

**Rapid Assessment of Drug Quality Assurance and Drug Quality Control
Capabilities of Ghana: USP DQI Planning Workshop
Accra, Ghana ♦ October 13-15, 2008**

Trip Report

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About USP DQI

The United States Pharmacopeia Drug Quality and Information (USP DQI) Program, funded by the U.S. Agency for International Development (Cooperative Agreement HRN-A-00-00-00017-00), provides technical leadership to more than 30 developing countries to strengthen their drug quality assurance programs, ensure the quality of medicines and promote public health.

USP DQI helps build local, national and regional capacity to improve the standards of drug manufacturing and distribution, reduce the impact of infectious diseases, mitigate the effects of the HIV/AIDS epidemic, and advance the appropriate use of medicines. This document does not necessarily represent the views or opinions of USAID. It may be reproduced if credit is given to USP DQI.

Abstract

United States Pharmacopeia Drug Quality and Information (USP DQI) Program conducted a two-day assessment of the drug quality assurance and drug quality control capabilities of Food and Drug Board of Ghana. During this short assessment, the USP DQI team met with key players of drug quality monitoring program. With country partners, USP DQI established a plan for future activities that USP DQI will carry out in Ghana under the auspices of the President's Malaria Initiative.

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Key Words

Ghana, drug quality assurance, drug quality control, pharmacovigilance, antimalarials, drug quality monitoring, drug registration, President's Malaria Initiative, PMI

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USP DQI team wishes also to express their sincere appreciation to all the Ghanaian partners they met with during this trip. Special thanks to Reverend Jonathan Martey who arranged for all meetings and assisted the USP DQI team during the visit. Thanks to Dr. Constance Marfouk, Director of the Malaria Control Program, and to Dr. Daniel Kertesz WHO-Ghana Representative, and his staff.

Special thanks to Mr. Anthony Boni and Ms. Veerle Coigneux at USAID/Washington for their guidance and helpful insight throughout the preparation stages of the workshop.

We are also grateful to the USP DQI staff who prepared, reviewed, and edited this report and assisted with the planning of this trip.

Acronyms

ACT	Artemisinin-based Combination Therapy
AIDS	Acquired Immunodeficiency Syndrome
CA	Cooperative Agreement
CDC	U.S. Centers for Disease Control and Prevention
Cedi	Unit of currency in Ghana
CMS	Central Medical Store
FDB	Food and Drug Board
GMP	Good Manufacturing Practices
HPLC	High Performance Liquid Chromatography
ITAP	International Technical Alliance Program
ITN	Insecticide-treated Net
IPT	Intermittent Pregnancy Treatment
MSH	Management Sciences for Health
MCP	Malaria Control Program
NDQCL	National Drug Quality Control Laboratory
NMCP	National Malaria Control Program
PV	Pharmacovigilance
QA	Quality Assurance
QC	Quality Control
SIAMED	WHO model system for computer-assisted drug registration
SOP	Standard Operating Procedure
SPS	Strengthening Pharmaceutical Systems
USAID	United States Agency for International Development
USP DQI	United States Pharmacopeia Drug Quality and Information
WHO	World Health Organization

Background

Bordered by the Ivory Coast on the west, Burkina Faso on the north, and Togo on the east, the Republic of Ghana sits on West Africa's Gulf of Guinea. Many ethno-linguistic groups — principally the Akan (Ashanti and Fanti), Mole-Dagbani, Ewe, and Ga-Adangme — comprise the country's 19 million people. Approximately 36% of the Ghanaian population dwells in urban locations. English is the official language in the country.

Ghana's main economy derives from mining and agriculture. The country is rich in natural resources: gold, timber, diamonds, bauxite, manganese, and fish; and 70% of its land is forested and arable. Ghana produces cocoa, coconuts, coffee, pineapples, cashews, pepper, other food crops, and rubber. Since the early 1990s, Ghana has experienced many positive developments on both economic and political fronts, including increased political freedom and the re-emergence of a free press. Ghana will start producing gas in 2010. The country is experiencing great economical development. Soon the Ghanaians also will elect a new president.

Despite economic growth, Ghana still suffers from health problems related to malaria. Malaria is hyperendemic in Ghana, accounting for over 44% of all outpatient visits and 22% of its under-five mortality. Malaria is still one the major causes of poverty and low productivity in Ghana. According to the Ghanaian Malaria Control Program (MCP), mortality has decreased in last two years because of better disease control and the availability of antimalarial drugs.

USP DQI has supported the Food and Drug Board (FDB) of Ghana since FY04. USP DQI equipped and trained quality control (QC) laboratory staff. USP DQI also trained FDB on drug registration and installed SIAMED for the department of drug evaluation. In addition, USP DQI has assessed several medicines manufacturers in Ghana. Drug quality assurance (QA) is still a major issue in Ghana because local manufacturers produce and sell products not in compliance with GMP. The QC lab staff are well trained, however, the lab facilities are old and do not offer a good work environment. Pharmacovigilance activities have been delayed.

