Assessment of Medicine Quality Assurance in Rwanda: Overview of Findings and Recommendations for Consideration

Kigali and Butare, Rwanda
November 9-13, 2009

Trip Report

Mustapha Hajjou, Ph.D., PQM
Abdelkrim Smine, Ph.D., PQM
Veerle Coignez, MA, MPH, USAID

Promoting the Quality of Medicines Program
Implemented by U.S. Pharmacopeia
12601 Twinbrook Parkway
Rockville, MD 20852 USA
Tel: (+1) 301-816-8162
Fax: (+1) 301-816-8374
Email: pqm@usp.org

Cooperative Agreement # GHS-A-00-09-00003-00
Sponsoring USAID Mission: USAID/Rwanda
Grantee: Promoting the Quality of Medicines (PQM) Program
Author(s) Name: PQM Staff
Language: English
Date of Publication: December 23, 2009

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 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.

Abstract

PQM conducted an assessment of the medicine quality assurance and quality control systems in Rwanda during November 9-13, 2009. Medicine quality assurance remains to be developed in Rwanda: the country has neither a medicine regulatory authority (MRA) nor a national medicine quality control laboratory – the two key institutions to ensure the quality, safety, and efficacy of medicines. The MOH Pharmacy Taskforce (PTF) is to be commended however for successfully controlling the pharmaceutical market to the extent that there is no informal medicines market in Rwanda. Based on its findings, the assessment team expects Rwanda to be able to make great strides in evidence-based medicines quality assurance in the short to medium term, provided it receives adequate technical assistance and financial support.

Recommended Citation

Coignez, V., Hajjou, M., and Smine, A. 2009. Assessment of Medicines Quality Assurance in Rwanda: Overview of Findings and Recommendations for Consideration. Rockville, Maryland USA; December 8, 2009. Submitted to the U.S. Agency for International Development by the Promoting the Quality of Medicines Program. Rockville, Maryland: United States Pharmacopeia.

Key Words

Rwanda, assessment, medicines quality assurance, quality control, medicine regulatory authority

Table of Contents

ACKNOWLEDGEMENTS

The PQM team would like to acknowledge the Ministry of Health staff in Rwanda for their support and participation, particularly:

- Dr. Corine Karema, Director, Programme National Intégré de Lutte contre le Paludisme (PLINP);
- Ms. Monique Murindahabi, Deputy Director, PNILP;
- Mr. John Patrick Mwesigye, Coordinator, Pharmacy Task Force; and,
- All other local partners who met with us during this assessment.

The PQM team would also like to express their great appreciation to:

- Dr. Annett Cotte for the planning and coordination of the assessment.
- Dr. Roopal Patel for coordinating all the meetings and for her valuable assistance and advice during the visit.
- Dr. Christopher Talley for his enthusiastic support.
- The PQM administrative staff and editors for their assistance with logistical arrangements and for editing the trip report.
- Mr. Anthony Boni and Ms. Veerle Coignez at USAID/Washington for their continued support.

ACRONYMS

AIDS	Acquired Immunodeficiency Syndrome
BUFMAR	Bureau des Formations Médicales Agrées du Rwanda
CAMERWA	Central d'Achat des Médicaments Essentiels, Consommables et Equipements Médicaux du Rwanda
DQI	Drug Quality and Information Program
GMP	Good Manufacturing Practices
HIV	Human Immunodeficiency Virus
LADAMED	Laboratoire d'Analyse de Denrées Alimentaires et des Médicaments
MOH	Ministry of Health
MOP FY09	Malaria Operational Plan, Fiscal Year 2009
QA	Medicine quality assurance
QC	Medicine quality control
QCL	Medicines Quality Control Laboratory
MSH	Management Sciences for Health
NUR	National University of Rwanda
PEPFAR	President's Emergency Plan for AIDS Relief
PMI	President's Malaria Initiative
PNILP	Programme National Intégré de Lutte contre le Paludisme
PQM	Promoting the Quality of Medicines Program
PTF	Pharmacy Task Force
QA	Quality Assurance
QC	Quality Control
RBS	Rwanda Bureau of Standards
RFDA	Rwanda Food and Drug Administration
USAID	United States Agency for International Development
USP	United States Pharmacopeia
USP-NF	United States Pharmacopeia National Formulary
WHO	World Health Organization

Background

With a land area of 9,633 sq mi and a population of more than 10 million, Rwanda is one of the most densely populated countries in Africa. In 2003, the total expenditure on health was 3.7% of the gross domestic product. The private expenditure was 56.5% of the total expenditure on health.

In 2006, Rwanda was selected as one of the 15 countries to benefit from the President's Malaria Initiative (PMI), in collaboration with the United States Agency for International Development (USAID). Recent data have shown a dramatic decrease in malaria incidence and child mortality, and malaria is no longer the leading cause of morbidity and mortality in Rwanda. However, the whole population remains at risk.

