

**Rapid Assessment of Drug Quality Assurance and Drug Quality Control
Capabilities of Liberia
Monrovia, Liberia ♦ November 17-21, 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 and advance the appropriate use of medicines, in order to reduce the impact of infectious diseases, mitigate the effects of the HIV/AIDS epidemic,. This document does not necessarily represent the views or opinions of USAID. It may be reproduced if credit is given to USP DQI.

Abstract

USP DQI conducted a one-week assessment of the drug quality assurance and drug quality control capabilities of Liberia. During this assessment, the USP DQI team met with USAID/Liberia, the Minister of Health and Social Welfare, the Malaria Control Program, the Pharmacy Board, the National Drug Services, the Medicine Regulatory Authority committee, the World Health Organization. USP DQI staff held a round table discussion with all stakeholders and presented the finding and the future activities that USP DQI will conduct in Liberia under the auspices of the President's Malaria Initiative.

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Key Words

Liberia, drug quality assurance, drug quality control, pharmacovigilance, antimalarials, drug quality monitoring, drug registration, national drug policy, President's Malaria Initiative, PMI

Table of Contents

<u>Acknowledgements</u>	4
<u>Acronyms</u>	5
<u>Background</u>	6
<u>Purpose of Trip</u>	6
<u>Source of Funding</u>	7
<u>Overview of Activities</u>	7
Meeting with USAID/Liberia	7
Meeting with National Malaria Control Program	7
Meeting with Pharmacy Board, NDS, and MRA Committee	8
Meeting with World Health Organization	11
Meeting with the Minister of Health.....	11
Round Table Discussion	12
USAID Debrief	12
<u>Recommendations and Next Steps</u>	13
Annex 1: USP DQI Presentation to Partners	15

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

Acronyms

ACT	Artemisinin-based Combination Therapy
CDC	U.S. Centers for Disease Control and Prevention
IRS	Internal Residual Spraying
ITN	Insecticide-treated Net
IPT	Intermittent Preventive Treatment
LBRI	Liberian Biomedical Research Institute
LMRA	Liberian Medicine Regulatory Authority
MRA	Medicines Regulatory Authority
MOH-SW	Ministry of Health and Social Welfare
NDP	National Drug Policy
NDS	National Drug Services
NMCP	National Malaria Control Program
PMI	President's Malaria Initiative
PV	Pharmacovigilance
QA	Quality Assurance
QC	Quality Control
RDT	Rapid Diagnostic Tests
RTI	Research Triangle Institute
UNDP	United Nation Development Program
USAID	United States Agency for International Development
USP DQI	United States Pharmacopeia Drug Quality and Information
WHO	World Health Organization

Background

Liberia is located in western Africa, situated between Cote d'Ivoire and Sierra Leone and partly bordered by the Atlantic Ocean. About 3 million people live in Liberia, and the population is spread across several ethnic groups: Kpelle (20%), Bassa (16%), Gio (8%), and Kru (7%) are the largest groups, and 12 more ethnic groups make up the remainder of the population. While English is the official language, there are 16 indigenous languages spoken.

Malaria is one of the major health burdens hindering Liberia's development. It is endemic and is the leading cause of outpatient attendance (38%) and inpatient deaths (42.3%) (National Malaria Control Program, Strategic Plan, Ministry of Health, Liberia). Transmission is caused mainly by *Anopheles gambiae*, *Anopheles melas*, and *Anopheles funestus*; the main parasite causing malaria is *Plasmodium falciparum*. The entire population is at risk year-round.

The National Malaria Control Program (NMCP) is fully engaged to implement the Abuja recommendations to meet the Roll Back Malaria targets aimed at reducing malaria morbidity and mortality in Liberia. NMCP established and adopted a National Malaria Policy in 2003, elaborated a National Malaria Strategic Plan in 2004, and implemented the Global Fund's 3rd round grant in the public and private sector in 2005. The Ministry of Health – in collaboration with WHO and other partners – has adopted new treatment guidelines using artesunate + amodiaquine (an artemisin-based combination therapy or “ACT”) in 2003. This malaria treatment policy was updated in 2008, and the treatment guidelines now recommend the use of artesunate + amodiaquine as first-line treatment with oral quinine as second-line. Complicated malaria cases are managed using quinine or artemether injections followed by quinine tablets or other first-line ACTs. Sulfadoxine-pyrimethamine is used as intermittent preventive treatment (IPT). NMCP elaborated the technical guidelines on Malaria Case Management in 2008.

