

Attend President's Malaria Initiative Meetings, Assess the National Quality Control Lab, and Present at Annual Pharmaceutical Society of Kenya Conference

**Nairobi/Mombasa, Kenya
May 24-June 3, 2010**

Trip Report

**Kennedy M. Chibwe, Ph.D., MBA
Senior Program Advisor**

Promoting the Quality of Medicines Program

Implemented by U.S. Pharmacopeia
12601 Twinbrook Parkway
Rockville, MD 20852 USA
Tel: (+1) 301-816-8166
Fax: (+1) 301-816-8374
Email: pqm@usp.org

Cooperative Agreement # GHS-A-00-09-00003-00
Grantee: Promoting the Quality of Medicines (PQM) Program
Author(s) Name: PQM Staff
Language: English
Date of Publication: August 10, 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. Chibwe travelled to Kenya to present PQM's accomplishments and a strategic plan to strengthen Medicines Quality Monitoring (MQM) activities to the President's Malaria Initiative (PMI) Malaria Operational Plan (MOP) team. In addition, Dr. Chibwe assessed the Kenya National Quality Control Laboratory (NQCL) for potential future reference standards packaging and management. While in Kenya, Dr. Chibwe also attended the *2010 Annual Pharmaceutical Society of Kenya Conference*.

Recommended Citation

Chibwe, Kennedy M. 2010, *Attend President's Malaria Initiative Meetings, Assess the National Quality Control Lab, and Present at*. Submitted to the U.S. Agency for International Development by the Promoting the Quality of Medicines Program. Rockville, Maryland: United States Pharmacopeia.

Key Words

Kenya, National Quality Control Lab, antimalarial, medicine quality monitoring

Table of Contents

<u>Acknowledgements</u>	4
<u>Acronyms</u>	5
<u>Background</u>	6
<u>Purpose of Trip</u>	6
<u>Source of Funding</u>	6
<u>Overview of Activities</u>	6
<u>Next Steps</u>	7
<u>Annex 1</u> : PQM presentation for PMI meeting	
<u>Annex 2</u> : PQM Presentation for Annual Pharmaceutical Society of Kenya Conference	

Acknowledgements

The author would like to thank:

- Dr. Gladys Tetteh, CDC Resident Advisor; Dr. Kaendi Munguti, Senior Malaria Advisor; and the PMI team.
- Dr. Ezekiel Chepkwony and staff at the National Quality Control Laboratory (NQCL) for hosting my assessment/audit.
- PQM colleagues for their valuable contributions in organizing the trip and editing this report.
- Mr. Anthony Boni and Ms. Veerle Coignez at USAID/Washington for their guidance and helpful insights.

Acronyms

CDC	U.S. Centers for Disease Control and Prevention
DQI	Drug Quality and Information Program
MOP	Malaria Operational Plan
MQM	Medicine Quality Monitoring
NQCL	National Quality Control Laboratory
PMI	President's Malaria Initiative
PQM	Promoting the Quality of Medicines Program
SOP	Standard Operating Procedures
USAID	United States Agency for International Development
USP	United States Pharmacopeia
WHO	World Health Organization

Background

The President's Malaria Initiative (PMI) Malaria Operational Plan (MOP) for 2009 highlights the importance of drug quality control, and USAID/Kenya has selected PQM to assist the Ministry of Health in monitoring the quality of antimalarials available in the market. Specifically, PQM's mandate as stated in the MOP FY 09 is: *"Support to strengthen drug quality and post market surveillance through the procurement of self-contained kits that permit limited on-site testing of medication (Minilabs[®]) and training of technicians on evaluating drug quality."*

An overarching framework document that focuses on quality assurance for all medicines in Kenya was written by key partners and is in place. Whereas PQM's focus is post-marketing surveillance of antimalarials, the partners agreed that a comprehensive Medicine Quality Monitoring (MQM) structure should be developed that will be useful for all therapeutic indications.

Purpose of Trip

- Present PQM accomplishments and discuss planned activities for the coming year with the MOP team.
- Visit and audit the National Quality Control Laboratory (NQCL) in Nairobi, Kenya as a possible future packaging facility in Africa, per FY10 Malaria Workplan.
- Present at the 2010 Annual Pharmaceutical Society of Kenya Conference in Mombasa to introduce the African Reference Standards System and discuss World Health Organization (WHO) Prequalification for African manufacturers of anti-tuberculosis (TB)

Source of Funding

This trip was funded by USAID Core funds for Malaria.

Overview of Activities

PMI Stakeholders' Meetings (May 25-26, 2010)

The objective of the first day was for all malaria control stakeholders to discuss 2011 priorities and to determine priority resource gaps for potential funding under PMI's FY11 MOP.

The following day, the PMI MOP writing team held consultations with the implementing partners to determine how to maximize the impact of the financial and technical support to malaria control in Kenya.