Because of the reported increase in the number of substandard and counterfeit medicines, PMI has decided to support strengthening the medicine quality control system in order to detect and monitor the quality of antimalarial medicines available on the Rwandan market (Source: FY09 MOP).

On this trip, Dr. Mustapha Hajjou, Ms. Veerle Coignez, and Dr. Abdelkrim Smine conducted an assessment of the medicine quality assurance and quality control (QA/QC) systems in Rwanda.

Purpose of Trip

- Conduct an assessment of the pharmaceutical sector in Rwanda;
- Meet with the teams from USAID, PMI, and the President's Emergency Plan for AIDS Relief (PEPFAR).
- Meet with staff from the Rwandan Malaria Control Program and other key partners; and,
- Recommend priority activities to strengthen antimalarial medicine quality control in Rwanda.

Source of Funding

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

Executive Summary

Medicine quality assurance (QA) in the Rwandan pharmaceutical sector remains to be developed. The country currently lacks two key institutional pillars—a Medicines Regulatory Authority (MRA) and a minimally functioning Medicine Quality Control Laboratory (QCL)—to ensure the quality, safety, and efficacy of medicines in the country.

That being said, the PQM assessment team fully commends the Ministry of Health (MOH) Pharmacy Taskforce (PTF) for the control it currently exercises over the pharmaceutical sector through the documentation requirements imposed for registration of medicines, and through the licensing and inspection of pharmaceutical establishments. The assessment team was most impressed that (1) the PTF, with the support of the Rwanda Bureau of Standards (RBS), has control over the medicines that enter Rwanda; (2) the pharmaceutical establishments appear to be compliant with relevant Ministerial Decrees, primarily due to PTF inspections and demonstrated readiness by the MOH to close down establishments that do not comply; and (3) there is no informal market for medicines.

The MOH, the PTF, and the Central Medicine Store (CAMERWA) have taken QA as far as they possibly can, based on administrative documentation review. However, because there is no technical evaluation of medicine dossiers during registration and no access to quality testing of medicines within the country, the quality, safety, and efficacy of medicines in Rwanda currently remain unchecked and, thus, not assured.

The Rwandan stakeholders, including the Malaria Control Program (called PNILP in Rwanda), are already fully cognizant of the need to establish an MRA with access to medicine quality control capability.

The PQM assessment team recommends that the PNILP consider taking the following measures with the funds available from PMI/USP to support strengthening the QA/QC in Rwanda in the coming year:

- Build QC capability at the University of Rwanda by:
  - Repairing and servicing equipment;
  - Providing the necessary reagents, references standards and basic lab supplies; and,
  - Training the staff in sampling and testing of antimalarials at the national and district levels. There is no need to introduce Minilabs® at this point.
- Provide technical support to the development of a post-graduate curriculum in QA/QC.

In the medium to long term, after an MRA is effectively established, the PNILP, other Rwandan stakeholders, and donors may consider supporting the following measures in order to further strengthen QA in Rwanda:

- Develop the MRA's capacity to conduct medicine registration through technical evaluation of the quality, safety, and efficacy of the medicines;

- Provide continued targeted support to speed up the strengthening of QC lab at the National University of Rwanda (NUR) as a QA/QC nucleus
- Expand the QA/QC nucleus into a full-fledged MQCL in Kigali;
- Develop a post-marketing surveillance strategy and system to monitor the quality of medicines, as the necessary complement to the pharmacovigilance activities;
- Provide support to the NUR Pharmacy Department to train pharmacists in QA. This will provide the potential technical human resources needed to staff and establish a regulatory authority and QC lab.

Based on its findings from the assessment, the assessment team has little doubt that, with the necessary technical assistance and financial support, Rwanda will be able to make great strides in introducing evidence-based QA, including medicines quality control (QC), in the short to medium term.

Overview of Regulatory and Institutional Medicines QA Context in Rwanda

This section provides an *integrated* overview of the medicines quality assurance context in Rwanda. The overview is based on information compiled from a variety of documents, including the PMI FY09 Malaria Operating Plan (MOP) for Rwanda and the Ministry of Health's 2008 Annual Report, as well as from many interviews, meetings, and site visits undertaken during this assessment. A *chronological* overview of the meetings and site visits, with selected highlights, is presented in the next section.

o Key Institutions

The MOH currently relies on the **MOH Pharmacy Taskforce** (PTF), in essence an MOH department, to develop pharmaceutical policy and to fill the role of a full-fledged Medicines Regulatory Authority to ensure the quality, safety, and efficacy of medicines. The PTF consists of three main departments: (1) Drug Registration; (2) Pharmacist Inspectors; and (3) Rational Use. The PTF is, by all reports, in control of the medicines on the Rwandan market. There was near unanimity among all counterparts interviewed that, basically, nothing gets on the market without PTF registration, except perhaps in the regions bordering neighboring countries. It was not possible for the PQM team to verify to what extent this assertion is correct during the assessment. However, it will be possible to obtain evidence in this regard once implementation starts of the proposed activity to sample and test antimalarial medicines on the market (aka post-marketing surveillance). For example, PQM-supported post-marketing surveillance in another African country have documented the presence of non-registered medicines on the market and have provided the necessary evidence base for the national regulatory authority to take targeted corrective action.