Malaria control efforts undertaken by NMCP are supported by the Global Fund and USAID's President's Malaria Initiative (PMI). PMI activities include residual spraying, purchase of malaria treatment and diagnostics, purchase of insecticide-treated nets (ITNs), support of efficacy studies and case management, and support with supply chain management and drug quality assurance. PMI activities are carried out by USAID partner organizations in collaboration with local partners. PMI aims to reduce malaria mortality and morbidity by 50% by 2013.

USP DQI has been selected by USAID/Liberia to strengthen the quality assurance of antimalarials in the country. The visit's objectives were to meet with key stakeholders and work together to identify major gaps and recommend ways to build drug quality assurance systems.

Purpose of Trip

- Review the Malaria Operational Plan activities where USP DQI will provide technical assistance
- Conduct a rapid assessment of drug quality assurance and quality control (QA/QC) capabilities of Liberia
- Meet with all stakeholders involved in the management, control, and distribution of antimalarial medicines
- Inform partners about USP DQI expertise and approaches in dealing with QA/QC
- Obtain buy-in from local stakeholders and USAID/Liberia about FY09 activities

Source of Funding

This trip was funded by the USAID/Liberia PMI program.

Overview of Activities

USP DQI Director Dr. Patrick Lukulay and USP DQI Consultant Dr. Abdelkrim Smine (the “USP DQI team”) traveled to Monrovia to conduct a rapid assessment of the drug QA/QC capabilities of Liberia. The USP DQI team met with key stakeholders involved in QA and the management of antimalarial drugs. The team worked with all country partners and engaged in fruitful discussions; gathered stakeholders’ inputs, comments, and recommendations; and reached consensus about planned FY09 activities through the USAID/Liberia PMI program.

Meeting with USAID/Liberia

Participants: Dr. Lukulay, Dr. Smine, Mr. Kassahun Belay, Mr. Kaa Williams and Mr. Filiberto Hernandez

After introductions, Dr. Lukulay gave a brief overview of USP DQI and its activities and programs in Africa. He explained the way that USP DQI provides technical assistance to USAID-supported countries and the kind of expertise the program has. Dr. Smine emphasized the importance of the assessment visit to learn the actual situation in Liberia from the local stakeholders. He also added that, based on the findings of the assessment, the funding received by USP DQI may not be enough to carry out all priority activities for this fiscal year.

USP DQI and USAID staff discussed the agenda for the week and made necessary changes. The USP DQI team was pleased with the assistance provided by USAID/Liberia, and in particular, the assistance by Mr. Kaa Williams, who coordinated with local partners, organized all visits, and accompanied the USP DQI team to all their meetings with local partners.

The team was informed that the Minister of Health was organizing a meeting outside the capital that week and that some of the stakeholders may not be available to meet with USP DQI. USP DQI and USAID staff agreed to hold a round table discussion with all key stakeholders on Thursday, November 20.

Meeting with National Malaria Control Program (NMCP)

Participants: Dr. Lukulay, Dr. Smine, Mr. Kaa Williams, and Dr. Tolbert G. Nyenswah

Following introductions, Dr. Nyenswah provided the team information about NMCP’s activities and the malaria situation in Liberia. While malaria remains endemic in the country, the manager of NMCP believes that control of this disease is now getting on the right track due to NMCP activities undertaken with the support from USAID and the Global Fund. NMCP has received funding from the Global Fund for all of the past seven rounds and it has also been selected to benefit from PMI. The PMI target to reduce malaria mortality and morbidity by 50% by 2013 is very optimistic given that Liberia just recently emerged from years of civil war. It will be a major challenge to build the pharmaceutical systems needed to reach the PMI targets. However, with the enthusiasm and the commitment of the NMCP staff, the USP DQI team believes that the target can be reached if NMCP receives the necessary assistance and resources.

NMCP changed its treatment policy in 2003, and the current treatment guidelines recommend the use of artesunate + amodiaquine co-packaged formulation as first-line treatment and quinine tablets as second-line treatment. Quinine injection or artemether injections are used to treat severe malaria cases. Malaria medicines are given free of charge to all malaria patients at all health care levels. Sulfadoxine-pyrimethamine is used for IPT. Diagnosis of malaria cases is done using microscopy and rapid diagnostic tests (RDT). When asked, the NMCP Manager confirmed that some issues with the acceptability of amodiaquine have been reported. Often patients choose to take only artesunate tablets and leave out amodiaquine. The NMCP is conducting efficacy studies using fixed dose combinations of artesunate-amodiaquine to assess their efficacy before replacing the co-packaged ACT being used currently.