USP DQI was selected by USAID to provide technical assistance to FDB to strengthen the QA/QC systems within PMI program. The objective of this visit was to meet with key stakeholders of the program and work together to define all the critical program elements.

Purpose of Trip

The aims of this trip were to:

- Review the Malaria Operational Plan activities where USP DQI will provide technical assistance;
- Conduct a rapid assessment of drug quality assurance and quality control capabilities of Ghana;
- Meet with all stakeholders involved in the management, control, and distribution of antimalarial drugs;
- Inform partners about USP DQI expertise and approaches in dealing with QA/QC; and,

- Obtain buy-in from local partners and the USAID/Ghana Mission about the activities to be conducted in FY08.

Source of Funding

This trip was funded by the USAID/Ghana Mission–PMI program.

Overview of Activities

To prepare for activities that would provide technical assistance to the Malaria Control Program of Ghana, USP DQI Director Dr. Patrick Lukulay and USP DQI Consultant Dr. Abdelkrim Smine (the USP DQI team) traveled to Accra, Ghana, to conduct a rapid assessment of the drug quality assurance and quality control (QA/QC) capacity of the Food and Drug Board of Ghana (FDB). The USP DQI team met with key stakeholders involved in quality assurance and the management of antimalarial drugs. The team worked with all country partners and engaged in fruitful discussion, accepted the participants' comments and recommendations, and built consensus about the program activities planned to be conducted in FY09 through the USAID/Ghana–PMI program.

1. Meeting with the Food and Drugs Board of Ghana (FDB)

Present: Reverend Jonathan Martey, Dr. Patrick Lukulay, Dr. Abdelkrim Smine

Rev. Martey welcomed Drs. Lukulay and Smine and briefed them on preparations for the workshop to be organized the following. He called the Malaria Control Program (MCP) to confirm the appointment for the USP DQI team to meet with the MCP Director and discussed the details about the workshop premise, attendees, and catering services.

Dr. Lukulay presented the objectives of the USP DQI team visit and articulated the expected outcomes from the workshop. Dr. Smine asked questions about drug registration, postmarketing surveillance, pharmacovigilance as follow up on FDB activities since 2005 when USP DQI previously provided technical assistance to the FDB. He learned that pharmacovigilance is now under FDB responsibility and that postmarketing is still sporadic and was not continued within regular FDB activities. FDB has moved to the former USAID compound, while the QC lab is still in the same old facilities as in 2005. The new FDB building is under construction, but its completion was delayed by problems with the contractor. Rev. Martey said that FDB and the Minister of Health are working to find another contractor to complete the building.

The USP DQI team updated Rev. Martey on the QAMSA Study with the World Health Organization (WHO). They congratulated the FDB QC lab for having done such good work in the first and second phases of the Study as had been reported by the WHO QAMSA team. Rev. Martey arranged for Dr. Lukulay and Dr. Smine to visit the National QC Laboratory (NDQCL) upon their request.

The USP DQI team learned from Rev. Martey that the CEO of the FDB, E. K. Agyarko, will soon resign from his post as he is running for political office.

2. Visit to Food and Drug Board National Drug Quality Control Laboratory

Present: Dr. Lukulay, Dr. Smine, Senior NDQCL staff

Dr. Smine first checked the working condition and the status of equipment in the NDQC Lab based on his knowledge from 2005, when USP DQI had previously supported the lab. Dr. Smine found that the HPLC purchased by USP DQI, as well as those purchased by FDB the same year, are still working well and being used extensively. In addition, the FDB recently purchased two more HPLC units (Agilent HP 1200s). The temperature control unit of the dissolution tester purchased by USP DQI is out of order.

Aside from the equipment, Dr. Smine noticed that the NDQCL facility does not provide a suitable work environment. The fume hoods were not working properly and the poor aeration system in the lab makes it unhealthy for the working staff. Both food and drug testing has increased, which burdens all the lab systems and has left the staff facing a challenging environment. The staff complained about the working conditions as well as the lack of office and storage space.

Following their visit, Dr. Lukulay and Dr. Smine met with the senior laboratory staff and explained how the laboratory facilities are a handicap to making progress. The working conditions will affect the quality of the tests and analyses being done in the lab. Under these conditions, they felt that USP DQI support to the NDQCL would not be possible. Dr. Smine and Dr. Lukulay promised to report these facts to the Rev. Martey and try to convince him to resolve this situation as soon as possible, so as not to hinder the performance of the NDQCL or negatively affect the moral of the lab staff.

Dr. Lukulay and Dr. Smine congratulated the NDQCL staff involved with the QAMSA study for a job well done and an excellent report.

