

Establishment of an Antimalarial Medicines Quality Monitoring (MQM) Program and Assessment of a Nigerian National Drug Quality Control Laboratory

Lagos, Nigeria
June 17–22, 2013

Trip Report

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Executive Summary

In June 2013, members of the Promoting the Quality of Medicines (PQM) program staff traveled to Lagos, Nigeria, to conduct training to establish a medicines quality monitoring (MQM) program in Nigeria and to assess the quality management system of the National Agency for Food and Drug Administration and Control (NAFDAC) quality control laboratory.

To prepare for the medicines quality monitoring (MQM) program that was being established in Nigeria, PQM staff trained 23 individuals—14 from NAFDAC, 4 from the Federal Medical Store, and 5 from the National Product Supply Chain Management Program/Food and Drug Services—on both the theory and practical aspects of conducting basic tests using the Global Pharma Health Fund Minilab[®] to screen the quality of antimalarial medicines. The training covered correct and effective sampling methods, proper documentation of processes, and effective testing of products. With key input from the participating partners, the group developed an MQM protocol that outlined the steps and activities involved in the program.

By the end of the training, participants were fully competent in the three primary aspects of Minilab[®] testing: Visual and physical inspection, thin-layer chromatography (TLC), and simple disintegration. They also understood the importance of implementing MQM according to the protocol developed in order to conduct unbiased, representative sampling as well as documenting samples and testing in order to produce reliable and valid results.

In addition, two PQM quality assurance specialists assessed the QMS of NAFDAC's Yaba Central Drug Quality Control Laboratory according to ISO 17025 standards to evaluate its readiness to achieve ISO/IEC 17025:2005 accreditation and pursue prequalification status with the World Health Organization (WHO) Prequalification Programme. Results of the assessment and suggested next steps have been provided to the relevant parties. PQM will provide NAFDAC technical assistance to implement any corrective actions and to continue strengthening its QMS.

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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 U. S. Pharmacopeial Convention (USP). PQM is USAID’s response to the growing challenge posed by the proliferation of counterfeit and substandard medicines. By providing technical assistance to developing countries, PQM helps build local capacity in medicine quality assurance systems, increase the supply of quality medicines to priority USAID health programs, and ensure the quality and safety of medicines globally. This document does not necessarily represent the views or opinions of USAID or the United States Government. It may be reproduced if credit is given to PQM and USP.

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- PQM administrative staff and editors for their assistance with logistical arrangements and for editing the trip report

ACRONYMS

ACT	Artemisinin-based Combination Therapy
FDC	Fixed Dose Combinations
FDS	Food and Drug Services
FMOH	Federal Ministry of Health
GPHF	Global Pharma Health Fund
HPLC	High Performance Liquid Chromatography
ISO	International Organization of Standardization
KF	Karl Fischer Titration
NAFDAC	National Agency for Food and Drug Administration and Control
NPSCMP	National Product Supply Chain Management Program
PMI	President's Malaria Initiative
PQM	Promoting the Quality of Medicines Program
PV	Pharmacovigilance
QA	Quality Assurance
QC	Quality Control
QMS	Quality Management System
SOP	Standard Operating Procedure
SP	Sulfadoxine-Pyrimethamine
TLC	Thin Layer Chromatography
USAID	United States Agency for International Development
USP	U. S. Pharmacopeial Convention
UV	Ultraviolet Spectrophotometer
WHO	World Health Organization

Background

In 2012 the United States Agency for International Development (USAID) and President's Malaria Initiative (PMI) selected the Promoting the Quality of Medicines (PQM) program, implemented by the U.S. Pharmacopeial Convention (USP), to provide technical assistance to the National Agency for Food and Drug Administration and Control (NAFDAC) and the National Malaria Control Program (NMCP) of Nigeria.

PQM conducted a rapid assessment of the quality assurance and quality control (QA/QC) capabilities of Nigeria's National Malaria Control program and the National Agency for Food and Drug Administration and Control (NAFDAC) in April 2013, and held discussions with stakeholders on ways to strengthen the quality assurance of medicines, in general, and antimalarials, in particular.

Following these discussions, a work plan was developed identifying the main activities on which PQM will focus its technical assistance: Assessing the NAFDAC quality control lab, establishing a Medicines Quality Monitoring (MQM) program, and assisting national health programs to develop an integrated quality assurance policy to comply with requirements of The Global Fund to Fight AIDS, Tuberculosis and Malaria (GFATM).

