

Medicines Quality Monitoring Program: Implementation of the New Protocol and Evaluation of Activities at Touba Site

Dakar, Senegal
April 13-20, 2009

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

Dr. Latifa El Hadri traveled to Dakar and Touba in Senegal to finalize the new protocol for medicines quality monitoring and to train a Minilab[®] team to implement the new protocol. Dr. El Hadri also met with key partners to carry out the activities in the Senegal work plan.

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Key Words

Senegal, Touba, medicines quality monitoring, training, Minilab[®], pharmacovigilance, drug quality, counterfeit drugs.

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Our gratitude goes to Dr. Pape Thior, Dr. Ibrahima Diallo, Pr. Pape Diop, Dr. Birame Dramé, Pr. Omar Gaye, Pr. Amadou Diouf, Pr. Mounirou Ciss, and all staff of the health department for their contributions and feedback on the new medicine quality monitoring (MQM) protocol.

Thanks also to the Board of Pharmacists, IEC DPL, and SNEIPS respective representatives for their contribution in the agenda of the sensitization campaign “Street Drugs Kill.”

The author is particularly grateful to USAID staff: Akua Kwateng-Addo, Debbie Gueye, Robert Perry, Matar Camara, and Ramatoulaye Dioume for their useful discussions and suggestions.

Finally, the author would like to thank Mr. Anthony Boni, Ms. Veerle Coignez, and their team in Washington, DC, for their support and advice.

ACRONYMS

ADE	Adverse Drug Event
ACT	Artemisinin-based Combination Therapy
ADR	Adverse Drug Reaction
AM	Antimalarial
CAP	Centre Anti-Poison
CAPM	Centre Anti-Poison et Pharmacovigilance du Maroc
DPL	Direction de Pharmacie et Laboratoires
DQI	Drug Quality and Information Program
IEC	Information Education and Communication
LNCM	Laboratoire National de Contrôle de Médicaments
MOHP	Ministry of Health
MQM	Medicine Quality Monitoring
MSH	Management Sciences for Health
NPVS	National Pharmacovigilance System
PEPFAR	President's Emergency Plan for AIDS Relief
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
PV	Pharmacovigilance
QAMSA	Quality of Antimalarials in Sub-Saharan Africa study
QC	Quality Control
RDT	Rapid Diagnostic Test
SNEIPS	Service National de l'Éducation et de l'Information pour la Santé
SP	Sulfadoxine-Pyrimethamine
TB	Tuberculosis
UCAD	Université Cheikh Anta Diop
USAID	United States Agency for International Development
USP	United States Pharmacopeia
WHO	World Health Organization

Background

USP DQI began working in Senegal in 2002, establishing an antimalarial (AM) medicine quality monitoring (MQM) program in five sentinel sites using Global Pharma Health Fund (GPHF) Minilab[®] kits. In 2006, the MQM program expanded to include select antibiotics and anti-tuberculosis medicines. In addition, technical assistance was provided to support the Programme National de Lutte contre le Paludisme (PNLP) in establishing a pharmacovigilance (PV) program focused on Adverse Drug Reaction (ADR) reporting of Artemisinin-based Combination Therapies (ACTs). In 2007, USP DQI helped advance Senegal's national PV program by sending the PV team to be trained at the WHO Collaborating Centre in Morocco. In 2008, DQI provided training for 2 staff from PNLN and the Université Cheikh Anta Diop (UCAD) in order to conduct a joint DQI/World Health Organization (WHO) study on the Quality of Antimalarials in Sub-Saharan Africa (QAMSA). DQI staff traveled to Dakar to discuss the results of the 2006-2007 MQM report and to provide assistance to improve the content of the report. In addition to MQM activity, USP DQI proposed holding an intra-ministerial meeting to assess the strengths and weaknesses of the existing systems. In late 2008, USP DQI coordinated a workshop in Thiés, Senegal to launch the National PV System (NPVS). DQI provided technical assistance during the workshop and recruited a WHO PV expert to recommend improvements to the existing PV system and provide a future action plan. During that trip, DQI validated the collected samples for the QAMSA study and coordinated their shipping to USP for quality control. In 2009, DQI sponsored staff from Senegal to attend PV courses (a WHO course in Sweden and a francophone course at the PV center in Morocco) and added a new sentinel site to the MQM program, further expanding the program to include anti-retrovirals and additional anti-TB medicines.

