

Training on Registration Processes Using SHUYA™ Software and Presentation of Results of the Medicines Quality Monitoring Program in Senegal

Dakar, Senegal
May 2-11, 2012

Trip Report

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Executive Summary

Taking regulatory actions on failed medicines in a timely manner has been challenging to the Senegal Department of Pharmacies and Laboratories (DPL). One of the main issues has been the lengthy process to register medicines and to track down the failed samples by DPL inspectors. To address this challenge, PQM facilitated registration training May 2-11, 2012 for ten DPL staff on the use of new SHUYAH™ software.

In addition to this training, PQM presented the Minilab® results for the past two years and planned upcoming medicine quality monitoring activities.

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About PQM

The Promoting the Quality of Medicines (PQM) program, funded by the U.S. Agency for International Development (USAID), is the successor of the Drug Quality and Information (DQI) program implemented by the United States Pharmacopeia (USP). PQM is USAID's response to the growing challenge posed by the proliferation of counterfeit and substandard medicines. By providing technical leadership to developing countries, PQM helps build local capacity in medicine quality assurance systems, increase the supply of quality medicines to priority USAID health programs and ensure the quality and safety of medicines globally. This document does not necessarily represent the views or opinions of USAID or the United States government. It may be reproduced if credit is given to PQM and USP.

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- The head of the National Quality Control Laboratory for hosting the Minilab® presentation and to his staff for working diligently in planning the Minilab® training and other medicine quality monitoring activities
- The National Malaria Control Program and University Cheikh Anta Diop Minilab® supervisory teams for coordinating and monitoring field activities
- PQM administrative staff and editors for their assistance with logistical arrangements and for editing the trip report
- Mr. Anthony Boni and Dr. Maria Miralles at USAID/Washington for their support and guidance

Acronyms

AM	Antimalarial
ARV	Antiretroviral
ATB	Antitubercular
CDC	U.S. Centers for Disease Control and Prevention
DGPML	Générale de la Pharmacie du Médicament et des Laboratoires
DPL	Direction de la Pharmacie et Laboratoires (Department of Pharmacies and Laboratories)
DQI	Drug Quality and Information program
DSR	Division de la Santé de la Reproduction (Division of Reproductive Health)
ISO	International Organisation for Standardisation
LNCM	Laboratoire National de Contrôle des Médicaments (National Quality Control Laboratory)
MQM	Medicines Quality Monitoring
NAMCOL	Network of African Medicines Control Laboratories
PMI	President's Malaria Initiative
PNA	Pharmacie nationale d'approvisionnement (central medical store)
PNLP	Programme National de Lutte contre le Paludisme (National Malaria Control Program)
PQM	Promoting the Quality of Medicines Program
QA	Quality Assurance
QC	Quality Control
TB	Tuberculosis
UCAD	University Cheikh Anta Diop
USAID	United States Agency for International Development
USP	United States Pharmacopeia

Background

Since 2002, USAID and USP have been providing technical assistance to Senegal to strengthen their medicine quality assurance (QA) and quality control (QC) systems. In collaboration with the National Malaria Control Program (PNLP) and the University of Cheikh Anta Diop (UCAD), a medicine quality monitoring (MQM) program was launched in June 2002 at five sentinel sites to monitor antimalarials (AMs). In 2009, the program expanded to four additional sentinel sites and began covering antiretrovirals (ARVs), antituberculars (ATBs), and contraceptive products.

Up to 2009, PQM's technical assistance focused on supporting the surveillance of the quality of essential medicines and engaging all stakeholders, including PNL, UCAD, the National Quality Control Laboratory (LNCM), and the Central Medical Store (PNA), in medicines quality control. UCAD has taken the lead in supervising all related activities in the field and in coordinating the confirmatory testing at the LNCM. Over the past two years, DPL has taken ownership of the MQM program and took regulatory actions on the failed, expired, and unregistered medicines.

To take regulatory actions, confirmatory results must be provided in a timely manner, and information on nonconforming medicines must be verified. Having to manually enter data made this activity challenging and time consuming to DPL staff, and providing analytical methods from the dossier of registered medicines was also a tedious task, sometimes requiring months.

To address the issues of inefficient registration processes at DPL, PQM planned to install new registration software, named SHUYAH™, which has been used by the medicine regulatory authority in Burkina Faso (DGPML).

Purpose of Trip

Dr. El Hadri traveled to Senegal to facilitate registration training for DPL staff, organize a meeting with LNCM to present MQM results, and meet with relevant stakeholders to discuss workplan implementation.