NAFDAC is aiming to achieve ISO 17025:2005 accreditation and World Health Organization (WHO) Prequalification (PQ) status, enabling its quality control laboratory to meet international standards of operations in order to produce trustworthy and valid results. By establishing an MQM system with the NMCP, the agency also plans to build a post-marketing surveillance program to help ensure the quality of medicines circulating in the Nigerian markets and better protect the health of the general public.

Purpose of Trip

- Establish a medicines quality monitoring program for antimalarial medicines; conduct training on basic tests; and, work with MQM partners to draft an MQM program plan
- Work with National Products Supply Chain Management Program and national health programs for malaria, tuberculosis, and HIV to discuss developing a national quality assurance policy that complies with GFATM requirements and put it in place
- Conduct an assessment of the quality management system of the NAFDAC pharmaceuticals quality control lab and present an overview of the assessment findings to WHO and NAFDAC management

Source of Funding

These activities were supported by USAID/Nigeria through PMI.

Overview of Activities

Establishing a national Quality Assurance Policy for malaria, TB, and HIV control programs to comply with GFATM requirements

During the PQM assessment of quality assurance and quality control (QA/QC) capacities of the National Malaria Control Program (NMCP) conducted in April 2013, NMCP expressed the need for assistance in establishing a quality assurance policy to comply with requirements of The Global Fund to Fight AIDS, Tuberculosis and Malaria (GFATM or Global Fund). The Global Fund asked the NMCP, as its principal recipient, to start implementing QA measures to comply

with the GFATM policy; NMCP has allocated a limited budget for these QA activities. NMCP identified the QC laboratory of Singapore as the one to be used for testing its antimalarial medicines samples. During the stakeholders meeting organized by PQM in April 2013, PQM and NMCP agreed that establishing a QA policy would be considered a high priority.

Following the assessment, the Country Coordinating Mechanism (CCM) of the Global Fund asked PQM and the USAID/Nigeria Mission to expand support of the QA policy to also include the national TB and HIV control programs, both of which are also receiving GFATM funds. The NMCP and CCM suggested that the Ministry of Health's National Products Supply Chain Management Program (NPSCMP) play a coordinating role during the process of developing a single, integrated National QA Policy that encompasses all three health programs in Nigeria.

QA Policy Workshop

Dr. Abdelkrim Smine, PQM Consultant, organized a workshop attended by forty participants from the following agencies:

- Federal Ministry of Health
- National Products Supply Chain Management Program (NPSCMP)
- Malaria, Tuberculosis (TB), and HIV Control Programs
- Country Coordinating Mechanism (CCM) of The Global Fund
- Local Funding Agent (LFA) of The Global Fund
- UNICEF
- National Agency for Food and Drug Administration and Control (NAFDAC)
- Central Medical Store

Activities and Outcomes

- Dr. Smine presented an overview of the scope of the quality assurance policy and the objectives of each of its components. He emphasized the need for all involved institutions to work together with clearly assigned roles and responsibilities.
- The meeting was then opened to all participants for discussion and questions. The fruitful discussion helped participants to better understand the challenges as well as the benefits of establishing and implementing a comprehensive quality assurance policy.
- The participants agreed on the roles and responsibilities of each partner in the process of developing and implementing the QA policy.
- A focal point from each partner institution was identified.
- Dr. Smine introduced and the group adopted a template for drafting the QA policy.
- All participants agreed that Section 1 (introduction and generalities about each program) and Section 2 (selection, procurement, storage and distribution of each program's medicines and diagnostics) should be completed by June 30, 2013.
- Under the coordination of NPSCMP, the first drafts are expected to be shared and discussed at a meeting scheduled for July 8, 2013.
- PQM recommended that all health programs implement QA activities in parallel with working to establish a national QA policy.
- PQM will continue to assist NMCP with its planned QA activities, and suggested they start by collecting antimalarial medicines samples from central warehouses and sending them for testing to the selected QC lab in Singapore.

