Establishing a Network of Drug Quality Control Laboratories in USAID-supported African Countries

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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

USP DQI organized a workshop to establish a network of drug quality control laboratories in five USAID-supported countries in Africa. The workshop was attended by the heads of QC labs of Ethiopia, Ghana, Mali, Senegal, and Uganda. In addition to lab heads, three USP staff, and representatives from USAID, WHO, The Food and Drug Board (FDB), the Malaria Control program, and the regional FDB staff were also present. The objective of the workshop was to discuss the common challenges the QC labs face and study the possibility of establishing a network between these labs. A consensus was reached with an agreement to establish the "Network of African Medicines Control Laboratories (NAMCOL)". The participants set up four objectives and a first year work plan and agreed to be fully committed and respect the timelines of the work plan. DQI will coordinate the activities of the network.

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Key Words

network, quality control, laboratory, ISO 17025, Good Laboratory Practices, proficiency testing, pharmacopeia

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ACRONYMS

EQCP	External Quality Control Program
FDB	Food and Drug Board of Ghana
GLP	Good Laboratory Practices
ISO	International Organization for Standardization
MOH	Ministry of Health
MOU	Memorandum of Understanding
NAMCOL	Network of Africa Medicines Control Laboratories
NGO	Non-Governmental organization
OMCL	Official Medicines Control Laboratory
PAHO	Pan American Health Organization
PMI	President's Malaria Initiative
QA /QC	Quality Assurance / Quality Control
QMS	Quality Management System
SOP	Standard Operating Procedure
USAID	United States Agency for International Development
USP DQI	United States Pharmacopeia Drug Quality and Information
WHO	World Health Organization

Background

USP DQI provides technical assistance to the quality control (QC) labs of Ethiopia, Ghana, Mali, Senegal, and Uganda. In its quest to improve the quality assurance of medicines in Africa and promote regional collaboration, USP DQI organized this workshop to discuss the possibility of establishing an Official Medicines Control Laboratory (OMCL) network within these five countries that could expand in the future to include other African countries.

Purpose of Trip

USP DQI organized the workshop to:

1. Bring together five QC labs from USAID/USP DQI supported countries in Africa
2. Discuss common challenges and possibilities to resolve them
3. Reach consensus if a network could benefit the labs
4. If yes, set up clear and achievable objectives for the lab network
5. If yes, agree on roles and responsibilities and a one year work plan

Source of Funding

This trip was funded by USAID Core funding for Common Agenda.

Overview of Activities

September 3, 2009

Participants: Representatives of QC labs from Ethiopia, Ghana, Mali, Senegal and Uganda; USP DQI staff (Dr. Lukulay, Dr. Hajjou, and Dr. Smine); CEO of Food and Drug Board (FDB) of Ghana, Dr. Stephen K. Opuni; representatives from the World Health Organization (WHO), the Malaria Control Program, and FDB lab representatives; and Mr. Paul Psychas, USAID/Ghana PMI team leader.

The workshop was opened by Rev. Martey, DCE-FDB, Ghana, and Dr. Lukulay was designated as Chairman of the meeting.

Chairman's Opening Remarks

The Chairman's opening remarks emphasized the importance of assuring the quality of medicines as a priority public health need. Most African countries are under constant threat from counterfeit and substandard medicines and other health products. Collaboration between countries, donors, governments, and NGOs are the key to assure that essential medicines of assured efficacy, safety, and quality are available in the market. The objective behind creating a QC lab network is to bring African countries together to fight counterfeit medicines and assure the quality of pharmaceuticals in their market.

USAID/PMI-Ghana Representative

Mr. Paul Psychas, Team Leader of the PMI program in Ghana, emphasized the importance of pulling together resources to combat the threat of counterfeit and substandard medicines in African markets. He stated that he supports the lab network initiative and encourages participants to work together, further stressing that success will depend on ownership and effective leadership by the countries involved.