Overview of Activities

Briefing USAID/Senegal

Participants: Debbie Gueye, Resident Advisor, President's Malaria Initiative (PMI), and Julie Thwing, Malaria Advisor, U.S. Centers for Disease Control and Prevention (CDC), USAID/Senegal; Latifa El Hadri, PQM

Dr. El Hadri gave an overview of the registration training agenda and the planned meetings. She underlined that the new software, SHUYAH™, includes modules to support DPL's management of registration applications, importation, pharmacovigilance, and the exchange of medical and pharmaceutical information.

Mrs. Gueye requested that Dr. El Hadri talk with Mr. Francois Diop, team leader of the Health Systems Strengthening project, and Mr. Lamine Fall, who works with PNA, on the possibility of PNA adopting SHUYAH™.

Dr. El Hadri also informed the Mission that she will be presenting MQM results for round 2010 and 2011 at the LNCM, as indicated in the invitation sent by DPL.

Training activities of May 2-12, 2012 are summarized in the table below:

Item	Description
Specific Objectives and Expected Outcomes	<p>The goal of this training was to install SHUYAH™, electronic registration program software, at DPL and train DPL staff on the use of the software modules. At the end of the installation and the training, the staff are able to use the following software modules:</p> <ul style="list-style-type: none"> • Registration: Managing all types of applications for registration. The process goes from the receipt of applications to the issue of the marketing authorization • Importation: Granting import licenses to importers (in the case of medicinal products requiring marketing authorization) and granting special import permits (for other pharmaceutical drugs) • Pharmacovigilance: Supporting adverse drug reaction notifications • Exchange of medical and pharmaceutical information: Exchanging info via intranet or internet for health professionals and the public.
Venue/Location	DPL, Dakar, Senegal
Organizer	PQM and DPL
Trainer/Facilitator	Mr. Jean Francois Ouoba – Trainer; Dr. Latifa El Hadri – Facilitator
Agenda	See the agenda in <i>Annex 1</i> for detailed information
Trainees	Ten staff from DPL. See the list of participants in <i>Annex 2</i> .
Closing	Pr. Papa Diop, DPL director, presented certificates to the participants.
Training Evaluation	Participants indicated they benefited from the modules covered during the training, and expressed that the software is user-friendly and will help them in achieving their daily tasks efficiently. A summary of participant evaluations and recommendations is provided in <i>Annex 3</i> .
Conclusion	The training was successful, with all of the participants satisfied with the skills they learned.
Next Steps	PQM will provide the registration training report to DPL and USAID by the end of June. (completed)



Registration training at DPL

In addition to the training, PQM procured two filing cabinets that will be used to organize and archive the hard copies of dossiers received in 2010 and 2011.



Prior to organizing the antimalarial dossiers ... and after beginning the organization process

Presentation of the Results of the MQM Program: Rounds 2010 and 2011

This meeting was organized by DPL and was held at LNCM with representatives from PNLP, USAID/Senegal, Division of Reproductive Health (DSR), DPL, LNCM, and PQM (see *Annex 2* for the complete list of participants).

Pr. Yerim, the newly appointed LNCM director, welcomed the participants and thanked Mrs. Gueye for USAID's support through the PMI program. He gave an overview of the new lab organization chart and pointed out the creation of a department of metrology. He noted that having this department is one of the requirements of ISO 17025 accreditation. Following Pr. Yerim's remarks, Dr. Adama Diedhieu presented the Minilab[®] results for rounds 2010 and 2011.

Results for Round 2010

A total of 540 samples were collected from seven sentinel sites. The samples were collected from the private and public sectors. Since 2009 and the eradication of the Keur Serigne Be illicit market in Dakar, the informal sector has been excluded from sampling.

Samples collected included AMs (44%), ARVs (32%), ATBs (20%), and contraceptives (4%). The Minilab[®] results showed that 25% of the collected samples failed Minilab[®] basic tests. This includes samples that were not registered. Confirmatory results showed a failure rate of 7% for AMs and 14% for ATBs. All collected ARVs were conforming, and only one non-contraceptive failed QC testing.

Results for Round 2011

A total of 601 samples were collected from public and private sectors. The samples collected include AMs (60%), ATBs (20%), ARVs (12%), and contraceptives (8%). The Minilab[®] results showed that 68 passed, 17 failed, and 15 were not tested due to lack of Minilab[®] methods. The

confirmatory testing showed that all ARVs and combinations of artesunate and amodiaquine were conforming. The confirmatory testing of the remaining samples is ongoing at the LNCM.