Minilab[®] Training

Item	Description
Specific Objectives/ Expected Outcomes	<ul style="list-style-type: none"> • PQM presentations on aspects involved in establishing a medicines quality monitoring program • Training of participants in the use of Minilab[®] • Training on sampling of antimalarial medicines for the MQM program • Draft of an MQM protocol document developed by the trainees and PQM
Venue/Location	NAFDAC Central Laboratory Complex, Oshodi, Lagos Nigeria
Organizers and Sponsors	NAFDAC, NMCP, PMI/USAID, PQM
Trainers and Facilitators	<ul style="list-style-type: none"> • Mustapha Hajjou, PQM • Karim Smine, PQM • Lukas Roth, PQM
Trainees	<ul style="list-style-type: none"> • Staff from NAFDAC (14), Federal Medical Store (4), and NPSCMP/ Food and Drug Services (5) trained on the theoretical and hands-on components of Minilab[®] <p>See Participant List in Annex 1 for detailed information.</p>
Agenda	See Agenda in Annex 2 for detailed information.
Opening Ceremony	<ul style="list-style-type: none"> • Dr. Paul Orhii, NAFDAC • Ms. Stella Denloye, NAFDAC • Dr. Abdelkrim Smine, PQM • Dr. Mustapha Hajjou, PQM
Modules	<ul style="list-style-type: none"> • Introduction to Basic Tests • Sampling Guidelines • Physical/Visual Inspection (theory and hands-on) • Simple Disintegration • Thin-Layer Chromatography
Closing Ceremony	<ul style="list-style-type: none"> • Presentation of training certificates to participants <ul style="list-style-type: none"> – Dr. Mustapha Hajjou, PQM
Equipment Provided	<ul style="list-style-type: none"> • Consumables and some reference standards needed for training • See Annex 3 for detailed list of supplies/reagents/equipment provided.
Training Evaluation	See participant evaluations of each module in Annex 4 .
Outcomes/Conclusion	<ul style="list-style-type: none"> • Participants now have comprehensive knowledge in testing the seven most common antimalarial active pharmaceutical ingredients (APIs) included in Nigeria's essential medicines list (Amodiaquine, Artemether-Lumefantrine, Artesunate, Quinine, Sulfadoxine-Pyrimethamine) • Logistical issues that resulted in the delay of the six Minilabs[®] procured for MQM sentinel sites will need to be resolved to ensure efficient delivery of future supplies and equipment
Next Steps	<ul style="list-style-type: none"> • Finalize MQM protocol and disseminate to relevant implementing staff • Finalize budget for MQM Round 1 • Facilitate MQM Round 1 – October 2013 • Generate report from MQM Round 1 – December 2013

Development of MQM Protocol

Representatives of the stakeholders in the MQM program in Nigeria, which included all the participants of the Minilab[®] training, met to develop the MQM protocol for sampling and testing medicines in Nigeria. The National Malaria Control Program, NAFDAC, National Product Supply Chain Management Program/Food and Drug Services Department, Federal Medical Store, and PQM participated as stakeholders.

The stakeholders defined the following elements of the protocol:

Main objective:

- Monitoring the quality of AM in the market

Specific objectives:

- Align MQM with the national quality assurance policy for antimalarial medicines
- Use basic tests as a screening tool in the quality control approach
- Demonstrate that MQM can be effective in assuring the quality of antimalarial (AM) and other medicines
- Use MQM to build quality control capacity at the peripheral level

Roles and responsibilities of stakeholders:

Stakeholder	Role and Responsibilities
NMCP	<ul style="list-style-type: none">• Align MQM with QAP of NMCP• Coordinate sampling of AM medicines with other MQM partners• Contribute to supervisory role/monitoring and evaluation (M&E) of MQM program• Mobilize needed resources to implement and maintain the MQM program• Share medicines quality reports with appropriate stakeholders
NPSCMP/FDS	<ul style="list-style-type: none">• Contribute to sampling and testing of antimalarial medicines• Mobilize resources• Contribute to data reporting• Contribute to supervisory/M&E
Federal Medical Store	<ul style="list-style-type: none">• Contribute to the sampling and testing of antimalarial medicines• Contribute to data reporting
NAFDAC	<ul style="list-style-type: none">• Coordinate with NMCP on all aspects of MQM• Conduct sampling and screening• Conduct confirmatory testing• Provide supervisory/M&E oversight• Mobilize resources• Finalize MQM report
PQM	<ul style="list-style-type: none">• Coordinate with MQM partners• Provide technical assistance needed to support MQM• Mobilize resources• Provide supervisory/M&E oversight• Contribute to review of reports

Other elements of the MQM protocol will be finalized during a meeting of local MQM partners.

The stakeholders also agreed on the following timeline for MQM activities.