The registration procedure is entirely document-based; there is neither the technical capacity nor the necessary human resources for technical evaluation of a dossier. The document requirements for visas, authorization of importation, and registration include: (1) documentation of manufacture, wholesale, and export licenses; (2) certification of Good Manufacturing Practices; and (3) product-specific information. In the words of one of the counterparts interviewed, Rwanda is "at the mercy of donors and suppliers" for quality control of medicines.

The PTF has an inspection team comprised of four inspectors who primarily examine private-sector establishments. The inspectors verify compliance with administrative requirements, as spelled out in the relevant Ministerial Decrees. Only a few samples have been sent to laboratories outside the country for QC analysis.

The MOH has the reputation for closing down any pharmaceutical establishment that does not comply with requirements. Throughout these visits, pharmaceutical establishments showed respect for and compliance with MOH regulations and norms. That said, during a visit to a pharmacy in Butare, members of the assessment team were able to buy Coartem® for adults for the price of 2,000 francs. (The product was not displayed; the woman disappeared behind a curtain to get the product, which presumably was taken from a public health facility).

The **Rwandan Board of Standards** is involved in checking whether the imported and donated medicines meet the documentary standards upon entry to the country. Most medicines arrive by air; however, there is a dry port to which medicines that arrive over land are directed. The RBS has inspectors posted at the airport and now also sends three inspectors to crossings at the Western border (to deal with medicines coming from the DRC). An RBS pharmacist guides the inspectors. The PBS batch certification is based on document review; there is no visual inspection of packages nor quality control testing at the laboratory.

There is **no medicines quality control laboratory in Rwanda** capable of conducting the full spectrum of basic tests to determine the quality of the medicines. The National University of Rwanda (NUR) in Butare does have a basic lab facility that has the potential to become a basic medicine quality control testing lab: i.e. the lab of the NUR Pharmacy Department, LADAMED. The main findings of the site visit to the Lab are presented in the next section (pp 12-13).

As stated in MOP FY09, the **Central Medicine Store or CAMERWA** functions as the MOH's procurement arm and national medical store for Rwanda, procuring about 60% of public health facility medicines and supplies.

CAMERWA uses a document-based system to ensure, to the extent possible, the quality of the medicines procured. For program-donated medicines (including Global Fund, Clinton Foundation, PEPFAR, PMI, or HIV/AIDS, TB and malaria medicines), the products are pre-qualified either by the World Health Organization (WHO) or CAMERWA itself. Quality concerns focus on the essential medicines, which are procured through international bids. CAMERWA does pre-qualify suppliers based on documentation review (for a three-year period, at the moment). A GMP certificate and certificate of analysis are requested, but the agency is not always certain whether or not the documents are genuine. In addition to document reviews, CAMERWA sends some samples (about 50 samples, twice a year) for quality control testing by labs in Belgium, France, and South Africa, but the process is expensive and the results are not always timely. The sampling focuses on new products from new suppliers or on products that look suspicious upon visual inspection. CAMERWA stopped working with one supplier in recent years because of quality concerns.

CAMERWA has a central warehouse in Kigali, which is being refurbished, with donor support. A visit to the CAMERWA warehouse revealed that there is room for further improvement in terms of storage practices (for more details, see section below, p.11).

A secondary procurement agency is **BUFMAR**, which was set up by faith-based organizations. If a product is not available at CAMERWA, public health facilities can try to procure it from BUFMAR, using the private sector as a third and last resort. The procurement and QA capacity of BUFMAR is quite limited compared to CAMERWA. BUFMAR also uses document reviews for QA purposes; it does not do any sampling or testing. The BUFMAR President claimed not to have had any quality problems over the last two–three years under his tenure.

There is one public sector manufacturer, **LABOPHAR**, that produces some essential medicines, including antibiotics, but their quality control is reportedly not up to international standards. A WHO consultant reportedly concluded a few years ago that the facility should be closed.

[Source: the former President of the Pharmacists Association]. The assessment team did not have an opportunity to visit the manufacturing site during this assessment.

- **Legal and Regulatory Framework**

Currently, there are two key laws dating back to 1998 and 1999 that frame pharmaceutical policy in Rwanda: (1) Law No. 10/98 establishing the practice of the art of healing; and, (2) Law No. 12/99 relating to pharmaceutical arts.

