Workshop on Basic Tests and Sampling Procedures for Monitoring the Quality of Medicines in Senegal; and Meetings on FY10 Senegal Activities

Dakar, Senegal
January 4-8, 2010

Trip Report

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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.

Abstract

The PQM team conducted a workshop on the proper use of Minilab® basic tests and sampling procedures for laboratory analysts in Dakar, Senegal, January 4-8, 2010. The training was organized by PQM, University of Cheikh Anta Diop (UCAD), and Laboratoire National de Contrôle du Médicaments (LNCM) and consisted of hands-on testing of antiretroviral (ARV), antituberculosis (anti-TB), and antimalarial (AM) medicines. In total, 24 trainees from Malaria, HIV, and TB health departments – in addition to analysts from UCAD and LNCM – completed the training. The PQM team also met with major partners and stakeholders to present the results of the Quality of Antimalarials in Sub-Saharan Africa (QAMSA) study and to discuss the Senegal FY 10 work plan.

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Key Words

Senegal, sentinel sites, Medicine Quality Monitoring, antiretrovirals , antituberculosis , antimalarials, Minilab basic tests, sampling procedures, pharmacovigilance, Information Education and Communication (IEC), communication campaign.

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- The DPL director and his staff for hosting and preparing the roundtables on QAMSA, IEC, and pharmacovigilance
- All attendees from MOH, WHO, MSH, ChildFund, and Family Planning who attended roundtables and provided valuable feedback and information
- The LNCM director for clearing all training supplies and equipment in a timely manner and for providing an inventory list of received items from USP and GPHF/TTM
- The UCAD and LNCM staff for assisting in coordinating the workshop and for their support before, during, and after the training
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- The PQM administrative staff and editors for their assistance with logistical arrangements and for editing the trip report

ACRONYMS

ACT	Artemisinin-based Combination Therapy
AM	Antimalarial
ARV	Antiretroviral
CAP	Centre Anti-Poison
CO.PHA.SE	Corporation Pharmaceutique Sénégalais
DLSI	Division de Lutte contre le SIDA
DPL	Direction de Pharmacie et Laboratoires
DQI	Drug Quality and Information
DSR	Division of Reproductive Health
GPHF	Global Pharma Health Fund
HIV	Human Immunodeficiency Virus
IEC	Information Education and Communication
LNCM	Laboratoire National de Contrôle de Médicaments
MOH	Ministry of Health
MQM	Medicine Quality Monitoring
MSH	Management Sciences for Health
PEPFAR	President's Emergency Plan for AIDS Relief
PEV	Programme Elargi de Vaccination
PMI	President's Malaria Initiative
PNA	Pharmacie Nationale d'Approvisionnement
PNLP	Programme National de Lutte contre le Paludisme
PNLS	Programme National de Lutte contre le Sida
PNLT	Programme National de Lutte contre la Tuberculose
PQM	Promoting the Quality of Medicines
PV	Pharmacovigilance
QAMSA	Quality of Antimalarials in Sub-Saharan Africa
QC	Quality Control
SCM	Substandard/Counterfeit Medicine
SNEIPS	Service National de l'Éducation et de l'Information pour la Santé
SNPV	National System of Pharmacovigilance
SP	Sulfadoxine-Pyrimethamine
SPS	Strengthening Pharmaceutical Systems
TB	Tuberculosis
TLC	Thin Layer Chromatography
TTM	Technologie Transfer Marburg
UCAD	Université Cheikh Anta Diop
USAID	United States Agency for International Development
USP	United States Pharmacopeia
WHO	World Health Organization

Background

In 2002, with the support of USAID, a surveillance program for monitoring the quality of antimalarials was established at five sentinel sites by the United States Pharmacopeia (USP) Drug Quality and Information (DQI) program in partnership with the Program National de Lutte contre le Paludisme (PNLP), the Laboratoire National de Contrôle du Médicament (LNCM), the Direction de la Pharmacie et des Laboratoires (DPL), the Pharmacie Nationale d'Approvisionnement (PNA), and the University of Cheikh Anta Diop Dakar (UCAD). The program included strengthening DPL, enhancing technical capacities for drug quality, and implementing a new strategy for early detection of substandard and counterfeit medicine.

In 2003, PQM[1], in collaboration with PNLP, UCAD and LNCM, set five sentinel sites to monitor the quality of antimalarials, and one Minilab® training was provided to personnel from PNLP, UCAD and LNCM. In 2008, a sixth sentinel site was added, and the program was expanded to monitor the quality of HIV and TB medicines. In total, seven rounds of postmarketing surveillance have been performed by UCAD and LNCM personnel. The last round was organized using the new Medicine Quality Monitoring (MQM) protocol, which was developed with support from PQM and major health departments. The results of each round were submitted to DPL so action could be taken regarding failed samples.