Purpose of Trip

- Finalize the protocol for medicine quality monitoring (MQM)
- Meet with PNLN, UCAD, PNLN, PNLN and LNCM to discuss implementing the protocol
- Visit Touba and train a Minilab[®] team on implementing the new protocol
- Meet with DPL director to review DPL responsibilities within MQM activities
- Meet with the Board of Pharmacists to discuss the agenda of the IEC campaign
- Meet MSH group to coordinate PV activities
- Review sentinel site activities and prepare for the next round of sampling and testing

Source of Funding

This trip was supported with funds from the USAID/Senegal Mission.

Overview of Activities

April 14, 2009: Meeting with USAID/Senegal

Participants – USAID/Senegal: Akua Kwateng-Addo, Ramatoulaye Dioume, and Matar Camara
DQI: Latifa El Hadri

Dr. El Hadri debriefed USAID staff on planned activities during her visit. She gave an overview on the status of QAMSA samples tested at USP and assured them that the final results will be communicated by June 2009.

DQI staff pointed out that two round table meetings were planned during the trip: the first to discuss the new MQM protocol and the second to discuss action plans for the national PV system. Dr. El Hadri also informed USAID staff about the visit to the Touba site.

USAID staff requested that DQI discuss with Dr. Mangane (PNLS) the list of contraceptives to be added to MQM activities at the sentinel sites.

A follow up meeting was scheduled after the completion of planned activities.

April 14, 2009: Meeting with Quality Control of Antimalarials Committee

Participants – Mr. Abdoulaye DIOP, CT/Cabinet /MSP; Dr. Ousseynou NOBA, DLM; Pr. Mounirou CISS, LNCM, Président de Séance ; Pr. Yerim DIOP, Chimie Analytique/UCAD ; Dr. Madické DIAGNE, DPL; Dr. Mamadou NDIAYE, PNA; Dr. Serigne Abdou DIAGNE, MSH/SPS ; Dr. Matar CAMARA, USAID; Dr. Robert Perry, PMI/CDC; Dr. Latifa ELHADRI, USP DQI; Dr. Ibrahima DIALLO, PNLP Rapporteur

The main objectives of the meeting were to discuss the current status of:

- AM procurement and Pharmacie Nationale d'Approvisionnement (PNA) stock
- Registered AMs
- Quality control of AMs
- Quality control of AMs at sentinel sites
- Other questions regarding the new protocol

The following is a summary of the discussions and recommendations:

PNA

- Significant decline in ACT use due to increased use of Rapid Diagnostic Tests (RDTs)
- What action to be taken for ACTs with close expiry dates?
- Insufficient quantities of ACTs to cover need during winter season
- Need to sensitize the health authority on the current status of PNA procurement
- Involve partners in a meeting to discuss and find solutions to the shortage problems
- Reception of a new batch of Duo-Cotexcin by MOH.

For the last point, a debate took place about accepting such donations if there is no need by the recipient country. It was highly recommended that donated lots should be controlled by Laboratoire National de Contrôle de Médicaments (LNCM) before authorizing their use in the market. It is also noteworthy to mention that previous donations of the same medicine did not pass QC testing at the LNCM (3 out of 5 lots did not conform, according to LNCM director).

DPL

The DPL representative informed the group that in 2009, no AM was registered. Most AMs circulating in the market (such as Coartem) were registered in 2008. For almost two years, DPL has not granted marketing authorization for mono-therapies.

LNCM

All Minilab[®] samples were submitted to LNCM for testing. All basic tests were verified. However, some samples did not conform due to:

- no lot number listed
- no manufacturer name listed
- product expired
- failure of at least one of the three basic tests

USP DQI staff pointed out that after implementing the new MQM protocol, sample identification issues will be solved, and failed tests can easily be traceable. Coding samples is one aspect that was addressed in the new protocol, and the use of a master Excel sheet will allow tracing of non-conforming samples for action to be taken by DPL.

Confirmatory testing following Minilab[®] testing showed that:

- 8 out of 10 samples of SP failed
- 4 out of 4 samples of Amodiaquine failed
- 7 out of 8 ACTs failed

Pr. Mounirou gave all QC reports to Pr. Yerim, focal point for MQM at the sentinel sites.