In addition, there are a number of Ministerial Decrees that are relevant to medicines quality assurance. They focus mostly on regulating pharmaceutical establishments in the private sector: (1) defining pharmaceutical establishments; (2) establishing conditions for wholesale pharmacy; (3) establishing conditions for retail pharmacy; (4) introducing a limited list of medicines that can be sold at pharmacies; and, (5) outlining the practice of inspection of pharmaceutical establishments.

A process is underway to set up a full-fledged Medicines Regulatory Authority. Law No. 12/99 will be replaced by a new law that establishes a Rwandan Food and Drug Administration (RFDA) whose functions will be outlined in an accompanying law. The expectation is that the RFDA will be established sometime in 2010 and that it will ultimately regulate food, medicines, poisons, herbal medicines, cosmetics, health products and medical devices.

In conclusion: The MOH, the PTF, and CAMERWA have taken QA as far as they possibly can on the basis of administrative documentation review. However, because there is no technical evaluation of medicine dossiers during registration and no access to quality testing of medicines within the country, the quality, safety, and efficacy of medicines in Rwanda ultimately remain unchecked currently and, thus, not assured. The current process to review existing legislation and establish a MRA provides a window of opportunity to start strengthening medicines quality assurance in the country.

Overview of Assessment Team Meetings and Activities

Meeting with USAID/PMI, PNILP, and PTF – Monday, Nov. 9

- Counterparts: Monique Murindahabi, (PNILP Deputy Director); Dr. Roopal Patel (PMI advisor for U.S. Centers for Disease Control (CDC)); Dr. Patrick Condo (USAID-PMI advisor)
- Discussion: The PQM team reviewed the schedule of meetings and site visits with Dr. Roopal and gave a quick overview on how the assessment would be conducted. It was agreed that the assessment would be general in nature and not focus narrowly on antimalarial medicine quality alone.

Meeting with National University of Rwanda (NUR), Pharmacy Department – Monday, Nov. 9

- Counterparts: Prof. Pierre Claver Kayumba (Senior Lecturer, Pharmacy Dept, NUR)
- Discussion: Prof. Claver reported that the QC Lab at NUR leaves much to be desired in terms of space, equipment, reagents and reference standards, and technical capacity. We briefly discussed the merits of developing a QC Lab in Butare vs. Kigali. There was also discussion about the possibility of PQM providing assistance in supporting sourcing of QC/QA materials for courses and/or relevant information for proposal writing. The NUR Pharmacy Department would appreciate receiving the current *U.S. Pharmacopeia-National Formulary* (*USP-NF*), reference standards, and training materials.

Meeting with CAMERWA -- Tuesday, Nov. 10

- Counterparts: Ambassador Zephyr Mutanguha (Director General); the Deputy Director General; Immaculée Mukankubito (Head of Quality Assurance); the Warehouse Director; Christopher Talley (USAID, Health Commodity and Logistics Advisor); Caroline Healey (Supply Chain Management System (SCMS) Country Director); and Geoffrey Ngwira (SCMS Procurement Advisor).
- The team visited the CAMERWA warehouse. CAMERWA does not yet fully comply with good storage practices – for example, there is no temperature and humidity monitoring, no temperature mapping of the warehouse, numerous broken windows (would allow birds and insects to enter the warehouse), no apparent pest control, a door wide open to the outside environment, and poor storage and labeling.
- SCMS had provided CAMERWA with a computerized system for stock management of medicines, but the paper-based system is still active during this transition period.

Meeting with BUFMAR -- Tuesday, Nov. 10

- Counterparts: Ernest Rwagasana (Director); and Nathalie Furere (Pharmacist and warehouse manager)
- The meeting included a quick visit to its "production facility" for ointments and suppositories and to its warehouse. The assessment team found that the small manufacturing facility does not comply with good manufacturing practices (GMP). All manufacturing machines are used in complete open spaces with no respect to GMP, despite the fact that the products being manufactured are external skin preparations.

Meeting with Strengthening Pharmaceutical Systems (SPS) – Tuesday, Nov. 10

- Counterparts: Inès Buki Gege (Senior Technical Advisor); Felix Hitayezu (Senior Program Associate); Patrick Gaparayi; Aline Mukerabirori; and Denise Murekatete
- Discussion: SPS staff provided a useful overview of the pharmaceutical sector and SPS program work in Rwanda.

Meeting with the Pharmacy Task Force -- Tuesday, Nov. 10

- Counterparts: John Patrick Mwesigye (PTF Coordinator) and colleagues
- Discussion: The PTF is not an MRA, but it does have control of the pharmaceutical sector; together with the Rwanda Bureau of Standards, it carries out inspections and documentation-based control of medicines when they reach the port of entry. The PTF registers medicines based on paper review, and selects and tracks suppliers. According to

the PTF, Rwanda "is at the mercy of donors and suppliers" with regard to the quality of medicines. Some samples have been sent through the inspection team to Belgium, Nairobi, and South Africa. PTF also explained the ongoing process to revise pharmaceutical legislation. PQM offered to forward to PTF the draft legislation PQM and USAID helped draft and negotiate in Liberia.

