



U.S. Pharmacopeia
The Standard of Quality™

Memorandum to: USP Convention Members — Executives and Delegates
Official Observers — Executives and Representatives

From: Council of the Convention Section on Global Public Health

Date: September 10, 2009

Subject: USP Drug Quality and Information Program — USP DQI

The attached information sheet provides three short case studies that we hope will highlight for Convention member organizations, delegates, and observers the lifesaving work the USP Drug Quality and Information (DQI) Program is doing around the world. As constant witnesses to the human tragedies caused by counterfeit and substandard medicines, USP DQI staff work persistently, pragmatically, and also with a sense of urgency to build the technical capacity needed in developing countries to ensure access to quality medicines.

Through the USP DQI Program—a cooperative agreement with the U.S. Agency for International Development (USAID)—USP has strengthened its worldwide reputation as a public health organization committed to ensuring the quality and consistency of medicines, and has broadened its recognition as a global pharmacopeia.

USP DQI provides a wide range of technical assistance to a country's medicine regulatory authority, including:

- Conducting quality assurance/control assessments;
- Building the capacity of national quality control laboratories;
- Systematizing drug registration;
- Training on sampling, Good Laboratory Practices, basic laboratory tests, and compendial analytical methods;
- Establishing medicine quality monitoring and pharmacovigilance systems;
- Coaching medicines manufacturers on Good Manufacturing Practices towards ISO certification or WHO prequalification;
- Participating in studies of antimalarial medicine quality and resistance patterns; and,
- Partnering/collaborating with other health organizations and stakeholders in country / regional initiatives when appropriate.

The case studies demonstrate that, after almost a decade and despite enormous challenges, USP DQI is making a difference. And, there is much more to do.

Additional information about USP DQI:

- Director: Patrick H. Lukulay, Ph.D.
- Website: <http://www.uspdqi.org>
- DQI Matrix of reported counterfeit and substandard medicine incidents <http://www.usp.org/pdf/EN/dqi/ghcDrugQualityMatrix.pdf>
- USP DQI Resources: <http://www.usp.org/worldwide/dqi/resources/>
 - Staff Expertise/Facilities
 - Technical Reports
 - Abstracts, Presentations & Proceedings
 - Background Papers
 - Assessment Materials, including Visual Inspection Tool to identify suspicious drug products;
 - Other Publications;
 - *Ensuring the Quality of Medicines in Resource-Limited Countries: An Operational Guide*
- USPDQI@usp.org
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USP Drug Quality and Information Program

Training, Educating, and Building Capacity in Drug Quality Assurance and Quality Control in Developing Countries



CASE STUDIES

ASIA

Counterfeit drugs: Providing the tools for enforcement and education

Problem	Failure rates of antimalarial drugs ranged from 25 to 50% in the Greater Mekong Sub-region in 2003 when tested for identity and content. The volume of poor-quality drugs poses a significant health problem and contributes to the growth of resistant malaria strains.
DQI Actions	Built capacity in national drug regulatory agencies: assessed QA/QC systems in 5 countries; provided equipment and training to 4 national labs; equipped 39 sentinel sites with portable labs; trained personnel to sample local medicine outlets and perform basic quality tests; reported poor-quality medicines; and shared data with regional counterparts to take action against counterfeits.
Outcome (Sept. 2008)	Evidence-based data from quality monitoring programs in 4 countries were used in 2 INTERPOL investigations, resulting in 31 arrests and seizure of over \$9 mil. worth of counterfeit drugs. Drug quality monitoring has expanded from 17 to 39 sites in 5 years and now includes antimalarial, antiretroviral, anti-tuberculosis, anti-viral, and some antibiotic medicines.
What's Next for DQI?	Continued improvement of postmarketing surveillance. Public service announcements on TV, radio, and cell phones about the dangers of counterfeit medicines to encourage purchase from licensed pharmacies.

AFRICA

Government commitment: Ensuring a holistic approach to quality

Problem	By 2003, the availability of substandard and counterfeit drugs in Madagascar had reached a disturbing level and the country's drug regulatory authority had no quality control—the few suspect drug samples collected had to be sent out of the country for testing.
DQI Actions	Assessed the country's QA/QC systems: collected data from the field to determine marketplace quality level; supplied lab equipment and Minilabs®; installed computers and software for drug registration; and trained staff on QA/QC systems, good lab practices, testing methods, procurement, storage, distribution, and postmarketing surveillance.
Outcome (Feb. 2009)	Efficient drug registration system; 6 sites monitor DQ for antimalarials and ACTs; national drug quality lab performs advanced testing; Drug Information Center assists health professionals and the public; National Center of Pharmacovigilance qualified as full member of the World Health Organization International Drug Monitoring Programme.
What's Next for DQI?	Continue to provide technical assistance to streamline lab procedures, analyze sample data to take appropriate action, and enhance the nation's lab capabilities for advanced testing.

LATIN AMERICA

Amazon Malaria Initiative: Establishing a peripheral drug monitoring system

Problem	Rural areas in the Amazon Basin have a high incidence of malaria and limited access to public health services. Limited resources prevented monitoring drug quality, leaving patients at risk from poor efficacy, adverse reactions, and possible resistance to treatment.
DQI Actions	Helped establish 17 monitoring posts in remote areas in 7 countries: trained staff in sampling and basic testing; provided mobile Minilab® equipment for field testing; procured supplies; provided technical assistance; and oversaw monitoring activities.
Outcome (May 2009)	<ul style="list-style-type: none"> ▶ Since 2006, approx. 1,500 malaria drugs from the public sector have been sampled and analyzed: 8% were expired, 7% failed critical quality attributes. ▶ Drugs have been removed from circulation and corrective actions taken by the health authority in each country.
What's Next for DQI?	Studies in Colombia, Guyana, and Suriname to assess the quality of antimalarial drugs in the private and informal sectors, where the risk of substandard and counterfeit drugs is greater.