Sending reports in a timely fashion and taking action on failed samples is still challenging the MQM program. To tackle some MQM obstacles, PQM requested that DPL take ownership of the MQM program and delegate full technical responsibilities to UCAD and LNCM.

Purpose of Trip

Drs. Latifa El Hadri and Abdelkrim Smine traveled to Dakar, Senegal to:

- Train participants on HIV, TB, and AM medicine sampling, basic testing, and data reporting
- Present the results of the QAMSA study to major stakeholders
- Present the results of the MQM program and transfer management of the program to DPL
- Conduct roundtable meetings with relevant partners to discuss FY 10 activities regarding pharmacovigilance and communication campaigns
- Select the new sentinel site
- Create list of oral contraceptives to be tested by USP laboratories
- Debrief USAID about program activities

Source of Funding

This trip was supported with funds from USAID/Senegal, under PMI.

[1] The Promoting the Quality of Medicines (PQM) program is the successor of the Drug Quality and Information (DQI) program. To avoid confusion, the program will be referred to as PQM throughout this report.

Overview of Activities

Overview of the Workshop

Item	Description
Training Objectives	✓ Sampling procedures, logistics, data management ✓ Rationale for using basic tests to monitor the quality of antimalarial, antiretroviral, antituberculosis medicines at the peripheral level ✓ Basic theory of thin layer chromatography ✓ Training on medicine sampling at the sentinel site level ✓ Training on visual and physical inspection of medicines ✓ Training on thin layer chromatography using Minilab® tests ✓ Training on simple drug disintegration ✓ Training on proper reporting of medicine quality data
Training Venue	The opening and presentation of the program guidelines were carried out at LNCM. The hands-on training was carried out at UCAD, Department of Pharmacy, Laboratory of Chemistry, Dakar, Senegal
Local Organizers	UCAD, LNCM, PNLP, PNLT, PNLS and DPL
Opening Ceremony	Prof. Mounirou Ciss (LNCM), Prof. Yerim Diop (UCAD), Dr. Serigne Diagne (MSH), Mangane Talla, DPL trainees and the PQM team (Annex 1)
Course Proceedings	The training was organized as follows: • Day 1: opening, sampling logistics and budgets, sentinel sites and supervisory teams set up, and theory of TLC. • Day 2–3: TLC lab (amodiaquine, sulfadoxine-pyrimethamine, artemether-lumefanthrine, isoniazid, isoniazid-rifampicin, zidovidine, lamivudine, zidovudine-lamivudine fixed combination,) • Day 4: review of budget, wrap-up discussion, certificates
Training Modules	24 training manuals conceived by the PQM team, which include the following modules: medicine sampling, visual and physical inspection of medicine packages and dosage forms, thin layer chromatography, simple disintegration and data management and reporting
Trainers	Dr. A. Smine and Dr. L. El Hadri from PQM, assisted by senior staff of the MQM program: Dr. Adama Diehdiou and Dr. Amadou Diop
Medicines Tested by Minilab®	Amodiaquine, sulfadoxine-pyrimethamine, artemether-lumefanthrine, isoniazid, isoniazid-rifampicin, zidovidine, lamivudine, zidovudine/lamivudine fixed combination
Participants	Twenty-four trainees from the central and regional level were designated by the head of their respective health programs or entities: PNLT, PNLS, LNCM, UCAD (List of participants, see Annex 2)
***Equipment Provided**	All materials provided by PQM for training purpose were indicated in the list of supplies sent to LNCM (see Annex 3) .
Closing Ceremony	Ceremony chaired by Prof. Mounirou in the presence of attendees from health department and other staff from MOH (see Annex 4) Following the closing remarks, certificates were awarded to all participants who successfully completed the training.
Evaluation of Training	See Annex 5

Course Outcomes	At the end of the course, participants were able to: ✓ Understand the sampling protocol and sampling plan ✓ Carry out visual inspections and TLC testing of all AM, TB and HIV medicines ✓ Carry simple disintegration ✓ Report drug quality data as established by PQM program using standard procedures. *It is important to note that during the training, fake and substandard samples were found by the trainees. This fact motivated the trainees and demonstrated that basic tests are good quality control (QC) tools.* • A sample of ACT showed impurities (artediam: artesunate amodiaquine) • A sample of fixed-dose combination isoniazid-rifampicin was found without any isoniazid

**in addition to supplies for Minilab® training other equipments (supplies, reagents minilab reference standards, chemical, and 1 minilab) were also shipped to LNCM for the upcoming MQM round.*

Training Highlights

Meeting with Minilab® team coordinator
January 3, 2010

The PQM team met with the coordinator of the program, Dr. Adama Diedhiou, and reviewed the training program and agenda for the week. Dr. Diedhiou informed the team that an invitation letter from Farba Lamine, director of cabinet at the MOH, was sent to all trainees to attend the workshop (see Annex 10 for invitation letter).