NMCP is also carrying out vector control activities. ITNs are purchased and distributed free of charge. Internal Residual Spraying (IRS) will soon take place in selected areas in Liberia. IRS activities will be carried out with the support of Research Triangle Institute (RTI) within the PMI program.

The procurement of malaria treatment and diagnostics for NMCP is done by DELIVER for PMI and by the United Nations Development Program (UNDP) for Global Fund's supported activities. While medicines procured by Deliver and UNDP undergo rigorous quality control prior to shipment into country, there is no quality assurance of malaria medicines in general once the medicines are on the market. This is a gap in the malaria control systems in Liberia. NMCP has purchased a Minilab[®] and basic equipment to carry some quality control tests on antimalarial drugs; however, the small lab has neither the human resources nor the necessary training to conduct adequate quality control of antimalarial drugs.

The safety of antimalarial drugs used by the NMCP is not monitored. This is another area of work for the malaria control program, especially given the fact that the first-line treatment contains amodiaquine (a known molecule with serious adverse effects) and compliance problems with the treatment (in a co-packaged form) have already been reported. The use of artesunate monotherapy is already banned by WHO because of the possibility of creating drug resistance. Irrational use of amodiaquine could have serious side effects, especially on children.

The Manager of NMCP expressed his interest in starting a pharmacovigilance (PV) program to monitor the safety of ACTs used in Liberia. He requested the support of USAID and USP DQI to assist his program establishing a PV program.

Dr. Lukulay promised to send NMCP a document as a basis for including drug quality control components in the NMCP proposal for the next round of Global Fund applications. The document has now been sent to the USAID mission in Liberia.

Meeting with the heads of the Pharmacy Board, National Drug Services, and the Medicines Regulatory Authority Committee

Participants: Ambassador Clavenda Bright Parker, Chairman, Liberia Medicine Regulatory Committee; Reverend Tijli Tarty Tyee, Sr. Chief Pharmacist, NDS- Ministry of Health; Beyan Korzopoe Johnson, Chairman of Pharmacy Board of Liberia; Duredoh F. George, Sr., Head of

NDS QC laboratory; Joseph N.B. Jimmy, Asst. Pharmacist, Ministry of Health; Dr. Lukulay and Dr. Smine, USP DQI

Pharmacy Board of Liberia

The Pharmacy Board of Liberia is in charge of licensing professionals and facilities and plays the role of the drug regulatory authority. It is a semi-autonomous body consisting of 7 members and 12 inspectors. The board has established a drug registration system, but this system is not functioning well: it is estimated that only about 10% of drugs on the Liberian market are registered. In addition, UN agencies, NGOs, and other donors are bringing in many types of medicines without going through formal channels. As a result of the inadequacy of the registration system, counterfeit and substandard medicines are widely available and illegal sales of all types of medicines take place in the street. Aware of this situation, the Pharmacy Board of Liberia and other departments of the Ministry of Health (MOH) have established a Liberian Medicine Regulatory Committee (LMRC), charged with the responsibility to formulate legislation for regulation of the pharmaceutical sector. This recommendation emanated from an assessment study conducted by the European Union in 2007. The chairman of the Pharmacy Board is also member of the committee in charge of establishing LMRA

National Drug Services

National Drug Services (NDS) is in charge of procurement, distribution, and management of medicines for the public sector and non-profit institutions in Liberia. It functions under the Health Services Department of the Ministry of Health. NDS manages the central warehouse as well as the nine regional depots. Six pharmacists are each in charge of the regional distribution of medicines. NDS is also in charge of forecasting the needs in medicines for all MOH programs. NDS maintains an essential drug list and a national formulary. The essential drug list was updated in 2007. In line with the National Drug Policy (NDP), NDS establishes and updates treatment guidelines for all diseases in Liberia.