3. Meeting with Malaria Control Program

Present: Dr. Lukulay, Dr. Smine and Dr. Constance Marfouk

Dr. Lukulay gave an overview about the USP DQI program and its activities in PMI-funded countries in Africa. He said that for FY08, USP DQI will focus mainly on establishing a drug quality monitoring program using basic tests (GPHF Minilabs®). Dr. Smine added that it is crucial for MCP staff to be involved in this program, especially in the sampling of medicines to be tested. He asked that MCP staff attend the planned workshop with FDB because sentinel sites will be selected based on priority areas relevant to MCP activities.

Dr. Constance explained that antimalarial drug quality is still of major concern to MCP; the quality of many antimalarial drugs imported or locally manufactured is questionable. She also

talked about the major crisis caused by artemisinin-based combination therapy (ACT) medicines that were produced by local manufacturers few years ago. She confirmed that the manufacturer involved in the crisis is still operating and selling products in the country. Dr. Marfouk confirmed that the MCP receives funding from the Global Fund. The MCP passes on the funds to the FBD to conduct quality control testing prior to distribution of the drugs.

Dr. Constance added that, in addition to its regular program activities, the highest priority for the MCP is to improve malaria diagnostics. The disease is still epidemic in all of Ghana and still a major health burden in the country, even though in the last year data have shown that mortality has decreased as a result of MCP prevention and control activities.

Dr. Smine expressed his concern that the quality of locally-manufactured pharmaceutical products had not improved since 2005, when all were non-compliant with GMP, some in especially poor condition. He suggested that there should be a balance between promoting local manufacturing in Ghana and continuing to raise the quality standards until GMP is met by all manufacturers.

Based on the discussion, apparently the drug quality situation Ghana has not improved. In fact, the medicines are widely sold in illegal stores and markets in many regions of the country; local manufacturers still operate and sell products despite noncompliance to GMP; there are too many brands of artesunate and ACTs on the market to ensure their effective control; and there are multiple ACT regimens being followed in the private sector, some even promote artesunate mono-therapy in addition to ACT. Unfortunately, the MCP has limited human resources to deal with the many complex issues.

At the end of discussions, the MCP Director and USP DQI team agreed on how they would work together to strengthen the antimalarial drug quality in Ghana. Dr. Marfouk promised to support USP DQI activities and conferred to the MCP some responsibility for setting up and carrying out the drug quality programs in the future.

USP DQI team was pleased with the fruitful discussion in the meeting and the feedback they received from MCP.

4. Meeting with WHO-Ghana Office

Present: Dr. Lukulay, Dr. Smine, Dr. Daniel Kertesz, Mrs. Felicia Owusu-Anti,
Mrs. Edith A. Annan

Dr. Lukulay presented an overview of the USP DQI Program and its activities and explained how USP DQI will provide technical assistance to the Ghana MCP through the PMI program. Dr. Lukulay emphasized the importance of assuring the quality of medicines for effective malaria control. He pointed to the gaps and challenges in quality assurance of medicines in Ghana. Dr. Smine summarized what USP DQI had done in Ghana before and where the challenges lie ahead. He pointed out where serious attention needs to be focused, such as

compliance weak GMP, weak control of all medicines in the Ghanaian market, and the lack of financial and human resources to deal with drug quality assurance. Dr. Lukulay and Dr. Smine presented the objectives of the planned workshop: to select sentinel sites and establish the program plan for drug quality monitoring at the periphery level using basic tests.

The WHO Representative, Dr. Daniel Kertesz, asked numerous good questions about how WHO and USP DQI can work together to strengthen pharmaceutical systems in Ghana. The USP DQI team agreed to collaborate on all future activities it carries out.

The USP DQI team learned that WHO-Ghana is involved in a number of activities through PMI, many in collaboration with MCP and PMI partners, such as the purchase of diagnostics and treatment commodities, residual spraying, efficacy studies, Intermittent Pregnancy Treatment (IPT), and training of community health workers.

The USP DQI also learned about the MeTA program and about WHO and FDB involvement in the program. The MeTA program is an initiative championed by The World Bank to increase access to good quality medicines. Ghana was chosen as one of the pilot countries. The USP DQI staff expressed interest in learning more about the program and how they might collaborate in a way that complements the program.

The USP DQI and WHO teams discussed strategies and guidelines on how to assist Ghana in strengthening its pharmaceutical systems and improving law enforcement. Dr. Saweka was very supportive of USP DQI plans and asked his staff to attend the workshop planned for the following day so they could participate in planning the drug quality monitoring program and selecting sentinel sites.

USP DQI agreed to share information about future activities and to communicate closely with the WHO-Ghana Office in Accra.