Meeting with LNCM director
January 4, 2010

Prof. Mounirou chaired a short opening ceremony and explained to the participants the importance of the MQM program and the commitment of himself and his staff in supporting and implementing the MQM program. Dr. Smine and Dr. El Hadri gave an overview of the PQM's objectives and emphasized the importance of collaboration between all parties involved in the MQM program. Dr. Smine reminded the group that the main objective of this program is to prevent patients from taking poor-quality medicines. The PQM team urged all participants to strictly follow the program guidelines and try to report the findings according to the timelines to allow DPL to take action while the medicines tested are still in circulation on the market.

Presentations

Dr. Smine gave a presentation on drug quality assurance and the importance of assuring the quality of medicines from manufacture to their use by the patient. In his second presentation, Dr. Smine focused on quality control of medicines and the rationale of using basic tests in countries with limited resources. The presentation covered the MQM guidelines, and the participants were given the opportunity to discuss each step and comment on the challenges faced in the field.

Dr. El Hadri gave a presentation on sampling strategies that included sample definition and diversification, as well as the characteristics that determine a single sample. She urged participants to work together and learn from the experiences of the senior sentinel site teams in order to conduct good and unbiased sampling. The MQM guidelines also cover testing in three levels. Dr. El Hadri guided the participants on how to fill out all required forms, from sample

collection to testing with Minilabs® at sentinel sites and confirmatory testing at the NQCL. All sample forms for data reporting and management were provided in the training manual and used as exercises during training.

The PQM team introduced the Minilab® to the participants and instructed them on how to handle the reagents and other supplies as well as basic safety measures. In the afternoon, the training moved to the lab of the Department of Pharmacy of UCAD. With the help of senior staff, five groups were set up and all supplies and training tools were evenly distributed among the groups to allow for a smooth training experience and better work environment.

January 5, 2010

The first two TLC runs were conducted in a step-by-step manner to allow the trainees to learn best practices. The group was able to carry out four full TLC analyses of three different medicines. After each step, the PQM team and senior program staff reviewed each TLC plate and made comments for improvement. By the end of Tuesday, all participants were able to run TLC individually.

January 6, 2009

Trainees were asked to use sampling and reporting forms for each sample they tested. They also were trained on how to carry out visual and physical inspection of medicine samples and packaging material. At the end of each TLC, trainees were instructed to calculate retention factor (Rf) values and fill out reporting forms. Three additional TLC runs were conducted on different types of malaria, TB, and HIV medicines.

The closing remarks were made by the director of LNCM, the PQM team, and Prof. Yerim Diop, the principal focal point in charge of the technical aspect of MQM activities at sentinel sites. The heads of the HIV and TB programs attended the closing ceremony and agreed on the sampling strategies for medicines of their programs.

Briefing USAID/Senegal
January 4, 2010
Participants: Debbie Gueye, Robert Perry, Matar Camara, Ramatoulaye Dioume, and PQM team

The PQM team visited USAID/Senegal to discuss the objectives of the trip. Dr. Smine gave a historic overview of USP MQM in Senegal, and Dr. El Hadri spoke about the positive changes in the attitude of DPL during the awareness campaign conducted last year, which was very successful in shedding light on the serious issue of the informal market in Senegal. DPL is now very involved in the MQM program and is willing to take ownership of sentinel site activities. The DPL director promised to take enforcement actions based on medicine quality data.

The PQM team also discussed the QAMSA study report with USAID staff and invited them to attend the pharmacovigilance and IEC roundtables, which were to take place at DPL with all program stakeholders. Dr. El Hadri emphasized importance of these roundtables in terms of joining financial resources, conducting relevant activities that aim to address the major issues facing SNPV, and raising awareness on the poor quality of medicines.

Roundtable Meeting on monitoring the quality of medicines and presentation of QAMSA report at la Direction de Pharmacie et Laboratories
January 7, 2010

Participants: USAID mission, DPL, UCAD, WHO, MSH, ChildFund, IntraHealth International, PNLP, PNLT, PNLS, PNA, Board of Pharmacists, and PQM team (list of participants, see Annex 6a and letter of invitation from DPL annex 6b).

The DPL director chaired the roundtable, and 25 participants attended this meeting. The main objectives of the meeting were to share information on the new PQM program, MQM results and challenges, and the QAMSA report. Other items discussed included selection of a new sentinel site and adoption of the MQM program by DPL.