The completion of confirmatory testing has been delayed due to:

- Slow transition of lab management from the former lab director, who retired in August 2011, to the new director, Pr. Yerim, who was officially appointed in February 2012
- An urgent request made by DPL to test new medicines
- High demand from PNA to test newly procured medicines
- An outbreak of meningitis last quarter pushed the lab to give priority to test Ceftriaxone, the medicine needed to treat this disease

After presenting the results of the last two rounds, Dr. Diedhiou stated that DPL took swift regulatory actions by recalling failed samples and destroying the expired ones. As for unregistered samples, DPL sent memos to the heads of the DSR and HIV departments.

At the end of this presentation, Dr. El Hadri shared the challenges and ways forward to improve the MQM program. This discussion led to the following action items and recommendations:

LNCM

- Assist the lab toward ISO 17025 accreditation to allow for testing medicines at their reception by PNA
- Continue strengthening LNCM technical capacity (only two analysts qualified to perform compendial testing) and assist in procuring new High Performance Liquid Chromatography (HPLC) equipment (only one operational)
- Continue participating in the Network of African Medicine Control Laboratories (NAMCOL) training and host next training in Senegal

PNLP

- Share MQM results with regional chief doctors and provide feedback to concerned parties
- Work with other health departments to ensure their active participation in future MQM rounds
- Reinforce Minilab® training for sentinel site staff
- Invite PNA and cabinet for next meetings

LNCM

- Share Minilab® planning for sampling and testing AMs with the other major health departments and request their collaboration for sampling and testing ATBs, ARVs, and contraceptives
- Need all health programs to meet and discuss ways of consolidating the MQM program
- Perform QC testing of artemether and lumefantrine for DPL

DSR

- Test the quality of other forms of contraceptives (injection and implants) and oxytocin

DPL

- Improve coordination and communication with all relevant parties involved in MQM
- Organize a meeting with the major health departments and present the planning for this year's MQM activities
- Follow up with LNCM, DPL, and PNLP to ensure good field implementation of MQM

Meeting with PNLP Staff

PQM staff organized meetings with PNLP staff (see *Annex 2* for a list of participants) in order to meet the new national malaria coordinator, select sites to be monitored during the 2012 round, and plan for Minilab[®] training for the new staff from Zinguichor and Louga.

Dr. Diallo provided the names of personnel from Louga and Zinguichor to be trained, and it was agreed to make field visits to Kaolack and Kédougou. Dr. El Hadri agreed to share the final plan for this year's MQM activities with PNLP in order to get their approval.

Meeting with LNCM and DPL

Dr. El Hadri met with Pr. Yerim and Dr. Diedhiou from LNCM and Dr. Diagne and Dr. Drame from DPL. The attendees discussed the plans for sample collection, sources of samples, and the budget for the activities.

Dr. El Hadri asked Dr. Diedhiou to share the MQM plan with other health departments and seek their financial contributions for this program. She also requested that he share the plan with PNLP for an update on the list of AMs to be collected and the collection sites (see *Annex 4* for details of MQM planning). The group also discussed the Minilab[®] training and the plans for the lab's ISO 17025 accreditation.

Debrief USAID

Dr. El Hadri met with Mrs. Gueye and Ms. Julie Thwing to provide them updates on the meetings and the training. She informed them that Mr. Ouoba will continue working with relevant personnel regarding the possibility of installing SHUYAH[™] at PNA. Mrs. Gueye asked Dr. El Hadri to continue sharing quarterly reports with the Mission and to inform them of details for upcoming workshops and meetings with health departments.

Conclusion

The registration training was successful, with all of the participants satisfied with the skills they learned. Dr. El Hadri was also able to plan for the upcoming MQM round and trainings.

Next Steps

PQM will:

- Finalize the planning of MQM activities and budget (completed)
- Inform USAID/Senegal of date and agenda of the regulatory workshop (pending)
- Follow up with LNCM on the lab's ISO 17025 activities (ongoing)

LNCM will:

- Provide the QC results of artemether and lumefantrine (HPLC is undergoing repair)
- Share plans for MQM activities and other trainings with PNLP and PQM (completed)

Training agenda May 2-12, 2012

A. Software presentation - 5/2/2012

Morning: Presentations

- Software presentation:
- Records software: 45 minutes
- Pharmacovigilance software: 15 minutes

Afternoon: Early stage software deployment

- Discovery of the environment of the DPL: organization, procedures and IT environment;
- Meeting with the department: detailed analysis of the computing environment: characteristics of the computers, server, backups, etc.
- Analysis of data related to drug registration