5. Meeting with Management Sciences for Health

Present: Dr. Lukulay, Dr. Smine, and Mr. Eghan Kwesi

Dr. Lukulay and Dr. Smine met with Mr. Eghan Kwesi, program manager for Ghana for the Management Sciences for Health/Strengthening Pharmaceutical Systems Program (MSH/SPS). Mr. Kwesi is in charge of all SPS–PMI activities in Ghana; he is setting up a new office in Accra. SPS activities focus on strengthening the supply chain for antimalarial drugs. Drs. Lukulay and Smine informed Mr. Kwesi of activities USP DQI has planned in Ghana and agreed to collaborate with SPS, as the two programs complement each other. The USP DQI team and Mr. Kwesi met later with Dr. Alex Dodoo, President of Pharmaceutical Society of Ghana—and learned that he will be working with the FDB to carry out PV work on antimalarial drugs monitoring adverse drug reactions.

Drs. Lukulay and Smine acknowledged Mr. Kwesi for assisting them with their hotel reservation and help with early communication with local partners. The USP DQI team agreed to share all program information with the MSH/SPS team in Accra.

6. Meeting with USAID/Ghana Mission

Present: Dr. Patrick Lukulay and Dr. Paul Psychas

Dr. Lukulay met with Dr. Psychas at the USAID/Ghana Office in Accra to debrief him about the meetings that USP DQI staff held with stakeholders and on the workshop that was conducted at the Food and Drug Board to select sentinel sites for the drug quality monitoring program. Because the PMI team had been involved in full-day activities for most of the week, Dr. Lukulay met with him after regular work hours; he expressed his appreciation to Dr. Psychas for making those arrangements.

Dr. Lukulay explained the objectives of this trip and provided highlights of the meetings he had held with the staffs at WHO, MSH/SPS, Malaria Control Program, Food and Drug Board, and the National Drug Quality Control Laboratory. Dr. Lukulay shared a draft of the sentinel site selection document with Dr. Psychas. He then explained the rationale the partners had followed in selecting the five sentinel sites that would be used for monitoring and laid out the timelines for training, sampling, and testing. They agreed that the next trip USP DQI made to conduct training should occur after the Ghanaian Presidential election in December.

Dr. Psychas inquired about the type of antimalarial medicines that would be sampled and tested, and he expressed his concern about the large number of them registered in Ghana. He displayed samples of various antimalarials that he had purchased from the Accra area. Dr. Lukulay provided a list of antimalarials that will be tested in the USP DQI drug quality monitoring program.

Later in the meeting, Ms. Bethanne Moskov, USAID/Ghana, stopped by and welcomed Dr. Lukulay to Ghana.

7. Planning Workshop: Establishing an Antimalarial Medicines Quality Monitoring Program in Ghana

7.1. Introduction

USP DQI and FDB organized a Planning Workshop to establish the plan for the medicines quality monitoring program in five selected sentinel sites. After the USP DQI team made a short presentation, participants worked together to set up all the program components. The participants included staff from the NDQCL, FDB registration and inspection departments, Malaria Control Program, and WHO-Ghana. The USP DQI team facilitated the working group discussion and all participants contributed in finalizing the program plan.

7.2. Structure of the Planning Workshop

Workshop Attendees:	22 participants from FDB, MCP and WHO (See Annex 1)
Facilitators:	Dr. Patrick Lukulay and Dr. Abdelkrim Smine
Organizers:	FDB and USP DQI
Date and Venue:	Conference Room, FDB, October 14, 2008
Agenda:	Opening by Acting CEO of FDB, Rev. Jonathan Martey Presentation by Dr. Patrick Lukulay and Dr. Karim Smine (See Annex 2) Group work led by Drs. Lukulay and Smine Finalize draft and Closing

7.3. Sentinel Sites Selections

The five sentinel sites were selected based on criteria considered as priority to FDB and MCP. All participants from FDB, MCP and WHO actively participated in the discussion until final agreement was reached by the group. The following were the criteria taken under consideration in the selection of the five sentinel sites:

- Epidemiology, geography and demography of each site;
- Proximity to FDB regional offices (Minilab[®] testing will be done at FDB regional facilities);
- Status as drug efficacy sentinel site (most are in the same area where antimalarial drug efficacy is monitored);
- Borders with other countries;
- Cities known for existing illegal market of medicines;
- Areas where fake and substandard drugs are often found; and
- The three Malaria zones listed by the MCP.

Based on the above criteria, the following sites were selected:

1. Bolgatanga (**Navrongo**, Bawku, **Bolga**, **Tamale**)
2. Kumasi (**Kumasi** district)
3. **Accra** (**Greater Accra**, Tema)
4. Hohoe (**Hohoe**, Kpando, **Ho**, Aflao)
5. Tarkwa (**Sekondi**, **Tarkwa**)

(**Red**=efficacy study sites; **Blue**=FDB sites)

7.4. Program Objectives

After selecting the sentinel sites where drug quality monitoring activities will take place, the participants set the following objectives for the program:

1. Produce evidence-based data on the quality of antimalarial drugs in selected sentinel sites.

2. Advocate for enforcement actions to be taken when substandard and counterfeit medicines are found;
3. Share information with relevant national and international authorities and stakeholders about the quality and sources of counterfeit and substandard antimalarials;
4. Demonstrate that basic tests are an effective screening tool to monitor the quality of antimalarials in Ghana; and,
5. Strengthen the quality control capacities at central and regional level.