NDS and the MOH have also issued the National Drug Policy in 2001 in collaboration with WHO and other partners. Dating back to 2001, the NDP has mentioned the need to establish a drug regulatory authority to enact and update drug regulations and legislation to regulate the pharmaceutical sector. The NDP also calls for the establishment of a national quality control laboratory under the drug regulatory authority. Because of the economic and financial constraints caused by years of civil war, most NDP provisions are not yet in place. NDS struggles to carry out all its functions because of the lack of human and financial resources. However, the situation continues to improve since the end of the war because of the commitment of NDS and Pharmacy Board staff and the increased assistance of foreign donors.

NDS Quality Control Laboratory

Because of widespread poor quality medicines throughout the distribution chains, in 2002 NDS established a small laboratory to carry out basic tests of selected medicines. The NMCP recently procured some equipment using resources from the Global Fund, and the QC lab has a dissolution tester, a disintegrator, one analytical balance, a water bath, two pH meters, and few Minilabs[®]. Two staff from NDS work in the laboratory running basic tests, and they coordinate with the Ghana QC lab for testing selected and suspicious drug samples. The USP DQI team visited the small laboratory and concluded that that facility could continue to be used to carry out

basic tests such as visual and physical testing and TLC. However, these tests do not constitute adequate quality control and should be seen only as interim measures in the current circumstances. Also, the large amount of chemicals stored in the lab needs to be moved to an adequate chemical storage facility; most of the reagents are flammables and pose a safety risk to the entire building because of the lack of a proper aeration system.

It was also apparent that the staff working in the NDS lab needs to be trained on the proper handling of equipment and chemicals. The dissolution and disintegration testers have never been used. When asked, the lab staff did not have any notebook or record of tests carried out in the lab. However, USP DQI acknowledged NDS for taking the initiative to at least conduct basic tests in the absence of a functioning QC lab. This laboratory needs to be better supported to continue to carry out basic tests while waiting for the opportunity to establish a fully-functioning quality control laboratory.

USP DQI staff perused a report of quality tests done for selected samples (manufactured in China and India) in the Ghana QC lab. All samples analyzed failed assay and dissolution tests.

The USP DQI team concluded that in Liberia there is a complete lack of quality control capacity, which will continue to contribute to the spread of fake and substandard drugs in the market.

It is imperative that the Liberian government establish its own QC lab to assure the quality of medicines and protect the health of its people. A functioning QC lab will be a deterrent to those profiting from the illegal trade of medicines and will support all health programs to meet their respective targets.

Liberia Medicine Regulatory Committee (LMRC)

The Minister of Health, the Pharmacy Board of Liberia, and National Drug Services constituted a committee in April 2008 to work on establishing the framework for a Liberian Drug Regulatory Authority. This committee is made of eight members chaired by Ambassador Clavenda Bright Parker. The members are selected from the Pharmacy Board of Liberia, the Ministry of Health, the Liberian Pharmaceutical Association, and medical and dental associations. The dean of the School of Pharmacy and the legal counsel of the MOH also serve on the committee.

The committee is now working on drafting legislation for drug regulation of the pharmaceutical sector. The Chairman said that the committee will focus primarily on pharmaceutical regulations and leave food regulation to the Ministry of Agriculture. A WHO consultant has assisted the committee, but the work is going slowly, and the committee is in need of technical assistance from international experts.

The committee will be in charge of drafting legislation, establishing a framework for the following regulatory activities:

- Drug regulation and enforcement
- Drug registration
- Drug quality control
- Inspections and surveillance

The chairman, as well as other members of the committee, considered drafting drug legislation as a priority step to set the framework for the Liberian Medicine Regulatory Authority. The committee members were pleased about the discussions and exchange of information with USP DQI staff. They asked for USP DQI assistance in helping this committee finalize the regulatory framework and the legislation needed to regulate the pharmaceutical sector in Liberia. It is now apparent that the lack of drug regulations is affecting all health programs and is the primary cause of the widespread illegal trade of poor quality medicines. Drug regulations are the basis for assuring the quality of medicines and improving health systems in Liberia. The business of licensing of pharmacies and professionals will continue to be done by the Pharmacy Board.

