U.S.
Pharmacopeia

Support to Malaria Control in Uganda
US President's Malaria Initiative

Proposed Work Plan FY 2006

Background

Malaria is endemic in Uganda; the disease is the leading cause of the country's morbidity and mortality and is responsible for up to 40% of outpatient visits, 25% of hospital admissions, and 14% of hospital deaths. The burden of malaria is greatest among children under five years of age and pregnant women.

In late June 2005, the United States Government announced a new five-year, $1.2 billion initiative — the President's Malaria Initiative (PMI) — to rapidly scale up malaria prevention and treatment interventions in high-burden countries in sub-Saharan Africa. Uganda was selected as one of the initial three countries to benefit from this initiative. In Uganda, the PMI is supposed to achieve 85% coverage of vulnerable groups with the correct antimalarial drugs, insecticide-treated bed nets (ITNs), intermittent preventive treatment (IPT), and indoor residual spraying (IRS).

The National Drug Authority (NDA) of Uganda monitors the efficacy and safety of pharmaceuticals and other regulated health products entering the country. NDA assumes the functions of quality control, pharmacovigilance, post-marketing surveillance, and drug information. The NDA, however, has a limited capacity to perform these functions and is in need of additional human and financial resources. As part of the plan, PMI provided financial support to the NDA to increase its ability to ensure the quality and efficacy of malaria-related commodities necessary to implement the PMI.

USAID Mission Uganda requested USP DQI to support Uganda in their efforts to assure the quality of antimalarial drugs within Uganda a PMI country. Consequently, two USP DQI staff conducted an assessment of the country's drug quality control system in June 2006 and identified weakness and areas where USP DQI could assist the NDA and National Quality Control Laboratory (NDQCL). USP DQI, in collaboration with NDQCL-Uganda, selected the laboratory equipment that would best serve the needs of the NDA for testing antimalarial medicine and insecticides. USP DQI purchased the specified equipment in the U.S. and arranged for it to be shipped and installed in NQCL-Uganda.

In September 2006 USP DQI trained the NDQCL staff on Good Laboratory Practices and major testing methods, such as High Performance Liquid Chromatography (HPLC), Dissolution, Ultraviolet Spectrophotometry (UV), and Gas Chromatography (GC). The laboratory training focused on the correct use of the *U.S. Pharmacopeia-National Formulary* or other international pharmacopeias, and standardization of the workflow in the quality control lab.

USP DQI Technical Objectives

The USP DQI Malaria objectives of the proposed scope of work are:

1. Strengthen drug quality control in Uganda
2. Strengthen the drug regulatory functions (pharmacovigilance, drug registration) of NDA
3. Provide TA to local manufacturers

Proposed Steps/Activities

1. **Establish a drug quality control program in four selected provinces and confirm part of the tests in NDQCL using specific monographs**

A training workshop on sampling of antimalarial medications and the proper use of the MiniLab testing kit will be provided (USP DQI plans to provide 4 MiniLabs). The monitoring of the quality of antimalarial drugs at the central and the periphery levels will be activated. Three rounds of collecting and testing will be done in FY06. USP DQI will collaborate with NDQCL on the testing of drugs collected. Data will be reviewed and report will be shared with the partners.

2. **Strengthen drug registration practices in the NDA and install in collaboration with WHO, the recent version of SIAMED registration software**

This activity will include a rapid assessment of the drug registration of NDA by WHO experts, identification of the priority users from the NDA registration division and adjustment of the new version of SIAMED. The training of all identified users on the proper use of SIAMED and its applications will be provided.

3. **Assist local manufacturer, especially those making antimalarials, with Good Manufacturing Processes**

USP DQI will provide a GMP training course for the local manufacturers which are involved in the manufacture, packaging or distribution of antimalarial drugs.

4. **Continue the training of the NDQCL and set a program for advance performance to gain an ISO 17025 certification.**

The assessment of the laboratory management system against the ISO17025:2005 will be provided. The guidelines on how to meet the ISO 17025 standard will be developed.

5. **Support NDA with pharmacovigilance focused on adverse drug reactions reporting related to ACTs.**

USP DQI will provide assessment of pharmacovigilance activities which are being conducted in Uganda and initiate the MCP/NDA activities on monitoring adverse drug reactions for newly introduced ACTs (Concerns about ADR of ACTs were raised in other African countries).

Uganda
President's Malaria Initiative (PMI)
USP DQI Proposed Work Plan for the period of October 1, 2006 through September 30, 2007

Objectives:

1. **Strengthen drug quality control in Uganda**
2. **Strengthen the drug regulatory functions (pharmacovigilance, drug registration) of NDA**
3. **Provide TA to local manufacturers**

Activities	Tasks	Human resources	Measurable Results	Estimated Budget	Timeline
1- Establish a drug quality control program in four selected provinces and confirm part of the tests in NDQCL using specific monographs	- Provide a training workshop on sampling of antimalarial medications and the proper use of the MiniLab testing kit (4 MiniLabs will be provided) - Monitor quality of antimalarial drugs at the central and the periphery levels. Three rounds of collecting and testing will be done in FY07. - Collaborate with NDQCL on the testing of drugs collected. - Analyze data and share the report with partners	ND SB AYS	- Data from central and selected periphery areas available. 3 times/year - Data about storage, distribution and quality	$90,000	Jan-March, 2007 Complete three rounds by September 2007
2- Strengthen drug registration practices in the NDA and install in collaboration with WHO, the recent version of SIAMED registration software.	- Provide a rapid assessment of the drug registration of NDA by WHO experts - Identify the priority users from the NDA registration division and install the new version of SIAMED - Provide a training of all identified users on the proper use of SIMED and its applications	USP DQI and WHO experts	- Better drug registration system - Shorter time to register drugs with NDA	$45,000	Jan-March, 2007
3- Assist local manufacturer, especially those making antimalarials, with Good Manufacturing Processes	-Provide a GMP training course for the local manufacturers which are involved in the manufacture, packaging or distribution of antimalarial drugs	ERT	-Better qualified personnel - Better manufacturing process - Better quality medicines	$40,000	Jan-March, 2007

4- Continue the training of the NDQCL and set a program for advance performance to gain an ISO 17025 certification	- Provide the assessment of the laboratory management system against the ISO17025:2005 - Provide ISO audit of the Lab	AYS, SB, ND	- Trained management of NDQCL - Specific recommendations/guidelines on how to meet the ISO 17025 standard	$45,000	Jan-Sept, 2007
5- Support NDA with pharmacovigilance focused on adverse drug reactions reporting related to ACTs.	- Assess what pharmacovigilance activities are being conducted in Uganda - Support MCP/NDA start monitoring ADR for newly introduced ACTs (Concerns about ADR of ACTs were raised in other African countries).	AYS and WHO experts	- Facilitate the establishment of ADR reporting mechanism focused on ACTs	$40,000	April-June, 2007
Total				**$260,000**	