7.5. Roles and Responsibilities of Program Teams

Program activities will be managed by FDB; however, program teams will also include staff from MCP and the Pharmacy Council. The team members will be nominated at the basic tests training. Each sentinel site will have a focal person to report to the supervisory team and to USP DQI. A contact person from the supervisory team will be the focal contact for the entire program.

7.5.1. Sentinel Site Teams

Each sentinel site will have a team of three staff, one each from MCP, FDB-Inspectors Office, and the NDQCL. They sentinel site team will have the following responsibilities:

- Sample and test the medicines according to program procedures;
- Draft reports and share them with the supervisory team;
- Secure and maintain the Minilab[®] and its components at the sentinel sites;
- Estimate the budget for each round of testing; and,
- Document and keep all program records.

7.5.2 Supervisory Team

Representatives from WHO, USP DQI, FDB, Pharmacy Council, and MCP/Ghana Health Service (GHS) will be selected to form a supervisory team. The team will be comprised of two people from FDB, one person from the Pharmacy Council, and one person from MCP. USP DQI, WHO, and USAID staff could join the supervisory team to participate in field activities whenever they wished.

The supervisory team will have the following responsibilities:

- Monitor and evaluate the work carried out by the sentinel site teams;
- Draft and share final reports with the program stakeholders;
- Arrange for training needs of the program;
- Review and approve sentinel site budget;
- Ensure adherence to timelines and deadlines;
- Advocate for enforcement actions when fake or substandard medicines are found; and,
- Provide technical assistance to the sentinel site teams.

7.5.3. Laboratory Team

A team from FDB-QC lab will be selected to be part of the program and will have the following responsibilities:

- Confirm selected samples from each round for all sentinel sites according to the program procedures;
- Finalize the report of the tests as defined by the program; and,
- Provide technical assistance to the program teams.

7.6. Medicines to be Collected and Tested

The participants agreed to include all antimalarials present in the market in Ghana. The sampling and the testing protocol will be finalized after the basic tests using Minilabs[®] training by USP DQI. The medicines used for malaria treatment in Ghana are:

Artesunate-Amodiaquine

Artemether- Lumefantrine

Sulfadoxine-Pyrimethamine

Quinine

Artemether Injection

Dihydroartemisinin–Piperaquine

Artemisinin derivatives as monotherapy, tablets, and suppositories

Amodiaquine, Chloroquine

Sulfamethoxine-Pyrimethamine

Halofantrine

7.7. Budget Elements

The participants were asked to think about the cost for the budget elements so that during the training on basic tests using Minilabs[®], the budgets will be set for each sentinel site with the help of sentinel site and supervisory team. The budget elements identified are:

Transportation, cost of medicine, per diem, accommodation, stationeries, sampling tools, information and communication material.

8. Conclusion

The USP DQI team conducted a two-day meeting with the key partners of the drug quality monitoring program to strengthen antimalarial drug quality in Ghana as part of the PMI program. It was apparent that the drug quality assurance systems have not improved since 2005. All of the partners, as well as USP DQI, expressed major concerns about the quality of medicines manufactured in Ghana without strict compliance to GMP. The drug quality control capacity in Ghana is good; however, the lab facilities are in need of rehabilitation and do not offer a healthy, proper work environment. The NDQCL personnel are well qualified and they provide a lot of technical assistance to many African countries; however, the condition of the laboratory facilities handicaps any advance toward international or WHO certification. The USP DQI team reached out, on behalf of FDB, to the advisor to the Minister of Health and explained to him all the

ramifications and negative impact of delaying the move of NDQCL to a new facility. The NDQCL plays a vital role in controlling the quality of medicines, food, cosmetics, and medical devices for the whole country. The USP DQI staff explained to the Minister's advisor that it is highly urgent to do whatever it takes to complete the new building to house the NDQCL.

The drug safety program has slowed down and pharmacovigilance has moved under the FDB. Ghana has well-qualified pharmacovigilance experts; it will take only good coordination and better collaboration with other institutions to get the system up and running.

The Planning Workshop organized by USP DQI was a great platform for FDB, MCP and WHO staff to work together to set the program objectives and identify sentinel sites based on a wide range of criteria considered priorities for health systems in Ghana. The participants worked actively to finalize the program elements and agree how to move forward with their plans.