Activity	Responsible Organization	Target Date–Completion
Work with Nigerian customs to clear and deliver Minilabs [®]	NAFDAC	Ongoing
Plan meeting of local MQM partners to develop MQM budget, designate sentinel sites focal points, and decide on the exact sites where the Minilab [®] kits will be based	NMCP to call meeting in Abuja	July 4, 2013
Install Minilabs [®]	NAFDAC	July 19, 2013
Finalize sampling plan for all sites	All MQM partners	July 19, 2013
Finalize logistical plan and budget	MQM partners	July 26, 2013
Begin MQM Round 1		July 31, 2013
Complete MQM Round 1		September 30, 2013

Assessment of NAFDAC Yaba Laboratory QMS

During this trip, a separate team of PQM quality assurance specialists evaluated the quality management systems of NAFDAC’s Central Drug Quality Control Laboratory of Yaba by performing a mock assessment (similar to an audit) according to the international accepted standards of ISO/IEC 17025:2005. The goal for the NAFDAC lab is to obtain ISO/IEC 17025:2005 accreditation and to be added to the list of medicine quality control (QC) laboratories by the WHO Prequalification Programme. Attaining working conditions that conform to these stringent standards will assure that the administrative and technical operations of the laboratory are functioning at the highest internationally-recognized standards, which will provide Nigeria’s Ministry of Health with a QC laboratory capable of producing accurate and valid results.

Meetings with USAID/Nigeria Mission

Briefing

- Dr. Smine initially met with Mrs. Celeste Carr and Dr. Uwem Inyang of the USAID/Nigeria Mission on Monday, June 17, to brief them about PQM activities. He presented an overview of the workshop being held to establish a unified national quality assurance policy for all health programs and detailed the process, roles, and responsibilities of all involved parties.
- Dr. Smine emphasized the importance of assisting the health programs to quickly comply with GFATM requirement, which became mandatory in 2009. Failure of Global Fund recipients to implement QA measures may jeopardize future funding and potentially put millions of Nigerian patients at the risk of not having adequate treatment.
- Dr. Smine asserted that the USAID funding allocated to PQM would not be sufficient to provide other health programs the technical assistance needed. He suggested that the PMI team discuss gaining additional financial support for PQM from USAID’s HIV or TB funds.
- Mrs. Carr and Dr. Inyang explained that the USAID Mission has hired new staff to support the activities for malaria, TB, and HIV.

Debriefing

- Dr. Smine met with Mrs. Celeste Carr, Dr. Uwem Inyang, and Mrs. Kelly Badiane; the staffs of the TB and HIV teams were unavailable because of other obligations.
- Dr. Smine gave an overview of the MQM program, summarized the training achievements on basic tests using Minilabs[®], and discussed the next steps.
- Dr. Uwem suggested that PQM should reach out to the USAID | DELIVER PROJECT, which is in charge of managing antimalarial medicines paid for with PMI funds.
- Dr. Smine informed USAID about the findings of the NAFDAC Yaba Central QC Lab assessment and the meeting that took place with the World Health Organization on June 21.
- Dr. Smine discussed issues related to the transfer of more than 20 staff of the NAFDAC QC lab to positions outside of quality control and the impact the loss of trained staff will have on any accreditation plan. Dr. Uwem suggested that this issue be discussed at some point with the state Minister of Health.
- Dr. Smine reiterated the need for additional funds to carry out the agreed-upon activities with NAFDAC and the national health programs, asking the PMI team to share PQM's plans with the Mission's HIV and TB teams.
- Mrs. Kelly agreed to assist PQM in sorting out per diems and logistics expenses for future activities.

Next Steps

Quality assurance policy for national malaria, TB, and HIV programs

- The list of focal points from each partner will be finalized and shared with the QA team.
- QA team activities will be coordinated by NPSCMP.
- NMCP will carry out sampling from the central warehouse and, if needed, seek assistance from PQM.
- QA team (all health programs and NPSCMP) will meet on July 8 and finalize Sections 1 and 2 of the draft QA policy.
- QA team, with guidance from PQM, will then begin working on Section 3.

MQM Program

- Work with Nigerian customs to clear and deliver Minilabs[®]
- NMCP and NAFDAC will meet to sort out where the Minilabs[®] should be placed and discuss the budget needed for MQM Round 1.
- Finalize sampling plan and logistics and install Minilabs[®] by July 19, 2013.
- Begin MQM Round 1 by August 1, 2013
- Complete MQM Round 1 by September 30, 2013

Establishing a Medicines Quality Monitoring Program in Nigeria
Screening Tests and Sampling Procedures Training
Lagos, Nigeria ♦ June 17–21, 2013

AGENDA

	Topic/Activity
Day 1	<ul style="list-style-type: none"> • Opening ceremony • Meeting with all stakeholders and selection of participants • Program: General Introduction • Presentations <ul style="list-style-type: none"> – Introduction to Basic Tests – Visual Inspection • Introduction to Minilab® • Work group: Pipetting, Spotting • Work group: TLC testing of Sulfadoxine-Pyrimethamine
Day 2	<ul style="list-style-type: none"> • Work group: TLC testing of Quinine • Work group: TLC testing of Amodiaquine • Work group: TLC testing of Artemether/Lumefantrine • Work group: Visual Inspection
Day 3	<ul style="list-style-type: none"> • Work group: TLC testing of Artesunate • Work group: Simple Disintegration • Work group: Review of TLC results • Group discussion • Sampling guidelines and plan
Day 4	<ul style="list-style-type: none"> • Simple Disintegration • Evaluation in Thin-layer Chromatography • Closing ceremony; certificate presentation