UCAD

Pr. Yerim reported that the 2006-2007 MQM report was shared, after edits resulting from the results presentation were included. He ensured that the new protocol and report template will help trace samples at all levels, ensuring better organization among samplers and analysts, improving reporting, and speeding up report writing and results dissemination.

In 2008, one round of activities was conducted at 6 sentinel sites; a final report is promised soon. One round of Minilab[®] activities will be conducted in 2009 that will include AMs, ARVs, and ATB drugs. This round will be conducted in collaboration with PLNT and PNLs.

Action Items

- Finalize the new MQM protocol and start implementing it during upcoming rounds
- Inform MOH and USAID of the high failure rates as well as the results of previous MQM activities

April 15, 2009: Meeting with the Board of Pharmacists

Participants: Board of Pharmacists in Senegal: Dr. Cheikhou Oumar Dia (President of National Counsel), Dr. El Hadji Malick Diop (President of Section B counsel), and Pr. Yerim Diop (Vice President of National Counsel) USP DQI: Latifa El Hadri

Use of appropriate Information, Education, and Communication (IEC) activities is an essential part of raising awareness about counterfeit/substandard drugs among target populations. Therefore, a meeting was held at the Board of Pharmacists to discuss various activities that target urban and rural areas. The agenda proposed by Dr. Dia includes TV and radio broadcasts in regional languages and dialects. It also consists of other modes of communications, such as sketches, planned outdoor activities, print media, posters, T-shirts, and a conference. DQI staff suggested that the implementation of this sensitization campaign should be prepared jointly with Service National de l'Éducation et de l'Information pour la Santé (SNEIPS) and IEC at DPL. All partners agreed to work together to finalize the proposed agenda. The final agenda, date, and location will be communicated to DQI.

April 15, 2009: Meeting at LNCM

Participants: See Annex 1

Over the years, USAID/USP DQI have made efforts to raise awareness about the seriousness of the poor quality of medicines in Senegal, the growing presence of the informal markets, and the lack of law enforcement. For action to be taken by DPL against these problems, a new MQM protocol was prepared by DQI and PNL and circulated to all partners to define their respective roles. In October 2008, a meeting was held for this purpose, and the current meeting will finalize all roles. Following the suggestions made by the group, Pr. Yerim will make the necessary corrections to logos and text and send the final protocol to all partners

Note: Dr. Madické informed Dr. El Hadri that he was unable to attend the meeting. He suggested that she discuss DPL's role at her scheduled meeting with Dr. Pape Diop on the following day.

April 16, 2009: Meeting at UCAD

Participants: Pr. Yerim Diop, Pr Mounirou Ciss, and Dr. Latifa El Hadri (Pr. Omar Gaye was unable to attend due to a conflicting meeting the same day)

Pr. Mounirou was pleased by sample identification and presentation of Minilab[®] information on the Excel sheet. He added that confirmatory testing is time consuming and there is a need for lab equipment, especially columns and glassware. A total of 147 samples were collected in 6 sentinel sites; 35 samples were tested in his lab, and 16 failed confirmatory testing. Dr. El Hadri suggested to Pr. Yerim to include these results into the master Excel sheet and to generate a report according to the new report template that was sent. Pr. Yerim stated that sampling for the next set of MQM activities will start by the end of May, and in two months, the results and report will be ready for dissemination to all stakeholders.

Dr. El Hadri informed the group that DQI is organizing a workshop in Uganda in July 2009 for countries with active drug quality monitoring programs to develop a network for sharing information. She explained that the goals of this network are to:

- Exchange and share the most up-to-date medicine quality data
- Exchange and share the most up-to-date information on product recalls and withdrawals from their respective markets, including lot numbers and manufacturers of product involved.
- Exchange and share the most up-to-date information on rogue manufacturers and suppliers
- Develop an early warning system for sharing and exchanging information on substandard and/or counterfeit products circulating in their countries
- Exchange and share information on manufacturer and supplier performance with respect to product quality.

Pr. Mounirou welcomed the idea, and he was willing to attend the workshop. Dr. El Hadri will coordinate with him for the invitation and all travel logistics.