Meeting with PSI – Wednesday, Nov. 11

- Counterparts: Staci Leuschner (PSI Country Representative); and PSI program manager
- PSI facilitated a visit to two wholesalers and two pharmacies in Kigali.
- Part of the meeting focused on the different levels of the public and private distribution systems. PSI confirmed there are about 40 private wholesalers and 46 private pharmacies in Rwanda, most of them in Kigali. The "comptoires pharmaceutiques" or pharmaceutical shops are allowed to carry a limited type of essential medicines, including a subsidized artemisinin-based combination therapy (ACT) named Primo for infants and children that are sold for 300 Francs per regimen. There was a brief discussion about the possibility of "leakage" from the public sector and a possibility of adults using double doses of subsidized ACTs.

Meeting with Rwandan Bureau of Standards – Wednesday, Nov. 11

- Counterpart: Jane Nyamvumba (Director of Quality Assurance Unit, RBS)
- Discussion: Ms. Nyamvumba provided an overview how the RBS assists the PTF in checking documentation requirements for medicines arriving in-country by air or land.
- RBS aims to train MOH staff so that all inspections will be carried out by MOH.
- RBS carries out some QC for food samples.
- The PQM team did not have an opportunity to visit the RBS laboratory facilities. Ms. Nyamvumba did state that the RBS has sufficient facility space to house a medicines quality control lab.

Site Visit to Medicine Quality Control Laboratory Site, National University of Rwanda, Butare (LADAMED)

- Counterparts: Prof. Justin Kadima (Head of Pharmacy Dept.); Prof. Pierre Claver Kayumba (Senior Lecturer, Pharmacy Dept.); LADAMED staff; Antoine Gatera (SCMS); Felix Hitayezu (SPS); and Patrick (PTF).

Overall Situation

- The Laboratoire de Denrees Alimentaires et Medicaments (LADAMED) is the laboratory of the NUR Department of Pharmacy. It was partially established with support and funds from the University of Liege in Belgium.
- It is the only facility with quality control capability in Rwanda. It consists of three units—microbiology, food and medicines QC—each of which has a supervisor who is faculty member. All LADAMED activities are coordinated by one faculty staff member. In

LADAMED laboratory in Butare

total, there are seven analysts dedicated to working in different units of the QC lab.

- The availability of both a physical entity and full-time dedicated staff make it possible to begin developing a medicines quality control capacity in Rwanda. The staff, the know-how, and the resources available at this lab could be strengthened sufficiently to constitute a nucleus for establishing a national MCQL at a later time.
- It is also worth noting that the lab receives regular requests from both public and private clients for quality testing of medicine samples. The reported requests come from both the public and private sector. LADAMED has had to turn down the requests due to lack of resources until now, but if strengthened, QC testing for both the public and private sector may ultimately represent an important income source for the lab.

Needs

- The rooms in the lab are small and inadequately aerated, but the lab could be used as an interim facility for QC until a full-fledged QC lab can be built.
- The lab has a new HPLC (Agilent technologies HP1200), but the majority of the lab equipment is not functional (HPLC, Dissolution tester, GC with Head space, Water deionizer, etc.).
- Additional basic equipment is greatly needed, including a UV spectrophotometer, IR, thin layer chromatography (TLC) apparatuses, and water filtration system.
- The lack of chemical reagents is one of the major handicaps in this lab. Most of the existing chemicals have expired. The lab needs the basic reagents to carry out basic medicine QC.
- The lab analysts and supervisors need training on quality control of medicines and in good laboratory practices.

Capacity Building Program

- The NUR Pharmacy Department is well advanced in planning a one-year postgraduate diploma for graduate pharmacists to specialize in QA/QC. The Chairman of the Department asked for PQM's support for developing training modules and training in theoretical practical courses in various topics about medicines QA. The program is scheduled to start next year by training 15 pharmacists.
- This proposed program merits technical and financial support in the opinion of the assessment team because it will provide the human resources and technical capacity needed to staff and establish a regulatory authority and QC lab.

Visits to Wholesalers, Private Pharmacies, and Public Pharmacies in Kigali and Butare – Wednesday-Thursday, Nov. 11-12

- The assessment team visited two private pharmacies and two private wholesalers in Kigali, and one comptoir pharmaceutique in Butare.
- All the facilities that were visited appeared to be very well maintained.
- Discussion: According to one pharmacist, a former president of the Pharmacists Association, there are too many wholesalers in Rwanda that do not merit the designation of wholesaler: they carry only a few medicines. He believes, in this regard, there is lack of regulatory clarity.