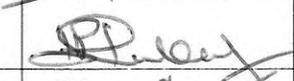
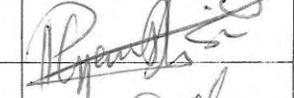
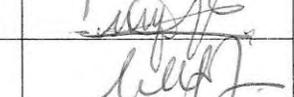
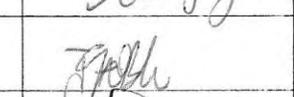
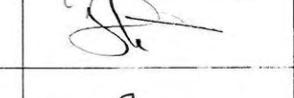
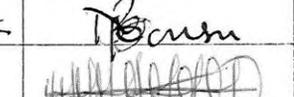
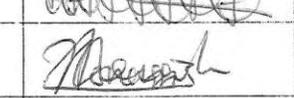
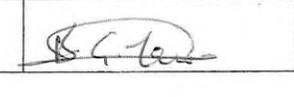
The quality of medicines in Ghana is still a major gap in the country's health systems. With good collaboration among local partners and adequate resources, USP DQI can offer the technical assistance needed to improve the drug quality assurance situation in Ghana.

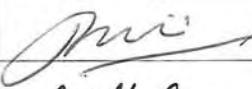
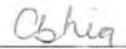
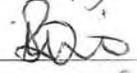
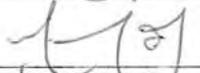
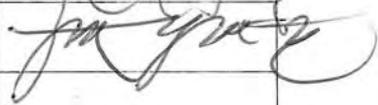
Next Steps

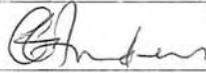
- USP DQI will purchase and send five GPHF Minilabs[®] to FDB.
- USP DQI and FDB will organize training on basic tests in early 2009, based on the timeline of Minilab[®] delivery to the FDB.
- A timeline to carry out two rounds of testing before September 30, 2009, will be set at the end of the training.

WORKSHOP ON IMPLEMENTATION OF POST MARKET SURVEILLANCE IN GHANA Annex 1

14th OCTOBER, 2008

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Annex 2

USP
USP Drug Quality and Information Program

Micro-planning Workshop • 14 October, 2008
FDB, Accra Ghana

Post-marketing Drug Quality Monitoring Program in Ghana

AKWABA

Patrick Lukulay, Ph.D.
Director, USP Drug Quality and Information Program

Abdelkrime Smine, Ph.D.
Consultant, USP DQI

USAID

USP
USP Drug Quality and Information Program

Workshop Agenda

- ◆ Introductions- ALL
- ◆ Welcome and Opening Address- USP
- ◆ Workshop Objectives USP DQI
- ◆ USP DQI Experience on Drug Quality in other parts of the world

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USP Drug Quality and Information Program

INTRODUCTION

USAID/Ghana Office of Health recognizes drug quality monitoring as critical to realizing the mission's objectives (under PMI) for treatment of Malaria.

In Collaboration with FDB and NMCP strengthen Ghana Malaria drug Quality Monitoring system.

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Workshop Objectives

- ◆ To develop strategy for the design, implementation and monitoring of a drug quality surveillance system in Ghana.
- ◆ Inform all stakeholders of monitoring methods under consideration and provide opportunity for input
- ◆ Gather information on current efforts, and materials being used for drug quality surveillance
- ◆ Refine tools and methods and develop a consensus position on drug quality monitoring in Ghana

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Characteristics of a good monitoring system

- ◆ The system being developed should be robust and sustainable
- ◆ It should continue to function several years from now
- ◆ Result in building people as well
- ◆ It should produce an impact on drug quality in Ghana

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USP Drug Quality and Information Program

Workshop Deliverables

Development of implementation plan

- ◆ Sites selection
- ◆ Selection of trainees and responsibilities
- ◆ Minilab training schedule
- ◆ Budget and timelines for reporting data
- ◆ Responsibilities for enforcement actions

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Workshop Expected Outcome

USP Drug Quality and Information Program

- ▶ Objectives of Program
- ▶ Sentinel Site Selection
 - ▶ Site selection criteria
- ▶ Sentinel Site Definition
- ▶ Sampling of antimalarial drugs
- ▶ Training on Basic Test
 - ▶ Training Premises, date, participants and training modules

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Workshop Expected Outcome

USP Drug Quality and Information Program

- ▶ Roles and Responsibilities
 - ▶ Role of sentinel site team
 - ▶ Role of Supervisory team
 - ▶ Role of QC laboratory
- ▶ Testing Rounds
- ▶ Budget
- ▶ Timelines
- ◆ Identify stakeholders who will ensure that enforcement actions are taken where necessary