Meeting with World Health Organization

Participants: Dr. Lukulay, Dr. Smine, Mr. Kaa Williams, and Dr. Nestor Ndayimirije

Mr. Williams introduced the USP DQI team to Dr. Ndayimirije and explained the objectives of their visit to Liberia. Dr. Ndayimirije welcomed the USP DQI team and acknowledged the USAID/PMI program for supporting the malaria control program with drug quality assurance. Even though Dr. Ndayimirije has been in Liberia for only one month, he is highly aware of the lack of drug quality assurance systems in Liberia. He added that building drug QA/QC in Liberia is an urgent matter and that all donors must collaborate to build health systems. In fact, he said that WHO has already provided a consultant to help the MOH deal with drug regulation issues. The WHO officer in charge of pharmaceuticals in Liberia was on duty travel, thus, the USP DQI team could not get much detailed information about specific activities that WHO is doing to support the Ministry of Health and Social Welfare with drug QA/QC.

Talking about the need for a quality control laboratory, Dr. Ndayimirije suggested that the MOH should consider hosting a QC lab in or near the Liberian Biomedical Research Institute (LBRI). He added that LBRI used to be a very advanced center before the war started, and now WHO and other partners are trying to help LBRI resume its research activities.

Dr. Smine emphasized the importance of collaboration between USP DQI and WHO in building QA/QC systems in Liberia. He gave a few examples where close collaboration between the two organizations was successful in other countries. Dr. Ndayimirije agreed to collaborate with USP DQI whenever possible and agreed that enacting drug legislation and regulations in Liberia is the first step in building adequate QA/QC systems in Liberia.

Meeting with the Minister of Health

Participants: Dr. Walter T. Gwenigale (Minister of Health), Dr. Lukulay, Dr. Smine, Mr. Kaa Williams, and Reverend Tijli Tarty Tyee

Reverend Tyee introduced the participants and briefly informed the Minister about USP DQI meetings with different partners of the Ministry of Health. Mr. Kaa gave an overview of USP DQI visit and the will that USAID/Liberia has to support the country in establishing drug quality assurance systems. Dr. Lukulay, on behalf of USP DQI, expressed his gratitude to the Minister of Health for his support and his time. He emphasized the urgent need to strengthen drug quality assurance systems in Liberia.

The Minister welcomed USP DQI and said that he is well aware of the drug quality situation in Liberia. He talked about the sale of drugs in the street and added that he knows that the NDS laboratory is not functional and does not have the capability to control medicines in his country. He said that the MOH has support from many NGOs and donors and that the Ministry does not even have the capacity to better coordinate what is purchased and introduced as medicines. The Minister said that his staff is working to improve systems, but without further technical support and with the lack of human and financial resources, the MOH will not be able to improve its services. The Minister added that he would like to know what it takes to establish a functional drug quality control laboratory and will discuss with donors to see if they can support this project as well.

Dr. Smine gave an overview of USP DQI findings and emphasized the importance to speed up establishing drug legislation to regulate the pharmaceutical sector as a high priority. The Minister agreed and offered his full support to do what he could to get the new legislation established.

Round Table Discussion

Participants: Ministry of Health, USP DQI, Pharmacy Board of Liberia, National Drug Services, and USAID

At the end of the assessment, a round table discussion was held between USP DQI and all stakeholders. Dr. Smine gave a presentation about USP DQI findings (see *Annex 1*). He prioritized the major gaps, offered recommendations, and explained the areas where USP DQI could provide technical assistance. Following the presentation, the group held a discussion and agreed that the urgent needs include building QA/QC systems, by first establishing drug legislation and regulations tailored to the realities of Liberia. The participants were also convinced about the urgent need for establishing a drug quality control laboratory to check the quality of essential medicines in the market. The last issue discussed was the need to establish a drug safety monitoring for ACTs in Liberia.

The USAID PMI team noted that while the program must stay focused on antimalarial drugs, other drugs will also benefit from USP DQI support.

The MOH representative pledged the full support of the Ministry for all initiatives aimed at building capacity in Liberia. He recognized that the lack of drug regulations in Liberia creates chaos in the pharmaceutical sector.

Dr. Belay (USAID) emphasized the importance of coordination between donors so that the available resources and the funds provided by donors can be used rationally.

