

Review of Pharmacovigilance and Laboratory Activities

Bamako, Mali
September 27–October 1, 2010

Trip Report

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Promoting the Quality of Medicines Program

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Cooperative Agreement # GHS-A-00-09-00003-00
Sponsoring USAID Missions: USAID/Mali
Grantee: Promoting the Quality of Medicines (PQM) Program
Author(s) Name: PQM Staff
Language: English
Date of Publication: November 15, 2010



This report is made possible by the generous support of the American people through the United States Agency for International Development (USAID), under Cooperative Agreement No. GHS-A-00-09-00003-00, and the President's Malaria Initiative. The contents are the responsibility of the Promoting the Quality of Medicines Program, implemented by the U. S. Pharmacopeia, and do not necessarily reflect the views of USAID or the United States Government.

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

PQM reviewed the status of the activities related to the strengthening of the Laboratoire National de la Sante (LNS) and the national pharmacovigilance (PV) program and discussed proposed activities for FY11. PQM also installed a new Karl Fischer titrator at LNS.

Recommended Citation

Dr. Mustapha Hajjou. 2010. Review of Pharmacovigilance and Laboratory Activities. Bamako, Mali; September 27-October 1, 2010. Submitted to the U.S. Agency for International Development by the Promoting the Quality of Medicines Program. Rockville, Maryland: United States Pharmacopeia.

Key Words

Pharmacovigilance, training, medicine quality, antimalarials, postmarketing surveillance, Minilab[®], quality systems, Mali

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ACKNOWLEDGEMENTS

I would like to thank:

- Pr. Benoît KOUMARE, Director General of LNS, for his support and assistance during the trip
- Pr. Ousman DOUMBIA, Director of DPM, for his availability and support of the program
- PMI team at USAID/Mali for their support, especially Dr. Sixte ZIGIRUMUGABE, PMI Malaria Advisor/Program Coordinator-Health Team, and Dr. Aboubacar SADOU, PMI Advisor-Health Team
- Dr. Daouda M. TOURE, DPM focal point for pharmacovigilance activities, for coordinating all the meetings
- Dr. Modibo KEITA, CNAM focal point for pharmacovigilance, for his availability
- PQM administrative staff and editors for their assistance with logistical arrangements and for editing the trip report
- Mr. Anthony BONI and Ms. Maria Miralles at USAID/Washington for their support

ACRONYMS

ADE	Adverse drug event
CDC	U.S. Centers for Disease Control and Prevention
CNAM	Centre National d'Appui pour la Lutte Contre la Maladie
CNRP	Centre National de Référence de Pharmacovigilance
DQI	Drug Quality and Information Program
DPM	Direction de la Pharmacie et du Médicament
FDC	Fixed dose combinations
GLP	Good Laboratory Practices
HPLC	High Performance Liquid Chromatography
LNS	Laboratoire National de la Santé
MOH	Ministry of Health
MQM	Medicine Quality Monitoring
NAMCOL	Network of African Medicines Control Laboratories
PMI	President's Malaria Initiative
PNLP	Programme National de Lutte contre le Paludisme
PQM	Promoting the Quality of Medicines Program
PV	Pharmacovigilance
QA	Quality Assurance
QC	Quality Control
TLC	Thin Layer Chromatography
USAID	United States Agency for International Development
USP	United States Pharmacopeia
WHO	World Health Organization

Background

The U.S. Agency for International Development (USAID) and U.S. Pharmacopeia (USP) have been assisting the Ministry of Health (MOH) of Mali in strengthening the medicine quality assurance systems, first through the USP Drug Quality and Information (DQI) program and, currently, through the Promoting the Quality of Medicines (PQM) program. Activities focus on strengthening the capacity of the Direction de la Pharmacie et du Médicament (DPM) and Laboratoire National de la Santé (LNS) in pharmacovigilance (PV), drug registration, and medicine quality control.

In 2009, following an assessment of Mali's quality assurance (QA) and quality control (QC), PQM facilitated a workshop to establish a national PV system, conducted a training workshop on drug registration and drug import verification using World Health Organization's (WHO) SIAMED software, and provided training to the staff of LNS medicine QC laboratory. The training covered good laboratory practices (GLP) and testing antimalarial samples using high performance liquid chromatography (HPLC) and dissolution. PQM has since provided refresher training in dissolution, conducted an inventory of lab equipment and supplies, and reviewed the lab quality manual and procedures.