After the introductions, the PQM team gave three presentations. The first covered the new PQM program, and the second discussed planned activities for FY 10. The final presentation shared the results of the QAMSA report. The report includes results for Madagascar, Uganda, and Senegal, the three countries funded through USAID. Dr. Smine mainly highlighted the findings

for Senegal, with emphasis on the results of confirmatory testing of ACTs and SPs collected from different sectors in the country. The basic Minilab® tests showed that 43% of the samples did not meet the requirements for visual inspection, identification, drug content, or disintegration, and full quality control testing at the USP laboratory showed a failure rate of 44%. Based on these shocking results, the DPL director promised to take the necessary measures and requested the full QAMSA data sheet to identify the sources of failed antimalarials.

Following the PQM presentations, Prof. Yerim Diop gave an overview of the MQM program and the results of the past two years. Sentinel site reports showed a lower failure rate compared to the QAMSA report. The differences observed in overall failure rates between the basic Minilab® testing and the full-scale QC testing at USP were primarily due to the fact that the Minilab® lacks the same capacity to identify dissolution and impurity test failures. In addition, LNCM is not fully equipped to perform all QC testing, especially for samples with no pharmacopeial method.

The last presentation, given by Dr. Birame Dramé, QA supervisor, covered the major activities run by DPL as a regulatory entity and the relevance of drug registration in medicine quality control. He highlighted the major challenges that DPL faces in terms of drug registration and verification of medicines at port of entry. Dr. Dramé pointed out that some of these issues are due to lack of technical and human capacity as well as financial resources.

Following the presentations, the DPL director opened the floor for questions and suggestions. Discussions on the need for taking action on suspected counterfeit and confirmed substandard medicines were raised by some partners. Challenges of reporting and informing in a timely manner in addition to providing necessary information and taking action on failed samples were also debated. The urgency of informing the concerned health department directly when a sample tested with Minilab® shows no API was stressed by the PNT representative and the PQM team. DPL mentioned that actions are considered by his entity regarding the non-conform lots found in sentinels site (See Annex 7 for more details).

In light of these discussions, ways of solving some issues in terms of communication were proposed, for instance: 1) identifying a focal point for each major health program to be involved in all MQM activities; and 2) setting up guidelines on how to streamline information on MQM activities from sentinel sites to LNCM to DPL.

Dr. Diop stated that there have been cases where there was not enough evidence to take action or a lack of specific provisions in Senegalese law and regulations pertinent to substandard and counterfeit medicines (SCMs). To combat SCMs efficiently, he said that there was a need to establish appropriate guidelines for taking action complementary to the existing regulatory procedures. He proposed having the involvement of MOH, customs, and other law enforcement agencies dealing with pharmaceutical trades in Senegal.

Selection of new sentinel sites and removing the illicit markets from MQM program, as these are targeted for elimination, were also discussed during this roundtable. The majority of the attendees agreed about selecting Matam as a new sentinel site and to not include the informal market in the upcoming MQM activities. The DPL director said that the previous communication

campaign helped in closing the illicit market in Dakar; hence, more IEC activities were needed to close other existing illicit markets.

At the end of the roundtable, DPL requested to include a new partner, the Division de la Santé et de La Reproduction, in the new MQM protocol. He asked Prof. Yerim to incorporate all recommendations and amendments proposed during the roundtables in the final MQM protocol and to send it to all partners for final review.

Before closing the meeting, the DPL director promised to adopt the guidelines of the new MQM protocol. He also expressed his willingness to work closely with relevant partners and the MOH for ensuring the success of MQM program.

Next Steps

- DPL to have the mandate of regulatory action on SCMs and oversight of MQM activities
- UCAD and LNCM to have the mandate for technical work, including coordination of MQM activities with other focal points and disseminating results
- DPL to work on providing appropriate guidelines for action to be taken on SCMs
- DPL to take action on failed lots encountered in the QAMSA study
- UCAD to be in charge of formulating the budget and timeline for MQM activities in consultation with focal points and LNCM
- The new MQM protocol to be amended, revised, and signed by partners
- Illicit market will not be considered in the upcoming MQM activities

Meeting with DLSI and IntraHealth International
January 7, 2010
Participants: Dr. Abdoulahath Mangane (DLSI), Dr. Papa Ndao (IntraHealth International) and PQM team

The purpose of the meeting was to discuss the list of oral contraceptives to be tested by USP and the level of sampling. Dr. Mangane and Dr. Ndao agreed on testing four products (three orals and one injectable). Dr. Ndao will collect the samples and send them to USP for QC testing. He suggested keeping Dr. Fatouma Ndiaye (pharmacist at DSR) and Dr. Bocar Daff (Chief of DSR) informed during the entire process. The first QC testing will be performed at USP. If funding is available, PQM will then assist LNCM in performing QC testing.

Following the meeting, the PQM team called Dr. El Hadji (USAID/Senegal) to debrief him.