Morning Session (Country Presentations)

In his presentation, the Chairman emphasized that the country presentations should discuss resources and needs and also identify gaps and possible areas of intervention to strengthen their quality control capacities. The key points the lab representatives were asked to cover are:

- Identify, analyze, and discuss constraints in conducting QC of medicines
- Explore and establish communication channels
- Share information and lessons learned
- Share expertise (training, testing, etc)
- Share expected results from the meeting

Ethiopia

- There is a framework in the country for regulating drugs
- The regulatory body needs capacity building, collaboration, networking, etc.
- The basic objective of the lab is to ensure the quality of samples by doing QC work and the focus will be on post-marketing surveillance
- The basic methods used are IP, BP, USP, EP and manufacturers' methods
- Well-staffed and well-equipped with analytical equipment including UV, HPLC, GC, LC-MS etc.
- Major limitations of the lab are its facilities, financial constraints, technical skill, equipment maintenance, documentation, reagents and chemicals (procurement procedures), reference standards, impurity standard, and methods for analysis of non-pharmacopeial samples
- Received support from USP DQI and Management Science for Health in the area of training, prequalification, and maintenance of equipment
- Need to move the lab to a new building and get WHO prequalification in the next 3 years

Mali

- The 39 technical staff members are considered to be the strength of the lab
- Have basic equipment like HPLC and UV but have maintenance problems
- Half of the budget for 2008 was for the running of the organization
- Space is a real limitation for QC lab
- The lab participates in proficiency testing coordinated by WHO
- The lab has financial constraints
- Equipment and standards are hard to purchase because of the lack of specialization of personnel
- Equipment maintenance is a major problem
- The way forward includes collaboration and development of analytical techniques

Senegal

- Challenges include inadequate staff, limited space, reference standards, training, etc.
- Lab is well-equipped; equipment calibrated and under service contracts
- Limitation of space available and lack of medical devices testing facility
- Problem with procurement of reagents, lab equipment, and standards
- Lack of training and adequate financial resources for retaining lab personnel

- Implemented a quality system and is working to comply with ISO 17025
- Participates in WHO proficiency as well as French Medicine Regulatory Authority (MRA) proficiency testing
- The way forward is to be an active member of the network, comply with ISO 17025, and continue to grow and improve

Uganda

- Under Uganda MRA, in charge of testing drugs, medical devices, and others
- Participates in setting up drug regulations and GMP inspections
- Performs batch to batch analysis for local manufacturers and dossier evaluations for market authorizations
- Testing medicines using Minilabs at peripheral level
- In the process of preparing to get ISO 17025 accreditation
- Have 14 technical staff and basic equipment like HPLC, UV, Dissolution tester, etc.
- Lab has a quality manual, SOPs, etc. and is involved in proficiency testing
- Used to do mandatory testing, but now the lab has adopted a risk-based approach to controlling medicine samples
- Challenges include reference standards, chemicals/reagents, HPLC column, validated test methods, procurement procedures, limited human resource, limited financial support, training needs, limited space, and a heavy work load
- The risk-based approach gives a better understanding of the quality monitoring of drugs
- Needs a microbiology lab, herbal medicines lab, pesticide residue lab, and Laboratory Information Management System (LIMS)

Ghana

- Lab operates under a regulatory framework backed by law
- Performs post marketing evaluation of approved drugs, research into quality and safety of products, GMP audits, etc.
- Maintains Quality Management System (QMS) and good documentation
- Has analytical equipment such as HPLC, UV, etc.
- Self-motivated staff with 28 people of various backgrounds
- Participates in proficiency testing in medicines, medical devices, and food
- Trains analysts from the sub-region
- Accreditation process is ongoing for all the units within the lab
- Conducts various projects in collaboration with other stakeholders
- Challenges include space, financial (reagents, solvents, reference standards, calibration and maintenance of equipment), accreditation, re-tooling, staff motivation and retention
- Needs a new building, expanded scope of analysis, training center, self financing lab

Questions and Discussion

Following the country presentations, a session of questions and answers was opened. Many questions related to the mandate, status, and working practices were asked. After more than one hour of discussion, it was apparent that the five QC labs face similar problems, such as procurement of reagents, equipment, and standards; limited human and financial resources; old or limited lab facilities; a lack of training; and difficulties retaining lab personnel. On the other

hand, the level of skills and the implementation of good laboratory practices seem to be very different between the five labs. All heads of labs agreed that working together and exchanging information will benefit all and will address many weaknesses faced by each lab.

Examples of other QC lab networks

Dr. Smine presented the model of the External Quality Control Program (EQCP) initiated by USP and the Pan American Health Organization (PAHO) in Latin America. This program includes a network of 23 labs in 21 countries that has been operational since 2002.

