

# Monitoring and Evaluation of Minilab<sup>®</sup> Activities at Selected Sentinel Sites, and Discussion of SURE/NDA activities

Kampala, Uganda  
September 22-25, 2010

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## *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/Uganda  
**Grantee:** Promoting the Quality of Medicines (PQM) Program  
**Author(s) Name:** PQM Staff  
**Language:** English  
**Date of Publication:** November 1, 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 through the President's Malaria Initiative (PMI). 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, PMI, 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**

Dr. El Hadri traveled to Kampala, Uganda September 22-25, 2010, to monitor and evaluate Minilab<sup>®</sup> activities at selected sentinel sites. During this trip, Dr. El Hadri also met with Dr. Birna Trap, Chief of Party of the SURE project, to discuss DQI/ PQM initiated projects and how to assist SURE in carrying out future activities with NDA.

## **Recommended Citation**

El Hadri, Latifa. 2010. *Monitoring and Evaluation of Minilab Activities at Selected Sentinel Sites, and Discussion of SURE/ NDA activities*. Kampala, Uganda: September 22-25, 2010. Submitted to the U.S. Agency for International Development by the U.S. Pharmacopeia Promoting the Quality of Medicines Program. Rockville, Maryland: United States Pharmacopeia.

## **Key Words**

Uganda, USAID, SURE program, monitoring and evaluation, Minilab<sup>®</sup>, counterfeit/substandard, sentinel sites.

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## ACKNOWLEDGEMENTS

I would like to thank:

- USAID/ Uganda for their financial support, valuable communications, and the extra time they dedicated for briefing PQM staff on their bilateral activities with the SURE program.
- The Executive Secretary/Registrar of the National Drug Authority (NDA), the Head of the National Control Laboratory, and their staff for their hospitality and for facilitating the monitoring and evaluation missions to the sentinel sites.
- The Chief of Party of the Securing Ugandan's Right for Essential Medicines (SURE) project for sharing with PQM staff SURE/NDA activities and for discussing ways of collaboration to ensure the continuation of DQI/PQM initiated activities.
- The regional inspector and Minilab<sup>®</sup> team for their hospitality and the coordination of travel logistics to Hoima sentinel site.
- Mr. Anthony Boni and Ms. Maria Miralles and their team in Washington, D.C., for their support and advice; and,
- The PQM administrative staff and editors for their assistance with logistical arrangements and for editing this report.

## ACRONYMS

|        |  |
|--------|--|
| COP    | Chief of Party   |
| DID    | Drug Information Department                              |
| DQI    | Drug Quality and Information Program                     |
| ESR    | Executive Secretary/Registrar                            |
| MQM    | Monitoring the Quality of Medicines                      |
| NDA    | National Drug Authority                                  |
| NDQCL  | National Drug Quality Control Laboratory                 |
| PQM    | Promoting the Quality of Medicines Program               |
| PMI    | President's Malaria Initiative                           |
| PV     | Pharmacovigilance  |
| SIAMED | WHO Model System for Computer-assisted Drug Registration |
| SURE   | Securing Ugandans' Right for Essential Medicines         |
| TLC    | Thin Layer Chromatography                                |
| UMSP   | Uganda Malaria Surveillance Project                      |
| USAID  | United States Agency for International Development       |
| USP    | United States Pharmacopeia                               |
| UV     | Ultra-Violet Spectroscopy                                |

## **Background**

The U.S. Agency for International Development (USAID) and the U.S. Pharmacopeia (USP) have been providing technical assistance to Uganda since 2006, first through the USP Drug Quality and Information (DQI) program and, currently, through the Promoting the Quality of Medicines (PQM) program, to strengthen its medicines quality control and quality assurance systems. In the past four years, DQI/PQM has trained National Drug Quality Control Laboratory (NDQCL) staff on laboratory techniques, helped establish a Medicine Quality Monitoring (MQM) program, and provided technical assistance regarding drug registration and import verification. DQI/PQM also supported Uganda's participation in the ground-breaking Quality of Antimalarials in Sub-Saharan Africa (QAMSA) study.

## **Purpose of Trip**

PQM staff traveled to Uganda to:

- Meet with Securing Ugandan's Right for Essential Medicines (SURE) project Chief of Party (COP) and NDA focal point to discuss ways forward for Minilab<sup>®</sup> activities
- Review sentinel site reports and provide guidelines/recommendations
- Monitor and evaluate Minilab<sup>®</sup> activities at one or two sentinel sites
- Review the implementation of the new protocol
- Conduct a working session on managing reported Minilab<sup>®</sup> data and the results of confirmatory testing
- Provide operational tools in light of the findings
- Debrief USAID/Uganda

## **Source of Funding**

This trip was supported with funds from USAID/Uganda, through the President's Malaria Initiative (PMI).