At the end of the meeting, Pr Yerim gave Dr. El Hadri the MQM report along with an official letter addressed to the Minister of Health. Dr. El Hadri assured the group that she will give the items to Dr. Thior at her meeting the next day. Pr. Mounirou also gave the 2008 Annual Report

of LNCM activities along with a letter that addresses the needs in lab supplies, building capacity, and technical support for lab ISO 17025 certification.

April 16, 2009: Meeting at DPL

Participants: Dr. Dramé Birame, PV National Coordinator; Dr. Pape Diop, DPL Director; and Dr. Latifa El Hadri, DQI

Dr. Pape welcomed Dr. El Hadri and requested that future MQM meetings take place at DPL. He provided his remarks for the new protocol and requested that his comments be taken into consideration. He ensured that after reception of all information regarding the failed samples, action will be taken by DPL according to the cause of failure. Dr. Pape also mentioned that technical assistance is needed from DQI for drug registration and import verification for 10 pharmacists currently working at DPL.

After the meeting, Dr. El Hadri spoke with Mme Diop (in charge of IEC) and Dr Dramé to brief them on the meeting with the Board of Pharmacists. Mme. Diop provided DQI staff with a copy of a TV broadcast that was prepared by DPL and SNEIPS. IEC, SNEIPS, and the Board of Pharmacists will work together to prepare the agenda for the sensitization campaign. The final agenda was promised to be sent to DQI.

April 17, 2009: Meeting with the PNLN

Participants: Dr. Pape Thior, PNLN coordinator; Dr. Ibrahima Diallo, technical consultant and focal point of PV at PNLN; and Dr. Latifa El Hadri (DQI)

A short meeting was held at the PNLN to present the MQM report and the official letter to Pr. Thior. The latter stated that he will deliver them to the cabinet of the Minister. Dr. El Hadri showed the new confirmatory testing that was discussed previously during the committee meeting of AM quality. Dr. Thior highlighted the list of AMs that failed confirmatory testing and asked Dr. Diallo to follow up with Pr. Mounirou for relevant data on these failed lots.

April 17, 2009: Pharmacovigilance meeting at the PNLN

Participants: *See Annex 2*

In October 2008, DQI and PNLN organized a workshop to launch the National System of Pharmacovigilance (SNPV). During the workshop, an action plan was recommended by the WHO expert, PNLN PV coordinator, CAP director, and DPL representative. As a part of the action plan, DQI/USAID supported the training of two staff (one from DPL to take a WHO PV course in Sweden and one from CAP to take a francophone course and hands-on PV practice in the Center of PV in Morocco).

At the meeting, the DPL national coordinator provided an update on what was achieved on the recommended action plan at DPL level:

- PV coordinator has been nominated
- PV system that governs all health programs exists
- SNPV is an associated member of UMC
- Creation of one adverse drug event reporting form
- Creation of a PV guide

- A new decree for the national system of PV (in progress)
- Guidelines for the pharmaceutical laboratories on regulatory requirements
- Designation of PV focal point at each department of HIV and TB
- Re-organization of PV with technical responsibilities at CAP level and administrative responsibilities at DPL level
- Audit of PV system by WHO

The PV focal point informed the audience that 761 health workers were trained in reporting ADE. Dr. Diouf addressed the point of how to roll out this training to health workers and include reporting on all medicines, not only AMs.

The CAP director added that the existing PV manual needs to be harmonized with a revised reporting document. Dr. Diallo suggested approaching SNEIP for raising awareness on the importance of reporting.

In terms of reported cases, PNLN informed the audience that in 2008, 45 adverse drug events were reported: 33 on Falcimon (ACT), 7 on quinine, and 5 on other non-AM medicines. Causality assessments were performed on all 45 cases; however, these results were not submitted to UMC yet. The national coordinator preferred to wait until he received his PV training in Sweden before submitting PNLN cases and others existing at CAP to UMC via Vigiflow.

A working group will be formed that will meet once a month. DQI staff will assist the group in making a training manual and a reporting document and will assist with strategic planning for cascade training from regional to district levels, taking into consideration reporting not only for malaria, but also for other diseases, like TB and HIV.

Following this meeting, the PV national coordinator organized the first meeting of the working group in PV (*See Annex 3*). Another meeting was organized by PNPL to share their annual PV results with national PV technical committee (*See Annex 4*).