Roundtable on Pharmacovigilance and Communication Campaigns at the Direction de la Pharmacie et Laboratoire
January 8, 2010

Roundtable on Pharmacovigilance

This roundtable was chaired by Dr. Birame Dramé, National Pharmacovigilance Coordinator, and attended by 14 participants (see Annex 8 for list of participants). The PNLT, PNLS, and PEV discussed how to efficiently use the allocated funds under PMI FY 09 and which PV activities should be funded this year.

In terms of efficient use of PMI funds, the majority of the health departments suggested to join PMI funds to other pharmacovigilance budgets within their respective departments. Another proposed way of joining efforts is using the previously trained personnel in pharmacovigilance to roll out PV training from the regional to district level. As for the relevant activity needed to boost the SNPV action plan, several propositions were recommended. The most suggested activities included providing pharmacovigilance documents to CAP, training pharmacists and health professionals in Adverse Drug Event reporting and training experts (personnel previously trained in pharmacovigilance) in causality assessments. Besides discussion on PV activities for this year, challenges hindering the advancement of the SNPV system were also raised.

Since there was no consensus on which activity to be undertaken this year, USAID/Senegal requested Dr. Birame to provide an analysis of the current status of SNPV with identification of gaps and a list of activities that can address the existing gaps. USAID/Senegal and PQM will decide on which activities will be carried out with PMI funds for FY 10. USAID/Senegal suggested working jointly with Dr. Serigne Diagne from MSH/SPS.

Next Steps

- The Pharmacovigilance National Coordinator to provide the SNPV an action plan with a priority list of PV activities to be undertaken this year
- PQM to share the SNPV action plan with USAID/Senegal and decide on which activities to fund this year
- PQM to coordinate with MSH/SPS in Senegal regarding PV activities

Roundtable on Communication Campaign

The second roundtable was chaired by Colonel Mamadou Ngom and attended by 21 participants from USAID/Senegal, DPL, CAP, LNCM, PNLT, PNLS, MSH, ChildFund, PNA, CO.PHA.SE, SO.Di.Pharm, Laborex, UCAD, LNCM, SNEIPS, and PQM. (for the list of participants, see Annex 9)

The main objective of this meeting was to present an evaluation of the previous communications campaign and to propose IEC activities for 2010. In the first part of the meeting, Mrs. Diop, head of IEC at DPL, shared with the audience a copy of the report from the previous communication campaign and gave an overview of the main activities that took place (July 20 - August14, 2009 in Dakar. After this review, the audience requested that Mrs. Diop amend the communication campaign report with the following items:

- Activities planned but not achieved
- Activities funded by each partner
- Challenges

In the second part of the meeting, Dr. Rokia Ndiaye gave a presentation on IEC activities planned for 2010. The target audiences for the proposed activities include:

- General public
- Sellers in the illicit market
- Health professionals
- Administration, religious leaders, and political authorities

The main activities of the proposed IEC program contain:

- Communication tools, such as T-shirts, posters, banners, etc.
- Sketches
- Information day in 14 regions for health educators, collaborators, and partners
- TV and radio announcements
- A wrestling game
- Artist awards on best painting on illicit market

The estimated budget of the above activities was $250,000.

The group suggested establishing activities at the regional level and working on a realistic budget. It was also recommended to work jointly with ChildFund, WHO, and other partners at the community level in order to establish a program based on the experienced of regional educators who work closely with communities.

Next Steps

- DPL to amend the report and submit a revised copy to relevant partners
- DPL to designate a working committee to plan the activities of the next campaign
- PQM to share action plan with USAID/Senegal and discuss activities that can be funded
- PQM to work closely with IEC committee in establishing the agenda of 2010 IEC

Meeting at LNCM with Prof. Mounirou
January 8, 2009

The purpose of the meeting was to go over all items sent by USP and TTM, including the Minilab® for the new sentinel site. The PQM team thanked Pr. Monirou for clearing the shipments at the airport and convening the training. Prof. Mounirou provided the receipts of the equipment received, and the group reviewed the invoices and checked the packages.

Next steps

- Prof. Mounirou to consult with the MQM technical committee to determine if other items are needed for the next round
- The LNCM director and principal focal point will be in charge of placing the new Minilab® in Matam (the new sentinel site) and replenishing the existing Minilabs® with supplies and reagents

Annex 1

Feuille de présence: Opening Ceremony

J1 (Le 04 JANVIER 2010)

