DQI Proposed Work Plan

Senegal

October 1, 2008 – September 30, 2009

I. INTRODUCTION AND BACKGROUND

The United States Pharmacopeia Drug Quality and Information (USP DQI) Program, supported by USAID, has been assisting Senegal in strengthening quality control and quality assurance since 2002. Activities have ranged from supporting the Drug Regulatory Authority (DPL) with the registration process to building up national laboratory testing capacity.

In FY07, Senegal was one of four countries to start receiving support under the President's Malaria Initiative (PMI). Within this context, DQI has focused on (1) assisting the country in monitoring the quality of antimalarial medicines on the market, as well as (2) consolidating pharmacovigilance activities. Both types of activities are important because of the considerable presence of sub-standard and counterfeit medicines in Senegal. The use of sub-standard antimalarials - as well as the incorrect prescribing and dispensing of good quality antimalarials - increases the risk of resistance to artemisinin-based combination therapies, which in turn can threaten the impact of the PMI program in the country. Drug quality monitoring and pharmacovigilance activities allow national stakeholders and the USAID Mission to remain up to date with drug quality trends in the market, identify weaknesses, advocate or take appropriate corrective actions, and raise public awareness about the risks of sub-standard medicines and the importance of using good quality products.

<u>Regarding drug quality monitoring:</u>
PMI's Planned Obligations for FY08 include $100,000 for "maintaining the system of drug quality assurance". The Malaria Operational Plan explicitly states: "*The PMI in collaboration with the NMCP, UCAD, and the National Drug Quality Control Laboratory will continue to strengthen national capacity for drug quality surveillance including maintaining a system of drug quality assurance that enforces regulatory action to be taken when poor quality drugs are found*" (p. 33). In addition, the Senegal Mission is budgeting $50,000 for post-marketing surveillance of HIV/AIDS medicines and $43,000 for TB medicines

This provides the context for the proposed objectives and activities presented below. In particular: in order to ensure a smooth transition from post-marketing surveillance focused on antimalarials only to a system that spreads its net wider (including anti-TB, HIV/AIDS medicines, and antibiotics), USP DQI will coordinate with the National TB Health program and the National HIV/AIDS Health program to select the drugs to be included in the program.

<u>Regarding pharmacovigilance (PV):</u>
In a conference call between USAID/Senegal, USAID/Washington, and DQI on September 11, 2008, it was agreed that DQI should continue the pharmacovigilance-related work started in FY08, when USP DQI participated in a number of meetings organized by DPL and WHO and

provided recommendations on the necessary tools to address the existing gaps and weaknesses. In this context, DQI proposed and promoted the scenario, now endorsed by the stakeholders, to develop a system whereby one pharmacovigilance center functions as the nexus for all adverse drug event reporting, rather than continuing along the lines of different systems and PV centers for different programs or diseases. A first draft of a PV-related action plan has now been developed. DQI will continue to provide technical assistance to the pharmacovigilance initiative (of which the PNLP is the driving force), monitor developments and provide guidance, given the regular occurrence of close links between adverse drug events and the use of counterfeit and sub-standard medicines.

II. USP DQI OBJECTIVES:

1. Expand post-marketing drug quality monitoring activities.
2. Complete the "Quality of Antimalarial Medicines in Sub-Saharan Africa" (QAMSA) study in Senegal.
3. Continue to provide technical assistance to the development and implementation of a national pharmacovigilance program in Senegal

III. DESCRIPTION OF PLANNED ACTIVITIES

1. Continue to Support Drug Quality Monitoring

USP DQI will continue to support the National Malaria Control Program (Programme National de Lutte contre le Paludisme or PNLP), the University of Cheik Anta Diop (UCAD), and the National Drug Quality Control Laboratory (Laboratoire National de Controle de Medicaments or LNCM), in monitoring the quality of medicines available on the market. Concretely, DQI support will focus on the following dimensions and issues:

- To date, the post-marketing drug quality monitoring is based on five sentinel sites. The aim is to add one additional site this year and to organize one round of sampling and testing.
- In addition to the ACTs and SPs, post-marketing surveillance will be extended to selected HIV/AIDS and TB medicines. DQI will involve the national TB program and the national HIV/AIDS program in the drug quality postmarketing surveillance.
- To date, lack of communication between the different stakeholders has hampered timely reporting (see Note). The aim during this FY is to significantly streamline collaboration and communication between the partners involved. In this context, DQI will assist in the implementation of a new protocol for post-marketing surveillance program and it will closely monitor progress.
- Timely reporting will in turn facilitate timely follow-up by the Direction de Pharmacie et Laboratoires (DPL) and opportunities to use the data for raising public awareness. DQI will engage the Service National de l'Education et de l'Information pour la Santé (SNEIPS) in the dissemination of information on drug quality. DQI will share with SNEIPS its experience in collaborative work with partners from Southeast Asia relating to raising awareness and together will explore and introduce approaches that are appropriate for Senegal. Pending

agreement with the Ministry of Health, and in collaboration with SNEIPS, USP DQI proposes the following actions:

- DQI will actively advocate for, and promote, follow-up by the regulatory authorities on substandard medicines findings. DQI will maintain continuous communication with DPL, inquire on follow-ups regarding substandard and counterfeit drugs detected in the market, and, if useful, provide information on the type of activities undertaken in other DQI-supported countries. DQI will also keep the USAID Mission informed.

Note: Based on DQI experience in developing countries, it commonly takes several years to develop post-marketing surveillance into a well-organized routine activity, producing data in a timely manner. It also can take quite some time before national authorities start to routinely take corrective action on the basis of the post-marketing surveillance data and to use the information for raising public awareness. In Senegal, post-marketing surveillance started in 2003 but the situation has been especially complicated because of the multitude of actors involved in testing, namely the PNLP, UCAD and LNCM.

Implementing Partners: PNLP, UCAD, LNCM, SNEIPS and Direction de Pharmacie and Laboratoires (DPL)
Estimated Budget: **$133,000**

2. Finalize the QAMSA Study in Senegal

Last year, WHO and USP DQI launched a multi-country study on the quality of anti-malarial medicines in Sub-Saharan Africa. Senegal is one of three countries sponsored by DQI, alongside Madagascar and Uganda[1]. The aim of the QAMSA study is to establish base-line data regarding the quality of ACTs and SPs in select USAID-funded African countries. In addition, the drug quality results will be disseminated to allow for follow-up by national authorities and increased public awareness of the importance of using good-quality medicines.

Good progress was made in FY08 and the study (Senegal – portion) is on schedule to be completed by December 2008. In February 2008, two staff for Senegal received training in sampling and testing techniques, using Minilabs. Sampling in Senegal took place in April 2008. USP DQI validated the sampling in June 2008. The testing by Minilab kit is ongoing and will be completed in August 2008. The following activities remain on the agenda: (1) validation of Minilab testing; (2) selection of samples that require confirmatory testing by USP laboratory; (3) communication of results to WHO; (4) publication and dissemination of results for Senegal. The publication of the 10-country report is expected to take a few extra months. The cost of the second phase of the Qamsa study will mainly be supported by directed funding from USAID/Washington ($50,000).

Implementation Partners: WHO, PNLP, and UCAD
Estimated Budget: $**10,000**

[1] WHO is sponsoring Cameroon, Ethiopia, Ghana, Kenya, Nigeria, Tanzania**,** while the USAID-funded Strengthening Pharmaceutical Systems (SPS) Program supports the QAMSA study in Malawi.

3. Continue to Support the Development of a National Pharmacovigilance Program

USP DQI will continue to assist in developing a comprehensive national strategy and action plan for a functional pharmacovigilance system in Senegal. The strategy should define the responsibilities of the different stakeholders' involved, appropriate resources, systems and procedures.

USP DQI will facilitate the implementation of a strategic plan that will integrate all pharmacovigilance activities of different national health programs into a single national system. Concretely, and depending on the needs expressed in the national action plan, DQI may focus its assistance on the following:

- Review and provide comments on the recently developed action plan
- Develop a national adverse drug events reporting form to be used by all health programs in Senegal
- Develop a custom training curriculum to sensitize health professionals to drug safety and pharmacovigilance activities

Implementing partners: Centre Anti-Poison, DPL and PNLP
Estimated budget: **$50,000**

ANNEX 1

SENTINEL SITES IN SENEGAL

In June 2002 Senegal's malaria control program, Programme National de Lutte contre le Paludisme (PNLP), initiated a project to control the quality of AM drugs. The PNLP established a sampling and testing program in five sentinel sites using GPHF Minilab® kits to evaluate the quality of AM drugs circulating in local markets.

Senegal has six sentinel sites, each equipped with a Minilab
1. Guédiawaye
2. Richard Toll
3. Kaolack
4. Vélingara
5. Touba
6. Kedougou

Location of Minilab