## **Overview of Activities**

### ***Meeting with USAID/Uganda***

Dr. El Hadri met with Dr. Gunawardena Dissanayak, PMI Uganda focal point, and Mr. Joel Kisubi, Program Manager Specialist, and shared with them the planned activities of her visit (see trip agenda in *Annex 1*). After this introduction, Dr. Dissanayake gave an overview of SURE/NDA activities. This program was established in July 2009 and includes PMI activities that were supported previously by DQI/PQM. Dr. Dissanayake underlined the importance of these activities and requested PQM staff to share past and ongoing activities with Dr. Birna Trap and discussed ways of collaborating to implement the SURE/NDA work plan. At the end of this meeting, Dr. El Hadri informed USAID that NDA submitted the report of antimalarial MQM, which started in 2008. She pointed out that this is the only report that has been provided by NDA since the start of Minilab<sup>®</sup> activities.

### ***Meeting with SURE COP, Management Sciences for Health Office, Kampala, Uganda***

Dr. El Hadri met with Dr. Trap and briefed her on the PMI-funded activities that were supported by DQI/PQM. She also shared the challenges that the NDA is facing in completing the planned activities in pharmacovigilance and postmarketing surveillance. Dr. Trap mentioned that she was pleased with the technical assistance and recommendations that DQI/PQM provided to the NDA following interventions in strengthening NDA registration and laboratory capacities.

Dr. Trap presented the SURE/NDA 2010-2014 work plan and pointed out that the areas where PQM can continue to provide support. These areas include strengthening quality control for antimalarials and other medicines, improving quality of reporting in pharmacovigilance, and evaluating future NDA IT requirements and specifications. To better assist the NDA in implementing the five-year work plan, both parties agreed to have a meeting with Mr. Apollo and his staff on the following day.

***Meeting with SURE COP, NDA Executive Secretary/Registrar***

Mr. Apollo welcomed the group and gave a short summary of NDA and DQI/PQM supported activities since 2007. Currently, these activities are managed by the SURE program. Mr. Apollo and Dr. Trap expressed the need to continue collaborating with PQM.

Following Mr. Apollo’s remarks, Dr. Trap opened the floor to discuss ways of collaborating with PQM in implementing the five-year SURE/NDA work plan, particularly in the area where DQI/PQM used to provide assistance. Suggestions included providing monitoring and evaluation of Minilab® activities at the sentinel sites level, expanding Minilab® activities to other medicines, assisting in requirement specifications for computerized registration systems, and assisting NDQCL in gaining ISO 17025 accreditation.

At the end of the meeting, Mr. Apollo and Dr. El Hadri agreed to communicate via email after each party consulted with their respective team.

***Meeting at the National Quality Control Laboratory***

This meeting was attended by Dr. El Hadri; Dr. Anthonia Nakamya, head of NQCL; Annet Ssenkindu, senior lab analyst; Kamiat Lutaaya, lab analyst; and David Ekau, NDA inspector. The main purposes of this meeting were to discuss the results of the report and the challenges faced and to provide recommendations on improving future MQM activities.

The main outcomes of revising the protocol are summarized in the following table:

| <b>Protocol Guidelines</b>           | <b>Report Findings</b>   | <b>Ways Forward</b>   |
|--------------------------------------|--|---|
| Sampling strategies/<br>distribution | <p>Protocol not complied with, resulting in:</p> <ul style="list-style-type: none"> <li>• Huge discrepancy in sampling distribution. Number of samples collected from the public sector (214) vs. private (7)</li> <li>• Considerable variation in number of samples collected from each site. Tororo (46) vs. Kamapla (11)</li> <li>• No description of sample distribution</li> </ul> <p>Conclusion: this report may not reflect an accurate picture of the quality of</p> | <p>Sampling strategies should take into consideration the levels of distribution (manufacturers, central warehouse, wholesalers, regional warehouses, public and private hospitals, retailers, etc.).</p> <ul style="list-style-type: none"> <li>• Number of samples to be collected: ideally 100 samples per site</li> <li>• Sample diversification</li> </ul> |