N°	Prénoms et Nom	Programme	
1	Yankoba COLY	DLSI (Tamba)	
2	Bintou DIA	DLSI (Dakar)	
3	El Hadj Mactar MBOUP	DLSI (Kolda)	
4	Ousmane NIANG	DLSI (Ourossogui)	
5	Lam Toro Mamadou SECK	DLSI/PNA (Dakar)	
6	N'déye Ndack CISSE	PNT (Dakar)	
7	Issa COUNDOUL	PNT (Saint Louis)	
8	Binta DIOUF	PNT (Dakar)	
9	Bassine KA	PNT (Louga)	
10	Mme SAMB Fatou SAMBA	PNT (Kaffrine)	
11	Mariane CISSE FALL	PNLP (Kaolack)	
12	Amadou MBALLO	PNLP (Kolda)	
13	Maty NDAO NDIAYE	PNLP (Dakar)	
14	Ibrahima SECK	PNLP (Kédougou)	
15	Ndéye Maguette DIAO MBAYE	LNCN (Dakar)	
16	Awa SY NDIAYE	LNCN (Dakar)	
17	Sokhna Astou G. DIOP NDIOUR	LNCN (Dakar)	
18	Jean Louis PREIRA	LNCN (Dakar)	
19	Ndèye Marème DIOUF SARR	LNCN (Dakar)	
20	Moussa DIOP	UCAD (Dakar)	
21	El hadji Mama NDIAYE	UCAD (Dakar)	
22	Brice Hervé YEDEMON	UCAD (Dakar)	
23	Mounirou CISS	LNCN	
24	Sérigne Abdou DIAGNE	MSH	
25	Latifa El HADRI	USP PQM	
26	Karim SMINE	USP PQM	
27	Yérim Mbagnick DIOP	UCAD LNCN	
28	Adama DIEDHIOU	UCAD LNCN	
29	Amadou DIOP	UCAD	

Atelier de formation sur le Minilab GPHF

N°	Prénoms et Nom	Programme
1	Yankoba COLY	DLSI (Tamba)
2	Bintou DIA	DLSI (Dakar)
3	El Hadj Mactar MBOUP	DLSI (Kolda)
4	Ousmane NIANG	DLSI (Ourossogui)
5	Lam Toro Mamadou SECK	DLSI/PNA (Dakar)
6	N'déye Ndack CISSE	PNT (Dakar)
7	Issa COUNDOUL	PNT (Saint Louis)
8	Binta DIOUF	PNT (Dakar)
9	Bassine KA	PNT (Louga)
10	Mme SAMB Fatou SAMBA	PNT (Kaffrine)
11	Mariane CISSE FALL	PNLP (Kaolack)
12	Amadou MBALLO	PNLP (Kolda)
13	Maty NDAO NDIAYE	PNLP (Dakar)
14	Ibrahima SECK	PNLP (Kédougou)
15	Ndéye Maguette DIAO MBAYE	LNCN (Dakar)
16	Awa SY NDIAYE	LNCN (Dakar)
17	Sokhna Astou G. DIOP NDIOUR	LNCN (Dakar)
18	Jean Louis PREIRA	LNCN (Dakar)
19	Ndèye Marème DIOUF SARR	LNCN (Dakar)
20	Moussa DIOP	UCAD (Dakar)
21	El hadji Mama NDIAYE	UCAD (Dakar)
22	Brice Hervé YEDEMON	UCAD (Dakar)
23	Adama DIEDHIOU	UCAD LNCN
24	Amadou DIOP	UCAD

Supplies provided to LNCM for Minilab training

Item	Quantity
Graduate ruler	24
Lab glass bottle, 100-ml	30
Thermometer	15
Pre-set timer	10
Spatula	20
Pair of scissors	20
Aluminum foil	2
Funnel	20
10-ml glass bottle	50
25-ml glass bottle	30
40-ml glass bottle	30
1-ml pipette	30
2-ml pipette	20
5-ml pipette	30
10-ml pipette	15
25-ml pipette	15
Pipette filler	15
Rack	15
Label tape	10
Marker	24
Pencil	24
Pencil sharpner	8
Microcapillaries	15
Hot plate	10
Adaptor plug	10
TLC plates	3
TLC developing chamber	20
Filter paper	5
UV lamp	5
TLC dipping chamber	8
Tweezers	15
Replacement batteries	16
Safety glasses	30
Protection masks	50
Gloves	6 Packs

Feuille de présence : Closing Ceremony

J3 (Le 06 JANVIER 2010)