Following the meeting, Pr. Diouf gave a tour of the new CAP building to Dr. El Hadri.



New CAP building, under construction

April 18, 2009: Visit Touba

Participants: UCAD: Pr. Yerim Diop, Dr. Adama Diédhiou, and Dr. Modiane Faye; Touba Health District: Mrs. Cira and Dr. Sourang Msourang; DQI: Latifa El Hadri

Touba is located about 200 km north of Dakar. This holy city is where the tomb of Sheikh Ahmadou Bamba Mbacké, founder of the Mouridism, is located and is the nucleus of the most powerful sect in Senegal. Although Touba is a sacred place protected from corruption, it is known for a flourishing market of counterfeit and substandard medicines.



An illicit market in Touba

In Senegal, spiritual beliefs have a great impact in the local population. Political leaders at all levels try to get the blessing of the highest religious leader, El Hadji Mouhamadou Lamine Bara Mbacke, known as the Marabou of Touba. Because of his great influence on the population, Dr. El Hadri wanted to request his support to raise awareness of the dangers of the flourishing illicit market of all kinds of fake and substandard medicines in his city.

The meeting with the Marabou took place in his Zawiya (holy house) in the presence of his eldest son, Dr. Serigne Moustapha Mbacke. His son ensured the group that he will support planned activities to raise awareness about the dangers of fake drugs among the population of Touba and other cities.



Dr. El Hadri with the Serviteur du Marabou

After visiting the Marabou, Dr. El Hadri organized a session on how to implement the new MQM protocol. This session was held at the district hospital in Touba where the Minilab[®] is installed. Dr. El Hadri explained how to implement the new protocol, discussing sampling strategies – including purchasing samples from the illicit market – and explaining how to target the medicines that are most used by consumers and most recommended by retailers. After the samples are tested with the Minilab[®] and confirmed by the national lab, the resulting data will give the government of Senegal a better picture of what medicines are being consumed by the population and will help the people of the country better understand the risks that they take when purchasing medicines from the illicit market.



Minilab[®] at Touba

An overview on how to use the master Excel sheet for entering data and how to fill in the forms was given to the sentinel site team and staff from UCAD and National Lab.



Dr. El Hadri explains how to input data into the master form

April 20, 2009: Debrief with USAID/Senegal

Participants – USAID: Akua Kwateng-Addo, Debbie Gueye, Ramatoulaye Dioume, and Matar Camara; DQI: Latifa El Hadri

Dr. El Hadri met with the USAID team to brief them on her trip. The visit to Touba and the Marabou was very interesting to the team, and they welcomed the idea of seeking the support of religious leader to achieve the goal of raising awareness of faked/substandard medicines.

In terms of post-marketing surveillance, Dr. El Hadri presented the results of the confirmatory testing for the previous round. A summary report will be written by the UCAD focal point according to the new report template. Dr. El Hadri also informed them that the results were shown to the DPL director and that he asked for the full report before he takes any action.

DQI informed the USAID team about the progress achieved by DPL, PNLP, and CAP regarding PV. She pointed out that Senegal will be a full member with UMC after reporting ADRs via Vigiflow. This software is already installed at DPL, and it will be used by the PV national coordinator to report the ADRs after his training in Sweden.

DQI informed the team that DPL and LNCM expressed a need for technical assistance. DPL needs to have 10 pharmacists trained on SIAMED import verification, while LNCM needs lab training for their analysts, a review of existing SOPs, and planning for ISO 17025 certification.

The last point discussed was the budget for next fiscal year. DQI informed the USAID team that the allocated budget will not be enough to carry out MQM activities for AM, ARV, and ATB medicines in 3 new sites in addition to the 6 existing ones. The team reassured Dr. El Hadri that they will revise the budget.

After the meeting with USAID, Dr. El Hadri met with Dr. Serigne (MSH) and with Dr. Mangane (PNLS). A follow up email was sent to the USAID Mission the following day to share the outcomes with them:

- PNLS provided a list of samples and sites
- PNLS provided the prices of samples to be collected from designated sites
- MSH will coordinate with DQI on how to incorporate training in PV reporting into their planned activities

Next Steps

- Prepare and share MQM report with all stakeholders
- Follow up on failed samples
- Incorporate Dr. Pape's recommendations into the final MQM protocol
- Send the final MQM protocol to all concerned partners
- Coordinate with UCAD and LNCM the next Minilab[®] activities
- Obtain the agenda on the IEC campaign from Board of Pharmacists
- Organize IEC campaign (action to be taken by Board of Pharmacists, IEC team at DEP, and SNEIPS)
- Harmonize PV training module and reporting form
- Plan PV training at regional and district levels

15/04/09

Feuille de présence

LNCM

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Annex 1 | list of Participants at LNCM meeting.



