full quality control laboratory testing failed such testing and were thus substandard. "Substandard" medicines are those that do not meet the quality specifications set for them, primarily because they do not contain the correct amount of the active ingredient(s), do not dissolve properly in the body or include unacceptable levels of potentially harmful impurities.

"The results of the study paint a very unfortunate picture of the situation in Sub-Saharan Africa," said Anthony Boni, the Agreement Officer's Technical Representative for the PQM Program, USAID Office of Health, Infectious Diseases, and Nutrition. "With almost half of medicines in Senegal and more than one out of four medicines in Madagascar and Uganda failing quality testing, clearly much work needs to be done to provide patients with medicines that meet the level of quality they require—and deserve. These countries are committed to protecting the health of their citizens, but the authorities face many challenges in regulating their markets. We look forward to working together with them to reduce the morbidity and mortality caused by malaria, by improving the quality of the medicines used to treat this disease."

"Although alarming, this study offers extremely valuable information that has already been shared with



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those countries in the hope that local regulatory bodies will focus their attention on products, brands and geographical locations where substandard medicines were found to pose the biggest threats,” said Patrick Lukulay, Ph.D., Director of the PQM Program at USP. “The results show some significant differences in terms of where the problems lie. These findings can be used immediately by officials to target their efforts—an especially useful approach when resources are scarce, as they are in these countries.”

The main purpose of the study was to update and expand the knowledge base about the prevalence of substandard antimalarials in Sub-Saharan Africa, which are believed to contribute to antimicrobial resistance of *Plasmodium falciparum*. Already, *Plasmodium falciparum* has become resistant to traditional monotherapy drugs such as chloroquine, and more recently to SP products. The sustainability of treatment success depends to a large extent on preventing *Plasmodium falciparum*'s exposure to incomplete doses of these medicines to minimize the possibility of the emergence of drug resistance.

Beyond the overall failure rates, other noteworthy findings across the three countries were that SP products were most likely to fail dissolution tests (35 percent), while ACTs were most likely to fail impurity tests (29 percent). No samples in the full study completely lacked the active ingredient(s). The results also showed that, as a general rule, when a brand passed or failed in one country, it would also pass or fail in other countries. This indicates that the problem of quality is created at the source, rather than during passage through the distribution chain.

Despite some similarities, results by country varied in a number of areas, including at which points of sale the substandard medicines were found. In Madagascar, for instance, poor quality medicines appear to be widespread across regions and not limited to any particular type of distributor. In Uganda, samples fared much better in the public sector than in the country's private sector. Despite overall failure rates, this was one of the bright spots the study revealed; in Uganda's public sector, all ACT and SP samples passed quality tests.

The report is believed to be unique in terms of the large numbers of samples collected as well as the two-step testing approach employed in the study, which included initial screening on site using Global Pharma Health Fund portable Minilabs[®] and full-scale quality control confirmatory testing of roughly 40 percent of the total samples at USP's headquarters in the United States.

USAID is a U.S. government agency that provides economic, development and humanitarian assistance around the world in support of the foreign policy goals of the United States. USP is a nonprofit scientific organization that sets globally recognized standards for the quality of medicines. USP's work in developing countries to improve the quality of medicines—in large part by combating the availability of substandard and counterfeit medicines intended to treat malaria, HIV/AIDS and tuberculosis—is implemented under the PQM Program supported by USAID.

To obtain a copy of the complete report and for more information, please email mediarelations@usp.org.

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