N°	Prénoms et Nom	Programme	
1	Yankoba COLY	DLSI (Tamba)	
2	Bintou DIA	DLSI (Dakar)	
3	El Hadj Mactar MBOUP	DLSI (Kolda)	
4	Ousmane NIANG	DLSI (Ourossogui)	
5	Lam Toro Mamadou SECK	DLSI/PNA (Dakar)	
6	N'déye Ndack CISSE	PNT (Dakar)	
7	Issa COUNDOUL	PNT (Saint Louis)	
8	Binta DIOUF	PNT (Dakar)	
9	Bassine KA	PNT (Louga)	
10	Mme SAMB Fatou SAMBA	PNT (Kaffrine)	
11	Mariane CISSE FALL	PNLP (Kaolack)	
12	Amadou MBALLO	PNLP (Kolda)	
13	Maty NDAO NDIAYE	PNLP (Dakar)	
14	Ibrahima SECK	PNLP (Kédougou)	
15	N'déye Maguette DIAO MBAYE	LNCN (Dakar)	
16	Awa SY NDIAYE	LNCN (Dakar)	
17	Sokhna Astou G. DIOP NDIOUR	LNCN (Dakar)	
18	Jean Louis PREIRA	LNCN (Dakar)	
19	Ndèye Marème DIOUF SARR	LNCN (Dakar)	
20	Moussa DIOP	UCAD (Dakar)	
21	El hadji Mama NDIAYE	UCAD (Dakar)	
22	Brice Hervé YEDEMON	UCAD (Dakar)	
23	Mounirou CISS	LNCN	
24	Sérigne Abdou DIAGNE	MSH	
25	Latifa El HADRI	USP PQM	
26	Karim SMINE	USP PQM	
27	Yérim Mbagnick DIOP	UCAD LNCN	
28	Adama DIEDHIOU	UCAD LNCN	
29	Amadou DIOP	UCAD	

Evaluation by Participants

Eighteen participants returned the evaluation form.

Indicator	Strongly Agree	Agree	Disagree Somewhat
1. Course objectives were relevant to my needs	10	7	2
2. I was able to understand the content of the materials presented	13	5	
3. Overall the course was useful and will help me do my job better	13	5	
4. There were enough practical exercises to facilitate understanding of the course	14	3	1
5. The pacing of sessions was appropriate for my understanding of course materials	7	8	3
6. The instructors were knowledgeable on the subject	17	1	
7. The instructors allowed an appropriate level of participation in the class	10	8	

Any other comments/suggestions:

1. Which topic(s) or aspects of the course should not be included in future workshops?
The majority expressed the importance of Minilab training in their daily activities at regional level

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

- **Need of extra time to practice TLC techniques and interpretation of the results.**
- **Request by trainees to have a follow-up post training**
- **Need to have supervisory visit at regional level**
- **Increase the number of training days**
- **Request by trainees to do dissolution testing (not included in Minilab basic test) and highly need for testing the quality of SP**

The participant evaluations and experience of the facilitators during the course will be used to update the training materials at a later date.

Table Ronde Contrôle Qualité des Médicaments

January 7, 2010

LISTE DE PRESENCE (25 participants)

NOMS & PRENOMS	SERVICE	N° TEL & MAIL	EMARGEMENT
1 DIAGNE Serigne Abdou	MSH / SPS	338691485 sdiagne@msh.org	[signature]
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26				
27				
28				
29				

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RÉPUBLIQUE DU SÉNÉGAL
Un Peuple – Un But – Une Foi
****
MINISTÈRE DE LA SANTÉ,
ET DE LA PRÉVENTION
****
DIRECTION DE LA PHARMACIE
ET DES LABORATOIRES

N°_____MSP/DPL/PV

Dakar le, 05 JAN 2010

Le Directeur

INVITATION

Dans le cadre de l'appui technique de l'USP PQM au programme de surveillance de la qualité des médicaments, la DPL organise dans ses locaux une réunion qui se tiendra le jeudi 7 janvier 2010 à 9heures.

A cet effet, je vous invite à prendre part à cet important atelier.

P.J : agenda

Pr Papa Amadou Diop

Destinataires :

- **CABINET**
- **DPL**
- **LNCM**
- **UCAD**
- **PNA**
- **USAID**
- **PNLP**
- **PNT**
- **DLSI**
- **MSH**
- **INTRAHEALTH**
- **OMS**

REPUBLIQUE DU SENEGAL
Un Peuple - Un But - Une Foi
****

MINISTERE DE LA SANTE
ET DE LA PREVENTION
****

DIRECTION DE LA PHARMACIE
ET DES LABORATOIRES
****

N° .....MSP/DPL/DCAM

Dakar, le .....

15 JAN. 2010

LE DIRECTEUR

Objet : Résultats de contrôle qualité des antituberculeux effectués en juin 2009.
Référence : V/L n° 0119/MSP/DS/DLM/PNT

Monsieur le Directeur,

Par lettre citée en référence, vous demandez les résultats officiels des analyses effectuées sur les antituberculeux prélevés au niveau des sites sentinelles situés dans les districts de Guédiawaye, Kaolack, Touba, Richard_toll, vélingara et Kédougou.

En effet, la Direction de la Pharmacie et des Laboratoires a effectivement reçu en date du 03 décembre 2009, les bulletins d'analyse d'échantillons de médicaments d'antituberculeux des sites sentinelles qui ont fait l'objet d'un contrôle de qualité de la part du LNCM. Les résultats nous ont été transmis l'ont été sous forme de code, donc marqués du sceau de la confidentialité.