B. Software deployment - 5/2 to 5/4/2012

Day 1: Morning and afternoon: Installation and configuration

- Proposal and confirmation with the IT department of a deployment strategy;
- Configuring the server for software use
- Installation and configuration of the database of the records software;
- Installing the software on users' computers

Day 2: Morning and afternoon: Setup and data retrieval

- Recovery of existing data
- Data migration on the new software

Day 3: Morning and afternoon

- Test of backup procedures
- Various simulations of software operation
- Setting up user accounts
- Preparation of a demonstration environment for training

C. Training - 5/5 to 05/12/2012

Day 1: Morning: Start of Training

- Presentation of the environment of the records software;
- Creation/modification of products, laboratories, applicants.

Day 2: Morning and afternoon: Training (Continued)

- Creation/modification of registration fees
- Creation/modification of records for the receipt of registration applications;
- Various impressions related to records received;
- Updates and research on the national classification of products

Day 3: Morning and afternoon: Training (Continued)

- Update of the results of technical and regulatory analysis of registration records;
- Update of the opinions and comments of the recording technical committee;
- Generation of the authorizations for marketing (AMM);

- Generation of official documents for signing off on the AMM.

Day 4: Morning and afternoon: Training (Continued)

- Case studies;

Day 5: Morning and afternoon: Training (Continued)

- Case studies;
- Delivery of training materials;

Day 6: Morning and afternoon: Training (Continued)

- Assessment of knowledge acquired during training;
- Presentation of certificates;
- Conclusion meeting with the DPL

Day 7: Morning and afternoon: Training (End)

- Delivery of documents: User Guides and software installation CD;

Participants in the Registration Training

REPUBLIQUE DU SENEGAL
Un peuple- Un but- Une Foi

DAKAR LE

MINISTERE DE LA SANTE
ET DE L'ACTION SOCIALE


DIRECTION DE LA PHARMACIE
ET DES LABORATOIRES

FORMATION EN LOGICIEL D'ENREGISTREMENT

LISTE DES PARTICIPANTS

MADICKE DIAGNE

BIRAME DRAME

FATOU LOUM GUEYE

NENE ATTA DRAME

AMINATA BOYE DIARRA

ELH MANSOUR NDIAYE

NDEYE DOME FALL

ROKHAYA NDIAYE KANDE

NAFISSATOU DIA

TABASKY SENE

Participants in the Presentation of the Results of the MQM Program: Rounds 2010 and 2011

FEUILLE DE PRESENCE DE LA REUNION DE PARTAGE ENTRE L'USP DQM,
LA DPL ET LE LNCHM DU 08 MAI 2012

N° d'ordre	Prénoms et Nom	Structure	Emergement
1.	Mjerim Mbagnick DIOP	LNCHM	
2.	Mounamadou Ibra NGORA	LNCHM	
3.	Djibril FALL	LNCHM	
4.	Machické DIAGNE	DPL	
5.	Debbie Gueye	USAID/PMI	
6.	Ibrahima DIALLO	PMCP	
7.	Mbaye Magatte DIAO	LNCHM	
8.	Latifa El Hadri	USP/PAN	
9.	Aud Sy Ndiaye	LNCHM	
10.	Seigne Omar Sarr	LNCHM	
11.	Birane Dramé	DPL	
12.	Mounamadou NIANE	LNCHM	
13.	Jean Louis PRÉJICA	LNCHM	
14.	Ndiaye Ndeye Fatouma	DSR	
15.	Cheikh Jemba	DSR	
16.	Adama, DIETHOU	LNCHM	
17.	Ndouste Poudoul	LNCHM	
18.			
19.			
20.			
21.			
22.			
23.			

Participants in the Meeting with PNLP Staff

MINISTÈRE DE LA SANTÉ ET DE L'ACTION SOCIALE
 DIRECTION DE LA SANTÉ
 DIVISION DE LA LUTTE CONTRE LA MALADIE
 PROGRAMME NATIONAL DE LUTTE CONTRE LE PALUDISME

Dakar, le



FEUILLE DE PRESENCE POUR : Réunion avec Latifa USP/PAN

N°	Prénoms et Nom	Service	contact		Emargement
			Téléphone	E-mail	
1	Drabina Diallo	PNLP	775671584	han076@yahoo.fr	
2	Latifa El Hadri	USP/PAN	771526292	lwe@usp.org	
3	Alioune Badara GUEYE	PNLP	776313223	badou_guayle@hotmail.com	
4	Guisein BARIANE	PNLP	776514376	ouzmad@hotmail.com	
5	Moustapha CISSE	PNLP	776493512	dcusse@gmail.com	

Training Evaluation Form

In order for PQM to evaluate the efficacy of each training module and improve the level of the courses, we ask all participants to kindly provide their feedback by filling out this evaluation sheet.

