

**DQI Proposed Work Plan
(Following July 2008 Assessment)
BENIN**

October 1, 2008 – September 30, 2009

I. INTRODUCTION AND BACKGROUND

It is important that procurement of pharmaceutical commodities and other investments in pharmaceutical systems be accompanied by proper measures to ensure the quality of the medicines. The quality of medicines affects their efficacy and safety and hence their usefulness in obtaining positive health outcomes for patients. Poor quality medicines also represent an economic challenge, as their cost can absorb a significant portion of limited resources in developing countries (mostly in the form of out-of-pocket spending) without ultimately yielding the desired health impact. Finally, the use of substandard medicines plays a role in the emergence of antimicrobial resistance (AMR), which, in turn, poses additional long-term health and economic challenges.

The United States Pharmacopeia Drug Quality and Information (USP DQI) Program has been selected by the President's Malaria Initiative and the U. S. Agency for International Development (USAID)/Benin to support the National Quality Control Laboratory (NQCL).

The Malaria Operational Plan and Planned FY08 Obligations included \$150,000 for "Drug Quality Control". USP DQI is expected to support the NQCL by helping improve inspection, test ACTs, train staff, and replace or repair laboratory equipment per the Malaria Operational Plan for PMI in Benin.

In June 2008, Drs. Karim Smine and Mustapha Hajjou conducted meetings and assessment visits in Benin. The visits were intended to assess the country capabilities in drug quality in order to develop a detailed work plan for the introduction of drug quality monitoring in Benin. The USP DQI team met with the Drug Regulatory Authority (DRA), the National Drug Quality Control Laboratory (NDQCL) and the National Malaria Control Program (NMCP). Based on the assessment of the NDQCL, USP DQI proposes to strengthen the laboratory capabilities by providing training in Good Laboratory Practices that will include pharmacopeial testing relevant to anti-malarial drugs. The training will be followed up hands-on experience in a first round of post-marketing surveillance of antimalarials.

Within the framework of the funds provided, USP DQI proposes to carry out the following activities:

1. Procurement of Basic Standards and Reagents for Testing Antimalarial Medicines

USP DQI will procure the necessary reference standards, reagents, and basic tools to test all antimalarial drugs. It will not be possible to procure any analytical instruments with the funds provided.

Implementing Partner: NDQCL
Estimated budget: **\$50,000**

2. Training of National Drug Quality Control Laboratory

USP DQI will develop a training and performance plan, as well as training modules, for the NDQCL. The training modules will focus primarily on HPLC, Dissolution, and quality systems (including Good Laboratory Practices) relevant to the control of anti-malarial drugs. All this is necessary to prepare the NDQCL to undertake post-marketing surveillance.

USP DQI will conduct one training session in FY09, which will be followed up by practical hands-on training in a first round of pharmacovigilance (see below).

Implementing Partner: NDQCL
Estimated Budget: **\$30,000**

3. Quality Control of Antimalarial Medicines

After the NDQCL training, USP DQI will conduct one round of collecting and testing samples of anti-malarial drugs from public, private, and informal sectors. This will provide the NDQCL an opportunity to work in a collaborative way with USP scientists and learn to test the quality of medicines according to international standards. This study will also reveal the proportion of counterfeit and substandard medicines within the samples collected and provide an evidence-base for monitoring and evaluating eventual progress towards better quality control and assurance.

Implementing Partner: NDQCL
Estimated Budget: **\$45,000**

DETAILED WORK PLAN – BENIN

October 1, 2008 – September 30, 2008

Activity	Inputs	Target Indicators	Timeline	Est. Budget
Conduct Assessment of Drug Quality Control Capabilities in Benin	1- Participate in July NMCP Meeting 2- Meet with key stakeholders 3- Assess capabilities of National Quality Control Laboratory (NQCL)	Visit conducted and report delivered; Work plan developed and approved by USAID/Mission	FY08 Q4 (Visit completed)	\$25,000
Provide Basic Supplies	1- Determine list of basic standards and reagents to analyze antimalarial medicines during training and sampling round 2- Procure and supply	Lab supplies, reagents and reference standards provided	FY09 Q1 (This was done during the June 2008 Assessment)	\$50,000
Train Staff	1- Conduct training on analytical methods	NDQCL staff trained	FY09 Q2	\$30,000
Organize one collaborative study on anti-malarial drugs quality	1- Conduct sampling and testing of a limited number of antimalarials from private, public, and informal sectors 2- Report findings 3- Draw conclusions and provide recommendations on building up of post-marketing surveillance	Samples collected and tested Report issued and shared with stakeholders	FY09 Q3-Q4	\$45,000
Total				\$150,000