Reunion Pharmacovigilance

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Annex 2 : List of Participants at Pharmacovigilance Meeting

REPUBLIQUE DU SENEGAL

Un Peuple -Un But- Une Foi

Dakar, le 07-05-09



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

Annex 3

*report of the 1st meeting
of Pharmacovigilance
work group.*

**DIRECTION DE LA PHARMACIE
ET DES LABORATOIRES**

**RAPPORT DE LA 1 ère REUNION DU GROUPE TRAVAIL SUR
PHARMACOVIGILANCE**

La Direction de la Pharmacie et des Laboratoires (DPL) a organisé le mardi 04 mai 2009 la réunion de partage du nouvel arrêté de pharmacovigilance.

La rencontre qui s’est déroulée dans la salle de réunion de la DPL, a démarré aux environs de 09h 30mn.

Le Directeur de la Pharmacie et des Laboratoires le Pr P.A. Diop a ouvert la réunion par des remerciements à l’endroit des participants qui ont voulu honorer la rencontre de leur présence. Après avoir formulé des mots de bienvenue aux participants, il a déroulé l’ordre du jour qui se résume en ces termes :

- Partage du nouvel arrêté de pharmacovigilance,
- Mise en place du groupe de travail,
- Calendrier de travail (méthodologie et chronogramme)
- Le financement des activités
- Divers.

Etaient présents à cette réunion technique : la DPL, le Centre Antipoison (CAP), les Programme Nationaux de Lutte contre le Paludisme et la Tuberculose (PNLP ; PNT), la Division de Lutte contre le SIDA et les Infections Sexuellement Transmissibles (DLSI), le Laboratoire National de Contrôle des Médicaments (LNCM).

La Direction de la Prévention Médicale (DPM) et la Pharmacie Nationale d’Approvisionnement(PNA) n’ont pas été représentées lors de cette réunion.

Les travaux ont démarré par une présentation du nouvel arrêté par le Dr A. Diarra/LO du bureau de la pharmacovigilance. L’arrêté n°05036 du 22 avril 2009 remplace celui n°4012 du 06 février 1998 qui a été abrogé. Par ailleurs, ce nouvel arrêté fait état de la réorganisation du

Système National de Pharmacovigilance (SNPV) et définit les rôles des différents acteurs (la DPL, le CAP, le LNCM, la Commission Nationale de Pharmacovigilance, le Comité technique, les programmes de santé,...), ainsi que la composition des différentes structures qui s'activent autour de la pharmacovigilance. La présentation a montré également le circuit de transmission de l'information dans le cadre de la notification des effets indésirables des médicaments ainsi que celle des manifestations post vaccinales indésirables. Dans ce circuit, la DPL est la structure centrale qui coordonne toutes les activités du SNPV. Le CAP est chargé d'appuyer la DPL, en assurant le fonctionnement du comité technique. Les programmes de santé, quand à elles, contribuent à la surveillance des médicaments dont elles exploitent.

A l'issue de cette petite présentation une page de discussions a été ouverte :

Dr Fall du CAP a réitéré la disponibilité du centre à travailler en étroite collaboration avec la DPL et les autres structures s'activant dans le domaine de la pharmacovigilance, par ailleurs il a partagé ses inquiétudes par rapport à la non clarification du rôle du CAP dans le circuit de notification. L'imputabilité qui est assigné au CAP apparaît dans l'arrêté et dans le circuit de notification comme étant dévolue au Comité Technique qui n'est qu'un démembrement du SNPV convoqué à la demande du CAP pour une éventuelle validation d'une imputabilité déjà établit par le centre. En outre, il a déploré l'absence de certains acteurs du niveau opérationnel ainsi que celles de certaines structures (PNA, les districts sanitaires...) à cette réunion.