USAID

Workshop Expected Outcome

USP Drug Quality and Information Program

USAID

USP Drug Quality and Information Program

USP Drug Quality and Information Program

- ◆ About DQI and Experiences in Drug Quality Monitoring else where

USAID

USP Drug Quality and Information Program

USP Drug Quality and Information Program

- ◆ Cooperative agreement between USP and USAID
- ◆ October 2000-September 2010
- ◆ **Objectives:**
 - ▶ Develop or Strengthen Quality Assurance and Quality Control systems in developing countries
 - ▶ Increase availability and use of unbiased drug information
- ◆ www.uspdqi.org

USAID

USP About USP & USP DQI RESOURCES

USP Drug Quality and Information Program

- ◆ USP is the official Pharmacopeia of USA
- ◆ Sets standards for drug quality- Act of USA Congress
- ◆ The oldest and the largest used pharmacopeia in the world
- ◆ USP DQI has access to over 400 USP Scientists and 1200 experts volunteer
- ◆ Four ISO 17025 QC labs (USA, India, China, *Brazil*)
- ◆ Access to over 3400 monographs and over 1500 RS

USAID

USP USP DQI Collaborations

USP Drug Quality and Information Program

- USAID
- The World Health Organization (WHO)
- Pan American Health Organization (PAHO)
- UNICEF
- CDC, US FDA
- Academia
- MSH/RPM+/SPS
- Ministries of Health
- Drug Regulatory Authorities
- INTERPOL- International Police
- United Nations Office on Drug Control (UNODC)

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USP USP DQI Program

USP Drug Quality and Information Program

- ◆ **The Technical mandate of USP DQI.**
- ◆ **Who we are and what we do**

USAID

USP USP DQI promotes international public health through —

USP Drug Quality and Information Program

- ◆ Education and training of regulators, QC labs, Health Programs and pharmaceutical manufacturers
- ◆ Raising awareness about drug quality
- ◆ Providing evidence-based data on drug quality

USAID

USP Drug Quality Basics

USP Drug Quality and Information Program

- ◆ **Medicine** – API, excipients, strength, label, package, shelf life, storage, indication of use.
- ◆ **Quality Control—Quality of product**
 - ▶ Test against pharmacopeial specifications
- ◆ **Quality Assurance—Quality of process**
 - ▶ Related systems (e.g. drug registration systems, product recall and national labs)
 - ▶ Manufacturer GMP compliance/inspections
 - ▶ Post-marketing surveillance of medicine quality

USAID

USP USP DQI Technical Assistance

USP Drug Quality and Information Program

<p>Drug Regulatory Authorities</p> <ul style="list-style-type: none"> • Drug registration procedures • Drug quality surveillance • BA/BE dossier evaluation • Pharmacovigilance programming • Drug Information Centers 	<p>Manufacturers</p> <ul style="list-style-type: none"> • GMP inspection and follow-up technical assistance • Support for WHO/UNICEF prequalification for medicines procurement
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USP DQI Technical Assistance

USP Drug Quality and Information Program

National Quality Control Labs

- Basic training in compendial methods, e.g. UV, HPLC, GC, TLC, Quality systems
- Training in QC method development and validation
- Guidance on procurement and maintenance of equipment
- Programs for lab certification

USAID and Global Initiatives

- Collaborative multi-country drug quality study (QAMSA)
- Monograph development for key medicines
- Product specifications for international procurement
- Drug Quality Matrix

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Countries where DQI is

USP Drug Quality and Information Program

- ▶ **Africa**
 - ▶ Senegal, Madagascar, Uganda, Mali, Benin, Liberia, Ghana and Ethiopia
- ▶ **South East Asia**
 - ▶ Vietnam, Thailand, Philippines, Laos, Cambodia, China's Yunnan province
- ▶ **Latin America**
 - ◆ Peru, Paraguay, Bolivia, Colombia, Ecuador, Venezuela, Guyana, Suriname and Brazil
- ◆ **Europe/Eurasia**
 - ◆ Russia- TB drug monitoring and Drug Information

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WHY Post-marketing drug quality surveillance

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The Importance of Post-marketing surveillance

USP Drug Quality and Information Program

- ◆ Can detect problems of poor storage and distribution practices and their effect on product quality.
- ◆ Detect and deter counterfeits
- ◆ Ensure that previously approved manufacturers continue to make good products
- ◆ Position country to determine link between possible adverse reaction and drug quality

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USP DQI Data on Anti-malarial Drugs

USP Drug Quality and Information Program

- ◆ Senegal 2002: 65% of SP, 54% of chloroquine were found substandard
- ◆ Cambodia 2003: 75% of quinine sulfate and 12% of artesunate were found fake (Wrong API)
- ◆ Ghana 2005: High percentage of non-conformed ACT, SP and Amodiaquin were found

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USP DQI/Madagascar

USP Drug Quality and Information Program

- ◆ Support drug quality monitoring in Madagascar
- ◆ Six months after setup and training of QC lab, 50 samples were tested out of which 3 drugs were recalled nationwide
- ◆ In 2006: with the addition of Minilabs, a total of 355 samples collected in the four provinces
- ◆ Corrective actions taken:
 - 11 drugs were withdrawn from the market