Debrief with USAID

Participants: Kassahun Belay, Kaa Williams, Patrick Lukulay, and Filiberto Hernandez

Dr. Lukulay met with USAID and CDC staff to debrief them about the assessment trip, key findings, and recommendations of plans of action going forward. Dr. Lukulay emphasized the key findings of their assessment trip including lack of adequate quality control of pharmaceuticals in the country leading to a high prevalence of substandard products, the need to

rapidly finalize the legislation being drafted, and the urgent need to coordinate donor activities in Liberia. Mr. Belay indicated that he will be meeting with donors and NGOs involved in providing assistance in the health sector to discuss each others' activities in order to avoid duplication of work. On the issue of pharmacovigilance, Dr. Kassahun asked USP DQI to provide Adverse Drug Reaction (ADR) forms so that he could work with medical doctors to start collecting ADR data from patients. Dr. Lukulay cautioned that, prior to collecting data, there is the need to conduct training of health workers and doctors on the proper way to collect information that will be useful and actionable. USP DQI proposes to include pharmacovigilance in MOP FY 09 to provide technical assistance to adequately monitor the safety of ACTs in Liberia.

Recommendations & Next Steps

The USP DQI team was satisfied with the outcome of the assessment of drug quality assurance systems in Liberia. The team gathered all needed information and received full support and cooperation from USAID/Liberia and the Liberian partners and stakeholders.

The drug quality assurance and drug quality control systems are not functional and a pragmatic approach is needed to build these systems on solid foundations. The absence of drug quality assurance has serious impact on all health systems in Liberia, and without such capacities, the USAID health targets will not be met.

The USP DQI team discussed all drug quality issues and gaps with the Liberian partners and acknowledged the strong support of USAID/Liberia staff as well as all MOH staff to change the situation. It was apparent that all those who met with USP DQI team are well aware of the serious problems and the urgent need to resolve them.

In FY 09, USP DQI proposes to focus technical assistance on the following activities:

1. Provide technical assistance to the LMRC to finalize the draft legislation relating to quality assurance issues and submit to parliament

A national committee has already been established and is working to establish drug legislation to regulate the pharmaceutical sector. This committee needs technical assistance from international experts to speed up finalizing the legislation which will serve as the basis for regulation of the pharmaceutical sector. USP DQI considers this task as the first priority, because without laws and regulations any support will not be effective. USP DQI will collaborate with other mechanisms to assist LMRC establish and finalize a drug legislation. In general drug legislation must cover the following areas:

- Categories of medical products and activities to be regulated
- Mission and goals of drug regulation
- Administrative bodies necessary for implementing drug regulation and their functional and structural relationship
- Roles, responsibilities, rights, and functions of all parties
- Qualification and standards required for personnel
- Norms, standards, and specifications necessary for ensuring the safety, efficacy, and quality of drug products

- Mechanism for ensuring transparency and accountability of the drug regulatory authority to the Government, the public and consumers
- Administrative measures and legal sanctions
- Terms and conditions for suspending, revoking, and canceling licensees to import, manufacture, export, distribute, sell, promote and supply
- Mechanism for ensuring government oversight

A USP DQI team of experts are available to travel to Liberia to work closely with the LMRC to put all necessary provisions in the legislation based on international norms and standards tailored to the realities in Liberia. DQI could work in collaboration with other USAID funded mechanisms such as Strengthening Pharmaceutical Systems (MSH/SPS) to provide the needed assistance and support now and in the future.

2. Develop a framework for the establishment of a national QC laboratory

USP DQI will develop a high level proposal containing key components of a national QC lab with estimated costs for personnel and equipment. This proposal would be used by the Ministry of Health to request assistance from international donors and NGOs for the establishment of a national QC laboratory in Liberia

Future assistance for strengthening quality assurance and drug safety mechanisms in Liberia

In FY 09, technical assistance will be provided for drug legislation and developing a framework for a national QC laboratory. In order to have a sustainable impact on quality assurance of pharmaceuticals in Liberia, certain key provisions must be in place in the near future. USP DQI has identified the following areas for future support to strengthen QA and drug safety in the country.

- ***Establish drug quality control capacity***

Liberia needs a national drug quality control laboratory. Such a project requires capital investment which could be raised by the support of multi-donor funds or government loans. In this area, USP DQI could assist in areas from the design of the lab to its certification. Based on the discussion with the Minister of Health, USAID/Liberia, and other partners, USP DQI will draft a comprehensive business plan to establish a QC lab, conduct training of laboratory personnel and develop standard operating procedures for laboratory functions.

- ***Establish a drug safety program***

The safety of ACTs needs to be monitored in Liberia. The manager of NMCP insisted on the need to establish a pilot pharmacovigilance program using ACTs, as a start, in Liberia. USP DQI proposed to assist NMCP establish a pharmacovigilance program in collaboration with WHO and Uppsala Monitoring Center as it has done with other USAID-supported countries. There are issues with irrational use and reported adverse reactions to the ACTs used in Liberia.