Le représentant du PNLP, le Dr Diallo a évoqué les efforts consentit pour aboutir à un arrêté de pharmacovigilance qui dans le fond pose uniquement le problème d'une modalité de mise en œuvre qui pourrait empiéter l'opérationnalité du système. Il recommande une simplicité dans les procédures de pharmacovigilance pour faciliter sa mise en œuvre.

Dr Karim Diop du DLSI s'est félicité de l'acquis de ce présent arrêté qui vient de combler un gap dans le système de santé. Les ARV, du fait des procédures accélérées d'AMM, doivent être surveillés efficacement pour pouvoir prendre les mesures idoines. Dans ce cadre la DLSI est tout à fait disposé à appuyer cette pharmacovigilance notamment dans le renforcement du système de santé.

Dr Dramé, point focal de la PV a rappelé que l'arrêté est issue de l'atelier de réorganisation du SNPV qui s'est tenu à Thiès les 4, 5 et 6 juin 2008. Donc ce document juridique a d'une part, fait l'objet d'une réflexion approfondie au cours de cet atelier et d'autre part, l'objet d'envoies auprès de tous les acteurs de pharmacovigilance pour amendements. Cependant tous les feedback escomptés n'ont pas été reçus, et des contraintes juridiques et réglementaires sont intervenues lors de la finalisation de l'arrêté. Il a poursuivi en affirmant la nécessité de mettre à l'épreuve cet arrêté afin de voir les manquements pouvant faire l'objet d'une correction. Dans la partie technique, l'imputabilité est une fonction qui est assurée par le Centre Antipoison, donc il est nécessaire de faire la distinction entre le CAP et le comité technique ; en d'autres termes l'imputabilité reste propre au CAP. Par rapport aux districts qui n'ont pas été convoqués, le Dr Dramé a évoqué le problème de financement des indemnités de déplacement.

Le Dr Diagne, chef de la division du contrôle administratif des médicaments a émis l'hypothèse d'une procédure rectificative explicitant le rôle du CAP comme structure chargée de l'imputabilité. Il a également justifié le rôle de la DPL comme structure coordinatrice et carrefour de l'information dans le circuit de notification par la traçabilité de l'information sur le médicament. ✓

Concernant le financement de la PV, Dr Talla Diop du PNT, de même que ses collègues des autres programmes de santé ont indiqué qu'il y a possibilité de financer certaines activités et de les mener ensemble. Dr Dramé a rappelé la possibilité de financement par USP.

Dans la dernière rubrique des divers, le représentant du PNLP a fait état de l'AMF-m et des possibilités offertes en matière de PV. Il a invité l'assistance, à une réunion de restitution des activités de PV par le PNLP.

La suite de la réunion a porté sur les autres points de l'ordre du jour. Il a été retenu de :

- Formaliser le groupe de travail par note administrative
- Définir les termes de références du Groupe de travail,
- Décliner les stratégies et les activités de PV
- De faire une proposition de budget qui sera discutée lors de la prochaine réunion du GT
- Tenir une autre réunion technique avant fin juin

Le Rapporteur
Dr Diarra Aminata/LO, DPL

Ci-joint la liste des participants.

Liste des participants

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Dakar, le 07 MAI 2009

LE MINISTRE

CONVOCAATION

Dans le cadre de la mise en œuvre des activités de pharmacovigilance, le Programme National de Lutte contre le Paludisme, en collaboration avec les partenaires, organise une réunion de partage des résultats obtenus en 2008 avec le comité technique de pharmacovigilance.

Cette réunion se tiendra le Mercredi 13 mai 2009 à 10 heures au PNLP.

Je vous pris de prendre toutes les dispositions pour participer à cette importante rencontre.

Destinataires :

- MSPHP/Cab (1)
- CT/Pharmacie
- DS (1)
- DLM (1)
- DPL (2)
- LNCM (1)
- CAP (2)
- PNA (1)
- DPM (1)
- Service Pharmacologie UCAD (1)
- Service Parasitologie UCAD (1)
- Service Chimie Analytique UCAD (1)
- PNLP (6)
- OMS (1)
- USAID/CDC (1)
- MSH (1)
- Pr. Boubacar Camara (HEAR)
- Division Sida (1)
- PNT (1)

Ampliatiions

- MSPHP/Cab/SG



Cheikh Issa SALL