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USP DQI/Madagascar

USP Drug Quality and Information Program

- Expanded program to include the capital city of Antananarivo and one sentinel site in Antsiranana
- Tested total of 1635 samples to date using Minilabs®
- Drug Regulatory Authority withdrew 16 lots of drugs from the market and closed two pharmacies

In addition to QC, USP DQI assisted DRA in establishing the national pharmacovigilance program, strengthened drug registration and established a Drug Information Center

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USP DQI/Senegal

USP Drug Quality and Information Program

- Support drug quality monitoring in Senegal since 2004
- Six anti-malarials at six sentinel sites
- Of 452 samples analyzed, 128 failed quality control tests (28.3%)
- Expanded the program to cover QC of anti-TB and anti-HIV

Drug	Percentage of Failed Tests
Chloroquine	20%
Quinine	2%
Artesunate	34%
Sulfadoxine-Pyrimethamine	18%
Artemisinin-Lumefantrine	20%
Other	24%

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Amazon Malaria Initiative Summary of MiniLabs Results

USP Drug Quality and Information Program

- Total Number of Samples: 808
- Non-registered (except Venezuela): 21
- Expired: 56
- Failed Disintegration: 4 (2.4%)
- Failed TLC: 58 (5.2%)

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South American Infectious Disease Initiative Summary of MiniLab Results

USP Drug Quality and Information Program

- Total Number of Samples: 177
- Total Number Failed: 26 (15%)
- Bolivia (68 samples: 2 rounds — 22% fail)
- Paraguay (33 samples: 1 round — 21% fail)
- Peru (76 samples: 1 round — 5% fail)

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Conclusions/Recommendations

USP Drug Quality and Information Program

- All drugs used in different programs must be registered with FDB
- Quality Control of ACTs and SP MUST be done:
 - On mass-procured ACTs before their distribution regardless of their origin
 - On all SP used for IPT
 - On all drugs used for efficacy studies
- Quality Control must also be done on insecticides as well as RDT
- All active programs dealing with anti-malarials should test and pay for the testing to support the FDB lab

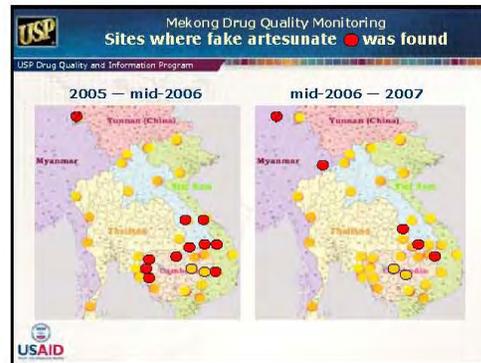
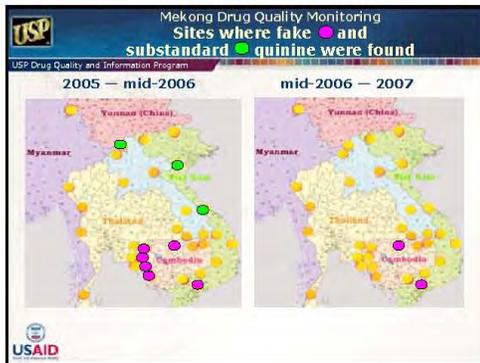
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Drug Quality Monitoring System What is it?

USP Drug Quality and Information Program

Sampling, Testing- minilab, confirmation and Enforcement

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Mekong Drug Quality Monitoring
Basic Tests Using GPHF Minilab

USP Drug Quality and Information Program

Visual Inspection Dissolution Test Colour Reactions Thin Layer Chromatography

Basic tests should never be considered as the sole means for drug quality control. Laboratory tests following official pharmacopeial methods and monographs are the only accepted tests to assure the quality, the strength, and the purity of drugs.

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- Mekong Drug Quality Monitoring**
Enforcement Partners
- USP Drug Quality and Information Program
- ▶ **Police and National Law Enforcement**
 - ▶ **Interpol**
 - ▶ **IMPACT- WHO**
 - ▶ **United Nations Office on Drugs and Crime (UNODC)**- Division of Policy Analysis and Drug Affairs
- USAID

- Mekong Drug Quality Monitoring**
Measures Taken 2006-2007
- USP Drug Quality and Information Program
- ▶ Seized fake/counterfeit products (Laos, Vietnam)
 - ▶ Issued regulatory warnings/notices to alarm health professionals and the public (Vietnam, Laos)
 - ▶ Raised public awareness (Cambodia, Laos)
 - ▶ Fined and closed down outlets (Laos)
 - ▶ Report to WHO Rapid Alert System (Cambodia)
 - ▶ Establishing exemplary sites (Cambodia)
- USAID