MQM Training and Other Activities

Lagos, Nigeria ♦ June 17–21, 2013

List of Participants

Name	Institution	Location
Osho-Folasade M.	NAFDAC/PV/PMS	Lagos
Waliu Olamide A.	NAFDAC/Drug Lab	Lagos
Junaid Simiat F.	NAFDAC/Drug Lab	Lagos
Toma G. Attah	NAFDAC/PID Minilab	Lagos
Gonsum W. Roland	NAFDAC/PV/PMS	Jos
Nwodu Chike H.	NAFDAC/Drug Lab	Lagos
Ogboh Helen Ufu	NAFDAC/Food Lab	Lagos
Yusuf Bashir Jafar	NAFDAC/Food Lab	Lagos
Smith S. Adegboyega	NAFDAC/PV/PMS	Ibadan
Ude Chinenye Vivian	NAFDAC/PV/PMS	Port Harcourt
Hauwa Makawa	NAFDAC/PV/PMS	Kano
Damilola Adesanoye	NAFDAC/New Tech	Lagos
Nwokolo Kenechukwu Raphael	NAFDAC	Enugu
Abdulmajid Rabi	NAFDAC/PV/PMS	Kaduna
Ushadari Ptil Kayam	NAFDAC/PID Minilab	Maiduguri
Nsofor I. Prince	NAFDAC/PID Minilab	Lagos
Abdulhameed Wasilat	NPSCMP/FDS/FMOH	Abuja
Johnson Ekaete	NPSCMP/FDS/FMOH	Abuja
Omolulu Faguwa	NPSCMP/FDS/FMOH	Abuja
Onunkwo Celine	FMS	Lagos
Oderinde Fausat	FMS	Lagos
Ihemefor C	FMS	Lagos
Akinola Abolaji	FMS	Lagos
Musa Danjuma Z.	NPSCMP/FDS/FMOH	Abuja

Equipment Provided to Facilitate Minilab[®] Training

Description of Item	Quantity
1 ml Pipette	12
2 ml Pipette	12
10 ml Pipette	12
25 ml Pipette	6
5 ml Pipette	100
Forceps	8
Thin-Layer Chromatography Plates (50 per pack)	8 packs
Amodiaquine secondary reference tablet (20 per tube)	1 tube
Quinine secondary reference tablet (20 per tube)	1 tube
Disposable Lab Coats	20
Laboratory Gloves (100 per pack)	2 packs
Laboratory Safety Glasses	24
Training Manuals	25
2 µl Capillary Tubes (pack of 100)	10 packs
Pipette Bulbs	5
Aluminum Foil (25 foot roll)	1
Black Markers	12
Rulers	12
Pencils	12
Flash Drives	25

Evaluation of Minilab[®] Training

Self-assessment of Impact of the Training

Topic	Before Training (average)	After Training (average)	Change (average)
Sampling Procedure	2.5	4.3	1.7
Physical/Visual Inspection	3.7	4.8	1.1
Disintegration	2.9	4.6	1.7
TLC	2.0	4.8	2.8
Management of Data and Reports	2.9	4.0	1.1
All	2.8	4.5	1.7

Lowest skill score: 1

Highest skill score: 5

Overall Evaluation of the Course

Statement	Average Score
My expectations/personal objectives have been met	4.7
The training material helped me understand the course better	4.8
There were enough practical exercises to facilitate understanding of the course	4.6
The instructor(s) was effective in presenting the material	4.6
The instructor(s) allowed an appropriate level of participation	4.6
I am satisfied with the overall content and topics covered	4.5
The training will make a difference in the way I do my work	4.8
Support for logistics (accommodations, registration, etc.) was adequate	3.6

Agree Strongly: 5

Disagree Strongly: 1

Overall Comments

Most participants indicated that the practical work was the best part of the training (11 of 19)

Several of the participants found the food to be the least enjoyable part of the training (7 of 19)

Many participants expressed their interest in incorporating other disease categories into the MQM program (10 of 19)

A large proportion of the participants also thought the logistics of the training were the least appreciated aspect (9 of 19)

Many participants felt the training could have been improved through better logistics and organization (7 of 19)

Some participants felt the training should have been longer (6 of 19)