Debriefing at the Center for Treatment and Research on AIDS, Malaria, Tuberculosis and Other Epidemics – Friday, Nov. 13

- Counterparts: Dr. Corine Karema (Director, National Malaria Program); Dr. Wayne Stinson (USAID Malaria Advisor); and Monique Murindahabi (PNILP Deputy Director)
- The PQM team provided an overview of the assessment, reported the major findings, and outlined proposed activities for PNILP consideration.
- The Power Point presentation of the main findings and recommendations is attached (Annex 1).

Recommendations on Next Steps

The Rwandan stakeholders, including the Malaria Control Program (PNILP), are already fully cognizant of the need to establish an MRA with access to medicines quality control capability.

In this context, and on the basis of available funding, PQM recommends the PNILP consider taking the following measures to support strengthening QA/QC in Rwanda in the coming year:

- Build QC capability at the University of Rwanda by:
  - Repairing and servicing equipment;
  - Providing the necessary reagents, references standards and basic lab supplies; and,
  - Training the staff in sampling and testing of antimalarials at the national and district levels. The training will focus on two key analytical methods. PQM will assist in the actual conducting of key quality tests to allow for immediate feedback and reinforcement. Relevant information to guide sampling is presented in Annex 2.
- There is no need to introduce Minilabs® at this point.

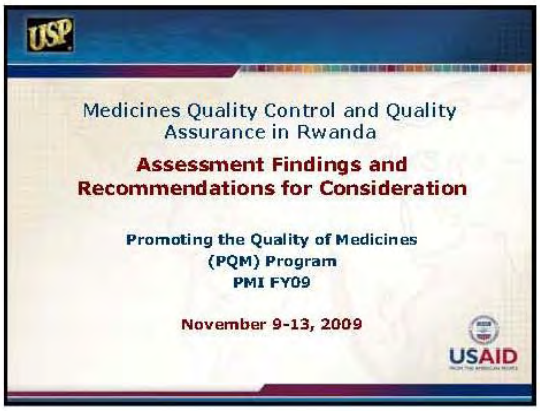
If limited additional funding can be made available, PQM strongly recommends providing technical support to the development of a postgraduate curriculum in QA/QC. As stated, this capacity building program merits full support because it will provide the human resources and technical capacity needed to staff and establish a regulatory authority and QC lab.

In the medium to long term, and after an MRA is effectively established, the PNILP, other Rwandan stakeholders, and donors may consider supporting the following measures in order to further strengthen QA in Rwanda:

- Develop the MRA's capacity to conduct medicine registration through technical evaluation of the quality, safety, and efficacy of the medicines;
- Provide continued targeted support to speed up the strengthening of QC lab at the National University of Rwanda (NUR) as a QA/QC nucleus
- Expand the QA/QC nucleus into a full-fledged MQCL in Kigali;
- Develop a post-marketing surveillance strategy and system to monitor the quality of medicines, as the necessary complement to the pharmacovigilance activities;

- Provide support to the NUR Pharmacy Department to train pharmacists in QA. This will provide the potential technical human resources needed to staff and establish a regulatory authority and QC lab.

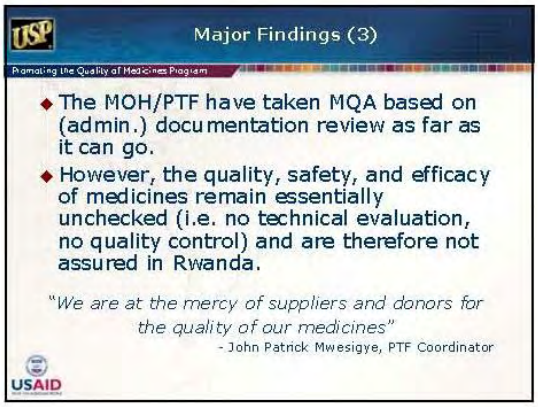
Annex 1

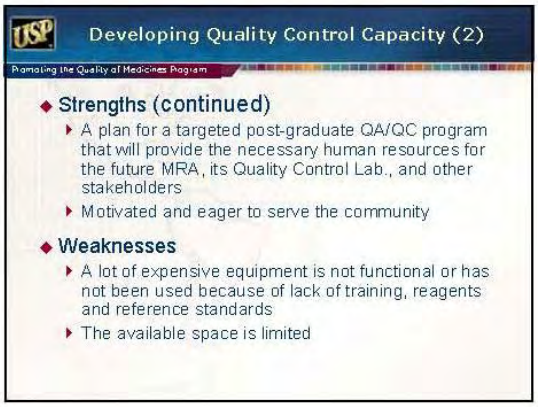

Medicines Quality Control and Quality Assurance in Rwanda
Assessment Findings and Recommendations for Consideration
Promoting the Quality of Medicines (PQM) Program
PMI FY09
November 9-13, 2009
USAID