|                   |  |   |
|-------------------|--|---|
|                   | antimalarials circulating at sentinel sites.   |   |
| Sample code       | Several sample codes were used at each sentinel site.  | Harmonization of sample code to permit sample traceability for getting more samples for compendial testing and/or for action to be taken in case the sample is found to be nonconformant.   |
| Sample collection | Inspectors were involved in sample collection, resulting in biased sampling (most retailers know the inspectors and will either hide bad samples or give away good samples). | Use of analysts from the lab and/or mystery shoppers.   |
| Sample handling   | Tested samples at sites were not sent to NQCL with their collecting forms and TLC plates.  | Proper sampling handling and storage is important for further testing and for verifying medicines information, if needed.   |
| Testing           | Some TLCs were not labelled properly and were not spotted according to the training. This may result in inaccurate interpretation of TLC test results.                       | Some samples were tested onsite and proper TLC plate spotting and recording information methods were shown to the team.   |
| Reporting         | Raw data on an Excel spreadsheet was not presented with the report.<br><br>Registration statuses were not captured   | Use of a spreadsheet will allow exploration of other findings on collected medicines and enable action to be taken on failed samples.<br><br>Registration status should be captured to permit NDA to know which medicines are illegally sold on the market. |

Positive action taken during the course of this round includes the recall of 8 failed products: 1 Arsuamoon (aretsunate amodiaquine), 2 Amodiaquines, 3 quinines, 1 Malarone (Atovaquone and Proguanil hydrochloride), and 1 Rimodar (sulfadoxine-pyrimethamine). Five out of these failed samples were found at the Lira site. This could be explained by the proximity of this region to the border with Sudan where monotherapies may be smuggled into Uganda. Thus, there is an urgent need to expand MQM activities to this region.

### ***Monitoring and Evaluation of Minilab<sup>®</sup> Activities at Sentinel Site Hoima***

This M&E session was planned to identify major gaps in the implementation of the protocol at level 1, testing collected samples using Minilab<sup>®</sup> basic kits. The session was held at the Hoima sentinel site and was attended by two analysts from the NQCL and two NDA inspectors.



Antimalarial samples from nearby private outlets were procured by Dr. El Hadri and one NCQL analyst. The office of the NDA officer was cleared of some equipment so that the group could use his desk to test the samples. Chemicals were handled on a separate table outside the office. Local TV journalists were informed, and they asked questions about the importance of NDA/PQM activities in testing medicines from the market.

PQM staff supervised the testing and provided recommendations to effectively conduct subsequent rounds of MQM activities.

The results of samples tested during this session revealed that one sample of quinine failed visual inspection and one sample of sulfadoxine-pyrimethamine needed to undergo dissolution testing at the national lab.

The whole team further agreed to have refresher training in testing so that the protocol will be followed to ensure quality results and reporting in a timely manner.

### **Next Steps**

- PQM will share the M&E findings and trip report with relevant partners
- PQM will have internal discussions on how to collaborate with NDA in implementing the SURE program after consulting with USAID/Uganda and SURE Program COP

**PQM Tentative Agenda**  
***Kampala, Uganda: September 22-25, 2010***

| <b>September, 2010</b>  | <b>Location</b>     | <b>Purpose</b>  |
|-------------------------|---------------------|---|
| <i>22<br/>Morning</i>   | USAID/Uganda        | <ul style="list-style-type: none"> <li>• Debrief USAID/Uganda</li> </ul>  |
|                         | SPS                 | <ul style="list-style-type: none"> <li>• Meet Sure project team and discuss Sure/NDA activities</li> </ul>  |
| <i>22<br/>Afternoon</i> | NDA                 | <ul style="list-style-type: none"> <li>• Continue discussion on Sure/NDA activities</li> </ul>  |
| <i>23</i>               | NDA                 | <ul style="list-style-type: none"> <li>• Review sentinel sites report/provide guidelines/recommendations</li> <li>• Review the implementation of the new protocol guidelines and evaluation of ongoing Minilab<sup>®</sup> activities</li> </ul>  |
| <i>24</i>               | Sentinel site visit | <ul style="list-style-type: none"> <li>• Monitoring and evaluation of Minilab<sup>®</sup> activities on site (Sentinel site TBD by NDA)</li> <li>• Conduct a working session on how to manage reported Minilab<sup>®</sup> data and the results of confirmatory testing.</li> <li>• Debrief USAID/Uganda</li> </ul> |
| <i>25</i>               | Sentinel site visit | <ul style="list-style-type: none"> <li>• Monitoring and evaluation of Minilab<sup>®</sup> activities on site (site TBD by NDA)</li> <li>• Provide operational tools in light of the M&amp;E findings</li> </ul>   |