Dr. Chibwe gave a presentation to the MOP team entitled "PQM Technical Support to Malaria Control in Kenya". The presentation summarized accomplishments and issues being faced with respect to MQM activities. The full presentation is included in *Annex 1*.

Assessment of Kenya's National Quality Control Laboratory, Nairobi (May 28 and June 2, 2010)

The assessment was hosted by Dr. Ekeziel Chepkwony and his staff.

Dr. Chibwe conducted a walkthrough of the main laboratory and storage areas. He was also able to interview laboratory management staff.

The main goal was to assess potential management capability for packaging reference standards, as described in the FY10 Malaria Workplan.

Summary of Assessment: It is noteworthy that this laboratory is WHO prequalified and is currently listed as being in compliance with WHO recommended standards. It is also noteworthy that the laboratory currently generates secondary reference standards for manufacturers.

General Overview: The sample management system and processes seem to be in place as judged through documentation review, interviews, and audit. There are clear procedures for sample receipt, storage, testing, record keeping and sample discard. While the laboratory areas seem well kept and clean, the location and layout is less than ideal.

Observations:

1. There are Standard Operating Procedures (SOPs) in place describing expectations for full cycle sample receipt, test results release, and sample discard. The manual system in place, while not ideal, is adequate to ensure there is proper chain of custody for samples throughout the analytical/microbiology testing cycle.
2. Most equipment appeared to be fully calibrated but there was a lack of calibration stickers to inform analysts whether instruments are still in calibration (no calibration stickers for some instruments).
3. The refrigerators/cold chambers appeared in good working condition and are continuously monitored. They had been temperature mapped. However, there is no notification process in the event of temperature spikes or power failures, and there is no power backup system.
4. The lab staff appeared knowledgeable and could articulate clearly their duties and work expectations. No review of the organizational chart was done.
5. The lab seemed to have good instrument calibration and maintenance procedures in place.
6. Observed broken glassware in use. This could be a safety issue.

Overall Evaluation: The Kenya NQCL appears have good systems and processes in place and is recommended for the next stage of evaluation.

2010 Annual Pharmaceutical Society of Kenya Conference, Mombasa (May 30, 2010)

Dr. Chibwe gave a presentation highlighting the African Reference Standards System and PQM's role in providing technical assistance to second-line TB medicine manufacturers toward WHO Prequalification. Attendees were interested in learning more about WHO prequalification and indicated that they would like to see efforts toward chemical reagents procurement.

Next Steps

- PQM will explore options for next steps for the African Reference Standards program with country partners
- Dr. Chibwe will follow up with individual firms interested in learning more about the WHO Prequalification program



President's Malaria Initiative — Stakeholders Meeting
Nairobi, Kenya ♦ May 26, 2010