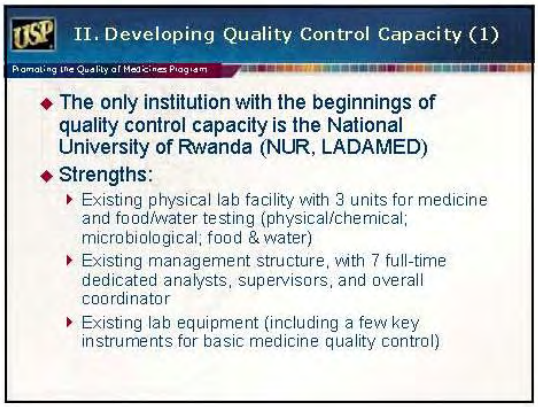

I. Major Findings (1)
Promoting the Quality of Medicines Program
The two *key* institutional pillars of medicines quality assurance (MQA) are currently still lacking in Rwanda:
There is no Medicines Regulatory Authority (PTF does not have legal mandate; a draft law for a MRA is in circulation)
There is no minimally functional Medicines Quality Control Laboratory (limited lab capacity in NUR)
USAID

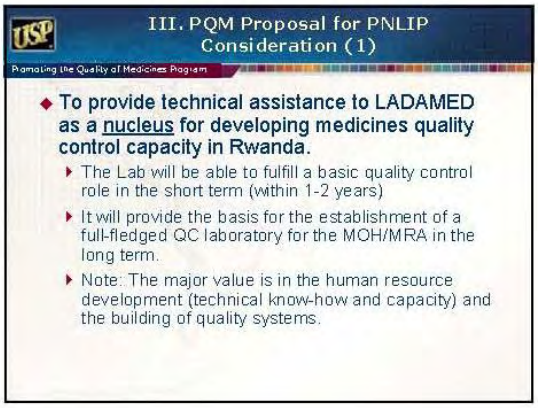

Overview
Promoting the Quality of Medicines Program
MQA/QC in Rwanda: Major Findings
Building Medicines Quality Control Capacity:
Analysis of LADAMED, NUR
Proposal for PNILP Consideration
Additional notes
Conclusion
USAID


Major Findings (2)
Promoting the Quality of Medicines Program
The MOH/PTF are to be highly commended for:
PTF market authorization of medicines (control of medicines in the market, with support from RBS)
PTF licensing of pharmaceutical establishments
PTF inspection and enforcement of pharmaceutical establishment compliance with relevant Ministerial Decrees
Absence of informal market
Regulation of donated medicines
USAID

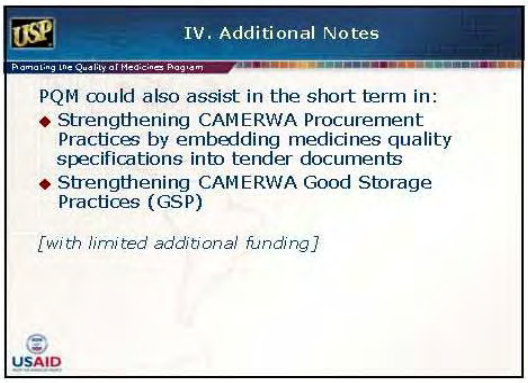

Major Findings (3)
Promoting the Quality of Medicines Program
The MOH/PTF have taken MQA based on (admin.) documentation review as far as it can go.
However, the quality, safety, and efficacy of medicines remain essentially unchecked (i.e. no technical evaluation, no quality control) and are therefore not assured in Rwanda.
"We are at the mercy of suppliers and donors for the quality of our medicines"
- John Patrick Mwesigye, PTF Coordinator
USAID

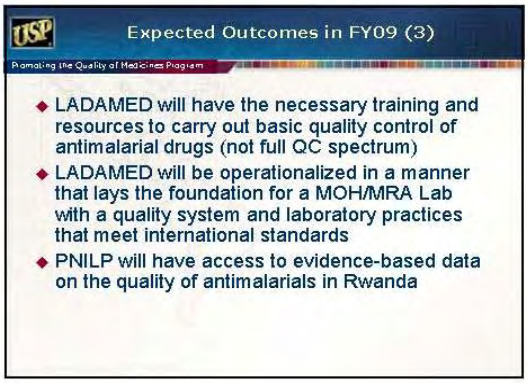

Developing Quality Control Capacity (2)
Promoting the Quality of Medicines Program
Strengths (continued)
A plan for a targeted post-graduate QA/QC program that will provide the necessary human resources for the future MRA, its Quality Control Lab., and other stakeholders
Motivated and eager to serve the community
Weaknesses
A lot of expensive equipment is not functional or has not been used because of lack of training, reagents and reference standards
The available space is limited