Key points

- Objectives include strengthening laboratories to improve performance, harmonization of procedures, collaboration between the laboratories, south-to-south cooperation, and mutual recognition
- Phase one of the project was the assessment of all labs by PAHO to identify various constraints and check the labs' staff, equipment, resources, quality systems etc.
- Phase two of the project was about testing medicine samples, at an average of one round per year
- The first results were quite diverse
- The results are then reviewed according to USP standards
- Phase three involved training; labs in need of training were identified and trained after each round
- In 2005, a GLP Working Group was established and is responsible for all trainings; they hold two meetings per year
- USP provided technical support and training, and PAHO was responsible for providing logistics, assisting with training, sampling, mailings and communications, etc.
- The network led to ISO17025 accreditation for the OMCLs in Peru and Guatemala
- Based on USP review, there is significant improvement in the performance of all OMCLs participating in the EQCP program
- Lessons learned include: network needs be coordinated by a strong technical organization (with available financial resources) and proper coordination.
- The key to success is 100% commitment by the participating laboratories

Round Table Discussion

The chairman opened the floor for discussion about the possibility of establishing a QC lab network between the five participating countries if USP would assure the coordination and support of such a network. The discussion first focused on identifying specific challenges facing all five labs and what potential solutions could be found if the labs were to work as a network. Many challenges were discussed and it was apparent that a network would benefit all the labs in some way. There was a consensus from all the labs and DQI that:

- A network of OMCLs starting with Senegal, Uganda, Mali, Ethiopia and Ghana will be established, with USP as its technical coordinator
- The network will be extended to other countries as and when necessary
- A memorandum of understanding (MOU) needs to be signed by all member laboratories

- The network will focus on collaboration, data sharing, proficiency testing, communication, and ultimately mutual recognition
- USP will be in charge of drafting and sending the MOU to the heads of the MRAs (for Ghana, Ethiopia, Uganda) and to the Ministers of Health (for Mali and Senegal)

September 4, 2009
A 10-minute film on Minilab analysis done at the Hohoe Sentinel Site in Ghana was shown to the participants. The chairman, Dr. Lukulay, moderated the discussion and urged the participants to determine all key components of the network program, starting by setting up a few solid and achievable objectives. The entire group participated and all heads of labs presented their views, summarized below.

Objectives of the Network

- Enhance performance and technical skill among labs through proficiency testing and sharing of resources
- Identify training needs from proficiency tests and carry out training
- Share information about counterfeit or substandard products; set up a virtual team for communication and a database
- Harmonize laboratory procedures and practices between network members

How the network will work

- The lab network will be coordinated by USP; an e-mail list was set up that includes the heads of QC labs from each participating country and a USP coordinator
- Two proficiency tests will be conducted per year, according to set deadlines
- One training will be conducted by USP each year for the network participants
- The medicines samples to be tested have to be selected by the network members
- All members agreed to exchange information about counterfeit and substandard medicines found
- The Members agreed on the work plan to be carried out by the network the first year.

Criteria for selecting medicines samples to be tested

- The medicine should be part of the essential medicines list available in all countries
- The medicine should have a monograph in one of the following authorized pharmacopoeia: USP, IP, BP, or EP
- Medicines may be of interest to some or all members of the network

The group agreed on the name “Network of Africa Medicines Control Laboratories” or NAMCOL.

Next steps

1. DQI will send letters to member MRAs stating recommendations and seeking endorsements for the network.
2. The program of work for the network for the first year is shown in the table below:

Work plan for NAMCOL Year One Activities

Objectives	Activities	Indicators	Timeline	Responsibilities
Enhance performance and technical skill	Two proficiency tests per year	Number of tests completed by end of the year	Oct 1 - Dec 31 June 1 - Aug 31	DQI, OMCLs
Identify training needs and carry out training	Conduct one training per year	Number of people trained	April 1 - May 31	DQI, OMCLs
Promote communication and information sharing between labs	Create email list and information database; meet once a year	Created email list Created database Meeting held	September 5 January 2010 September 2010	DQI DQI DQI, OMCLs
Harmonize laboratory procedures and practices	Harmonize at least 2 analytical procedures	Number of harmonized analytical procedures	September 2010	DQI, OMCLs

Conclusion

The workshop was very successful, achieving and surpassing its goals. The participants were open in presenting the challenges they face in their daily jobs and participated in all discussions to reach the consensus that all participating labs will be part of NAMCOL. The participants created work plans for first year activities and agreed to be committed members of this network. The work plans will begin to be implemented as soon as USP receives formal signed confirmation from the MRAs/Ministers of Health of the five countries.