U.S. PHARMACOPEIA
DRUG QUALITY AND
INFORMATION PROGRAM

Round Table Meeting
Monrovia, Liberia
November 20, 2008

**Drug Quality Assurance and Quality
Control in Liberia**



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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



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USP DQI Resources

USP Drug Quality and Information Program

- ◆ USP is the official Pharmacopeia of the United States
- ◆ The largest pharmacopeia in the world
- ◆ USP DQI has access to hundreds of scientists and more than a 1000 volunteer experts
- ◆ Four ISO 17025 QC labs (USA, India, China, Brazil)
- ◆ Access to over 3400 monographs and over 1500 RS



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USP DQI promotes international public health through —

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





Countries where DQI is active

USP Drug Quality and Information Program

▶ Africa

- ▶ Senegal, Madagascar, Uganda, Mali, Benin, Liberia, Ghana, and Ethiopia

▶ Southeast Asia / ANE

- ▶ Vietnam, Thailand, Philippines, Laos, and Cambodia

▶ Latin America

- ▶ Peru, Paraguay, Bolivia, Colombia, Ecuador, Guyana, Suriname, and Brazil

▶ Eurasia

- ▶ Russia

USP DQI assists manufacturers in France, Tanzania, Nepal, India, and Bangladesh





Drug Quality Challenges in Developing Countries

USP Drug Quality and Information Program

ACTs: Quality Assurance Challenges

- ◆ Semi-synthetic product with high impurity burden
- ◆ Non-GMP-compliant manufacturers
- ◆ Many brands on market, some unregistered
- ◆ Lack of proper standards or monographs
- ◆ Limited number of pre-qualified and/or reliable suppliers
- ◆ Weak quality control and quality assurance systems.



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Recommendations

- ◆ All drugs used in different programs must be registered with DRA
- ◆ 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 antimalarials should test - and pay for the testing - to support the NDQCL





Current Situation

USP Drug Quality and Information Program

- ◆ Consultative Meetings
 - ▶ USAID
 - ▶ NMCP
 - ▶ Pharmacy Board
 - ▶ NDS
 - ▶ Liberia Medicine Regulatory Committee (LMRC)
 - ▶ WHO
 - ▶ Visit NDS lab



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Major Findings - Gaps

USP Drug Quality and Information Program

- ◆ No functional DRA
- ◆ Committee formed to draft legislation for drug regulation
 - ▶ No functional drug registration
 - ▶ No adequate quality control in country
 - ▶ Widespread counterfeit and substandard medicines
 - ▶ Illegal trade of medicine
- ◆ Recommendation
 - ▶ Priority to finalize legislation for drug regulation
 - ▶ Input from international expert and acceptance by local stakeholders are highly recommended
 - ▶ Bench mark with international standards



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Major Findings - Gaps

USP Drug Quality and Information Program

◆ Quality Control

Functional QC lab is a cornerstone for all health systems

- ▶ Non functional
- ▶ NDS lab needs; equipment, training, procedures
- ▶ Facility is not fit for a QC lab
- ▶ QC testing is being done abroad with high cost

◆ Recommendation

- ▶ Liberia must have its own national QC laboratory
- ▶ New facility with trained staff and adequate quality system is highly recommended





Major Findings - Gaps

USP Drug Quality and Information Program

- ◆ NMCP
 - ▶ Issues with quality control of antimalarial treatments and diagnostics
 - ▶ Absence of ACT safety monitoring
 - ▶ Reported issues with acceptability and compliance to Amodiaquine/Artesunate

- ◆ Recommendation
 - ▶ NMCP should establish a Pharmacovigilance program to monitor safety of ACTs
 - ▶ Expand efficacy studies to assess the efficacy of other ACTs in the market





Priority Actions : DQI Assistance

USP Drug Quality and Information Program

Finalize legislation and drug regulations

- Provide TA by bring in senior experts to help drafting and reviewing legislation and drug regulations
- Assist in all steps of the establishment and the good functioning of LMRA

Build Quality Control Capacity

- Assist the existing NDS lab
- Assist with design, set up, equipment, staff hiring, training, quality system of a new QC lab

Assist NMCP establish a Pharmacovigilance program

- Build the PV system using ACTs; expand to other drugs





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Questions?



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Thank You

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