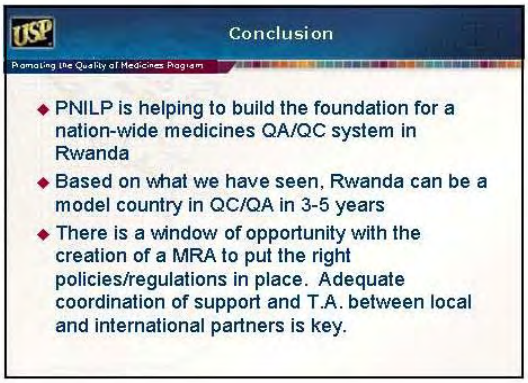

II. Developing Quality Control Capacity (1)
Promoting the Quality of Medicines Program
The only institution with the beginnings of quality control capacity is the National University of Rwanda (NUR, LADAMED)
Strengths:
Existing physical lab facility with 3 units for medicine and food/water testing (physical/chemical; microbiological; food & water)
Existing management structure, with 7 full-time dedicated analysts, supervisors, and overall coordinator
Existing lab equipment (including a few key instruments for basic medicine quality control)


III. PQM Proposal for PNLIP Consideration (1)
Promoting the Quality of Medicines Program
To provide technical assistance to LADAMED as a nucleus for developing medicines quality control capacity in Rwanda.
The Lab will be able to fulfill a basic quality control role in the short term (within 1-2 years)
It will provide the basis for the establishment of a full-fledged QC laboratory for the MOH/MRA in the long term.
Note: The major value is in the human resource development (technical know-how and capacity) and the building of quality systems.


Recommendations for Use of Allocated PMI FY09 Funding (2)
Promoting the Quality of Medicines Program
Repair HPLC machine (Alcott)
Provide the necessary chemicals and reagents for testing of antimalarial medicines in Rwanda
Carry out training on two major QC analytical methods (TLC and HPLC)
TLC will enable the Lab to carry all QC tests equivalent to Minilab capacity
HPLC is the primary analytical method used for QC of medicines
Collect and test selected antimalarial samples from Rwandan public and private sectors


IV. Additional Notes
Promoting the Quality of Medicines Program
PQM could also assist in the short term in:
Strengthening CAMERWA Procurement Practices by embedding medicines quality specifications into tender documents
Strengthening CAMERWA Good Storage Practices (GSP)
[with limited additional funding]
USAID


Expected Outcomes in FY09 (3)
Promoting the Quality of Medicines Program
LADAMED will have the necessary training and resources to carry out basic quality control of antimalarial drugs (not full QC spectrum)
LADAMED will be operationalized in a manner that lays the foundation for a MOH/MRA Lab with a quality system and laboratory practices that meet international standards
PNILP will have access to evidence-based data on the quality of antimalarials in Rwanda


Conclusion
Promoting the Quality of Medicines Program
PNILP is helping to build the foundation for a nation-wide medicines QA/QC system in Rwanda
Based on what we have seen, Rwanda can be a model country in QC/QA in 3-5 years
There is a window of opportunity with the creation of a MRA to put the right policies/regulations in place. Adequate coordination of support and T.A. between local and international partners is key.

Annex 2

Relevant Information for Developing Sampling Strategy

Rwanda in General

- Rwanda is approximately the size of the State of Maryland. The population is approximately 10 million, approximately 1 million of whom live in Kigali. It is one of the most densely populated countries in the world.
- There are 30 administrative districts.

The Rwandan Health Care and Pharmaceutical Sectors

- Public Health Care Sector: There are four national reference hospitals, some 40 district hospitals, and approximately 450 public and faith-based health centers.
- There also exists an extensive network of some 60,000 community health workers. They are the backbone of home-based healthcare management that has been formed to complement and extend the primary health care system.
- Private Health Care Sector: There are approximately 200 private clinics.
- Pharmaceutical Sector: CAMERWA and BUFMAR function as procurement arms of the public and faith-based organizations. There are approximately 40 private wholesalers (the large majority based in Kigali); 40 private pharmacies (offices, also mostly based in Kigali); and approximately 200 comptoirs (medical stores with a limited list of medicines, mostly outside the capital).

Treatment Policy

- Since 2006, monotherapies have been banned for first-line treatment of uncomplicated malaria. The standard treatment consists of Artemisinin-based combination therapies (ACTs) are used, specifically artemether-lumefantrine (Coartem®).
- The second line treatment for uncomplicated malaria is quinine tablets.
- Quinine and artemether are used for severe/complicated malaria. (According to some sources, only in injectable form; according to Dr. Monique, both in injectable form and as tablets).
- SP treatment for IPTp has been discontinued.

Distribution of Antimalarials

- Procurement: CAMERWA can legally import ACTs according to most sources/documents while PSI reported it thought selected private sector wholesalers could also import ACTs. There is no similar import restriction on other antimalarials.
- Quality Assurance: All antimalarials are WHO pre-qualified.
- Distribution Chain: There is nationwide distribution of ACTs through the public sector, the faith-based organizations, and the community-based health workers who seek their supplies from the health facilities they are affiliated with. The MOH also distributes through the private sector treatments for uncomplicated malaria in children under five years old. (PSI sells Primo products to the pharmaceutical depots only.)