C'est pourquoi, par lettre n° 00123 du 19 janvier 2010, nous avons adressé une correspondance au LNCM, pour solliciter la levée de la confidentialité et la mise à disposition des codes correspondants. Ce que nous n'avons pas reçu à ce jour. Néanmoins, l'analyse effectuée avec les documents fournis par l'UCAD qui pilote le programme, montre des résultats tres alarmants pouvant mettre en échec les efforts du PNT. Ces résultats sont très inquiétants pour les formes combinées fixes.

C'est ainsi que pour les 12 lots analysés par les LNCM, les résultats suivants ont été enregistrés :
Pour 4 lots de formes simples à base d'isoniazide ou de rifampicine, l'identification et le dosage des principes actifs sont conformes
Tous les lots de formes fixes sont non-conformes :

1) Pour les 06 lots renfermant selon le fabricant : isoniazide, pyrazinamide, rifampicine et éthambutol :
   a. Isoniazide et pyrazinamide ne sont pas détectés ;
   b. La rifampicine est très surdosée pour les 06 lots ;
   c. L'éthambutol est très surdosée pour 3 lots sur 6.
2) Pour 2 lots renfermant selon le fabricant l'association Rifampicine, Isoniazide : il y a un surdosage en rifampicine et une absence d'isoniazide

TSVP

L'analyse croisée de ces résultats a montré quelques incohérences qu'il faudra lever par de nouvelles analyses plus complètes.

Pour des analyses plus poussées, je vous demande de faire parvenir à la DPL dans les plus brefs délais, vue l'urgence, 100 comprimés des spécialités consignées dans le tableau suivant dont les références nous ont été fourni par le responsable des sites sentinelles :

Laboratoire	molécule	Lieu de prélèvement	Numéro de lot et date de péremption
Macleods	Pyrazinamide/Isoniazide /Rifampicine/Ethambutol	Centre de santé Richard -toll	n°lot RF 816 péremption 09/2011
Macleods	Pyrazinamide/Isoniazide /Rifampicine/Ethambutol	PRA saint louis	n°lot : RF 817 péremption 09/2011
Macleods	Pyrazinamide/Isoniazide /Rifampicine/Ethambutol	District sanitaire de louga	N°de lot : RF 817 péremption 09/2011
Macleods	Pyrazinamide/Isoniazide /Rifampicine/Ethambutol	District de Ndamatou	N°de lot : RF 816 péremption 09/2011
Svizera Labs	Pyrazinamide/Isoniazide /Rifampicine/Ethambutol	Hôpital Fann	N°de lot : SL 1106 péremption 03/2010
Macleods	Pyrazinamide/Isoniazide /Rifampicine/Ethambutol	District de kedougou	N°de lot : RF 816 péremption 09/2011
Macleods	Isoniazide/Rifampicine	PRA saint louis	N°de lot : RC 807 péremption 09/2011

Vous en souhaitant bonne réception, je vous prie de croire, Monsieur, à l'assurance de ma considération distinguée.

PROFESSEUR PAPA AMADOU DIOP

Professeur Ousmar FAYE
Directeur de la Santé

Réunion pharmacovigilance du 8 Janvier 2010 (14 Participants)

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Birame	DRAME	DPL / MSP	

IEC (21 participants) Réunion Bandia Mercredi 08 Janvier

IEC Meeting January 8-2010

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Annex 9

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REPUBLIQUE DU SENEGAL
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MINISTERE DE LA SANTE
ET DE LA PREVENTION

N° 015011 / MSP/DS/DLM/PNLP

Dakar, le 31 DEC 2009

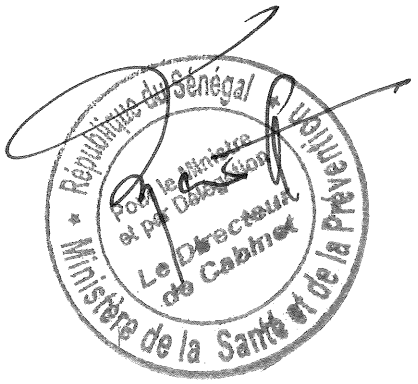
LE MINISTRE

INVITATION

Le Ministère de la Santé et de la Prévention, en partenariat avec l'USP PQM, dans le cadre de l'appui technique au programme de surveillance de la qualité des médicaments au Sénégal, vous convie à la **formation sur le contrôle de qualité** des antipaludiques, des antituberculeux et des antirétroviraux qu'il organise du **04 au 06 janvier 2010**.

Cette formation se tiendra dans les locaux du **Laboratoire National de Contrôle des Médicaments** et portera sur les techniques d'échantillonnage, les tests de base (inspection physique et visuelle, délitement et chromatographie sur couche mince) et enfin sur la gestion des données.

La participation de tous à cette importante session de formation est vivement souhaitée.



P.J. liste des participants

Farba Lamine SALL