In 2010, in collaboration with LNS, PQM established a postmarketing surveillance program focused on the monitoring of antimalarials quality. In addition to Bamako, the program involves seven regions where samples of antimalarials are collected and tested using Minilabs[®].

Purpose of Trip

Dr. HAJJOU traveled to Bamako, Mali, to review data from the sentinel sites, install a Karl Fischer titrator at LNS, and discuss planned activities for PV. Dr. HAJJOU also helped another PQM team organize a meeting of the Network of African Medicines Control Laboratories (NAMCOL). The NAMCOL meeting is discussed in a separate trip report.

Source of Funding

This trip was funded by USAID/Mali through the President's Malaria Initiative (PMI).

Overview of Activities

Discussing and Planning Pharmacovigilance Activities

Dr. HAJJOU met at LNS with Dr. Modibo KEITA, focal point of PV Technical Activities, at the Centre National d'Appui pour la Lutte Contre la Maladie/Centre National de Référence de Pharmacovigilance (CNAM/CNRP) to discuss planned activities. Dr. HAJJOU inquired about CNAM's planned PV activities, other than those that PQM was proposing, for which funding was secure. Dr. KEITA indicated that CNAM will plan activities complementary to the activities planned with PQM.

Dr. HAJJOU also attended a meeting at DPM with the Director, Pr. Ousmane DOUMBIA, and Dr. Daouda TOURE, focal point for PV, to discuss PV activities. CNRP has started receiving adverse drug event (ADE) reports, but the reports cannot be analyzed because there is a lack of expertise in causality assessments. Dr. HAJJOU indicated that PQM will facilitate intensive training of Dr. Modibo KEITA from CNRP in causality assessments and the use of Vigiflow software.

Pr. DOUMBIA stressed the need for those responsible for PV activities to be more engaged in order for the activities to advance and said that Dr. TOURE will prepare a budget for establishing regional and

local committees with well defined objectives. Dr. HAJJOU inquired about the precise roles and responsibilities of these committees, stressing that the flow of ADE reporting should be simplified and go directly to CNRP. The participants agreed that the Ministerial decree N° 224 GS-MS, which stipulates the procedures for the implementation of the national PV program, needed revision to clarify the roles and responsibilities of the key players as well as the flow of information and reports throughout the system. This includes, in addition to DPM and CNAM, the national committee and technical committee of pharmacovigilance, as well as the regional and local committees.

Medicines Quality Control Activities

Dr. HAJJOU met with Pr. Benoît COUMARE, the General Director of LNS, and discussed the progress of the antimalarial testing at the sentinel sites. Pr. KOUMARE indicated that the testing was completed at four of the eight sentinel sites, with the remaining testing nearing completion. Dr. HAJJOU had the opportunity to review reports from two sentinel sites, Gao and Ségou. He urged Pr. KOUMARE to have the lab verify and confirm the Minilab[®] results as quickly as possible.

During this visit, Dr. HAJJOU assisted a PQM team with organizing the second statutory meeting of NAMCOL. The review of the report from LNS on the inter-laboratory testing showed the impact of the training that PQM provided to the lab staff and also revealed the areas where the lab needed improvement. Pr. KOUMARE and Dr. HAJJOU agreed that specific interventions were needed to revamp the quality control section of LNS, including strengthening technical capacity by providing training and follow-up, as well as strengthening the quality system.

Dr. HAJJOU also installed a new Karl Fischer titrator at LNS. He inquired about the reagents for the titrator and suggested ordering new ones. PQM will plan training for the lab staff in Karl Fischer titration, to be scheduled according to the anticipated date of receiving the reagents.

Debriefing USAID/Mali

Dr. HAJJOU debriefed Dr. Sixte ZIGIRUMUGABE and Dr. Aboubacar SADOU on the activities he carried out during this trip, indicating the success and the positive outcome of the NAMCOL meeting.

Regarding pharmacovigilance, Dr. HAJJOU indicated that there is lack of clarity in the roles and responsibilities of DPM and CNAM. Dr. ZIGIRUMUGABE expressed the need for the revision of the ministerial decree N° 224 SG-MS.

Next Steps

By early 2011:

- PQM will propose detailed changes to the ministerial decree N° 224 SG-MS and share them with key players including DPM, CNAM, and all the members of the national committee of pharmacovigilance for discussion
- PQM will organize a workshop to revise the ministerial decree N° 224 SG-MS
- LNS and PQM will put in writing a comprehensive implementation plan to strengthen the lab technical and managerial capacities
- LNS will submit the annual report on MQM activities to PQM