A- Evaluation of Specific Aspects of the Training Workshop

	EXTENT TO WHICH THE TRAINING MET YOUR OVERALL EXPECTATIONS			
	Exceeded Expectations	Met Expectations	Met Some Expectations	Unsatisfactory
Registration Training	10	1		

B- Overall Evaluation of the Training Workshop

	Strongly agree	Agree	Somewhat disagree
Course objectives were relevant to my needs	10	1	
Training material helped me understand and better organize my data	9	2	
I was able to understand the content of the materials presented	7	4	
Overall, the course was useful and will help me do my job better	8	3	
There were enough practical exercises to facilitate understanding of the course	8	3	
The pacing of the various sessions was appropriate for my understanding of course materials	10	1	
The sequence in which the sessions were presented was appropriate for my understanding	9	2	
The instructors were knowledgeable on the subject	10	1	
The instructors allowed an appropriate level of participation	10	1	

C- Other Comments/Suggestions:**1. What did you like best about the course?**

- All modules of the training were important
- The instructor was highly knowledgeable about the use of the software
- The training was straight forward

2. What are your recommendations/suggestions for improvement of the course?

- DPL needs to recruit an IT staff to manage all software database
- DPL needs to have a separate server for software data
- Regular follow-up to ensure good software performance
- Adapt the software to register reagents used by the lab
- Organize visit where SHUYAH™ software is used
- Need a follow up visit to make sure that all modules are fully understood and used by DPL personnel without any difficulties
- Increase the period of practical training

MQM Planning

PLAN D'ECHANTILLONNAGE 2012

AXES	PROGRAMME				PERIODE	TECHNICIENS	Supervision
	PNT	DLSI	DSR	PNLP			
Dakar - Thiès	PNA			Magasin Central			
	District 01			Guédiawaye			
	District 02			Pikine			
	District 03			Institut d'hygiène et sociale (Dakar Sud)			
	District 04			Rufisque			
	Officine 01			choix laissé aux équipes			
	Officine 02						
	Officine 03						
	PRA			Thiès			
	District 01			CHR Thiès			
	District 02			Tivaouane			
	District 03			Mbour			
	Officine 01			choix laissé aux équipes			
	Officine 02						
Officine 03							
Diourbel	PRA			Diourbel			
	District 01			Touba			
	District 02			Diourbel			
	District 03			Mbacké			
	Officine 01			choix laissé aux équipes			
	Officine 02						
Officine 03							
Kaolack - Kaffrine	PRA			Kaolack			
	District 01			Kasnack			
	District 02			Kaffrine			
	District 03			Nioro			
	Officine 01			choix laissé aux équipes			
	Officine 02						
Officine 03							
Saint Louis - Richard Toll	PRA			Saint Louis			
	District 01			CHR ST Louis			
	District 02			CH Ndioum			
	District 03			CS Richard Toll			
	Officine 01			choix laissé aux équipes			
	Officine 02						
Officine 03							
Matam Ourossogui	PRA			Matam			
	District 01			CHR Ourossogui			
	District 02			CS Kanel			
	District 03			Pété			
	Officine 01			choix laissé aux équipes			
	Officine 02						
Officine 03							
Kolda - Vélingara	PRA			Kolda			
	District 01			CHR Kolda			
	District 02			Vélingara			
	District 03			CS Kolda			
	Officine 01			choix laissé aux équipes			
	Officine 02						
Officine 03							
Tambacounda Kédougou	PRA			Tamba			
	District 01			Kédougou			
	District 02			CS Tamba			
	District 03			CS Maka Colibantang			
	Officine 01			Choix laissé aux équipes			
	Officine 02						
Officine 03							
Ziguinchor - Sédhiou				Hôpital Régional Ziguinchor			
				CS Ziguinchor			
				CS Oussouye			
				CS Bignona			
Louga-Linguère				Hôpital Régional Louga			
				CS Louga			
				CS Linguère			
				CS Darou Mousty			

Dr Adama DIEDHIOU
 Dr Ibrahima DIALLO
 Dr Birame DRAME
 Dr Madické DIAGNE
 Dr Sérigne Omar SARR

For the other health programs, the focal point will complete the list after contacting the heads of PNT, DSR and DLSI