PQM Technical Support to Malaria Control in Kenya

Kennedy Chibwe, Ph.D., MBA

Promoting the Quality of Medicines Program

Implemented by United States Pharmacopeia



USAID
FROM THE AMERICAN PEOPLE



USP HQ, Rockville, MD



USAID
FROM THE AMERICAN PEOPLE



USP Switzerland



U.S. PHARMACOPEIA
The Standard of QualitySM

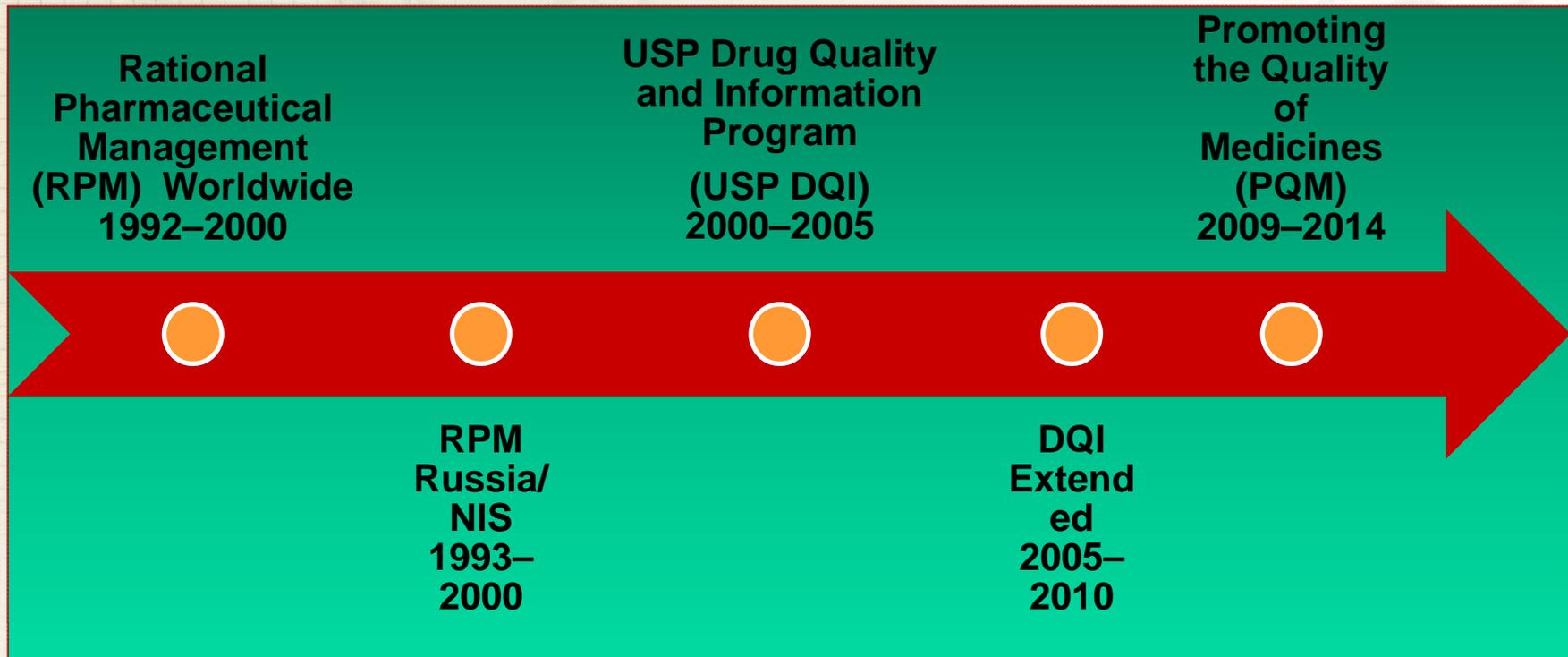
Europe



USAID
FROM THE AMERICAN PEOPLE



Promoting the Quality of Medicines Program



USAID
FROM THE AMERICAN PEOPLE



Program Implementation Progress

Promoting the Quality of Medicines Program

Accomplishments

- ◆ **Assessed medicine quality assurance**
 - ▶ Summarized current ad hoc PMS program
 - ▶ Developed strategic plan and well-defined protocol

- ◆ **Established medicine quality monitoring (MQM)**
 - ▶ Conducted hands-on Minilab training
 - ▶ Trained on sampling, data management, data reporting
 - ▶ Completed 1st round testing at 4 sites; 2 reported results
 - ▶ 201 samples collected, 187 tested: **15 failed, 9 doubtful**



Program Implementation Progress

Promoting the Quality of Medicines Program

Ongoing activities

- ◆ Minilab results to be reported next week
- ◆ NQCL to conduct confirmatory testing of failed & doubtful samples
- ◆ Report on MQM, monotherapy status due Jun/Jul 2010



Working Arrangements with DOMC

Promoting the Quality of Medicines Program

DOMC roles with —

- ◆ **PQM** provides technical assistance on set-up and roll-out of postmarketing surveillance (MQM)
- ◆ **PPB** supports taking action on failed antimalarial samples
- ◆ **NQCL** performs confirmatory testing on suspected poor-quality medicines



Working Arrangements with DOMC

Promoting the Quality of Medicines Program

DOMC roles with —

- ◆ **USAID/Kenya**, a key donor, supports implementation of national malaria strategy
- ◆ **WHO** advises on latest recommended policies for malaria control based on country epidemiology
- ◆ **MQM**
 - ▶ Supervises all activities at central and regional levels
 - ▶ Ensures coordination, communications with PQM, PPB, NQCL



Issues, Challenges and Lessons Learned

Promoting the Quality of Medicines Program

Issues, Challenges, Lessons, and Suggestions

- ◆ Lack of trained personnel at sentinel sites
 - ▶ Increase number of trained staff at sites
- ◆ Sentinel site teams' organization & coordination
- ◆ Lack of Minilab methods to test some antimalarials
 - ▶ Send samples to NQCL for compendial testing



Issues, Challenges and Lessons Learned

Promoting the Quality of Medicines Program

Issues, Challenges, Lessons, and Suggestions

- ◆ Need for supervisory visits and M&E at sites
- ◆ Lack of samples in public sector (e.g., shortage of artemether lumefantrine in Kakamega)
- ◆ Limited space in some facilities to perform analysis
 - ▶ Use hospital labs as alternative solution
- ◆ Some antimalarial medicines—not in treatment guideline—still used, e.g., amodiaquine monotherapy



Other Information

Promoting the Quality of Medicines Program

- ◆ **NQCL** being invited by PQM to join **NAMCOL** (Network of African Medicines Control Labs)
- ◆ **NQCL** being assessed by PQM for potential future **African Reference Standards System** packaging facility.



Minilab training

Promoting the Quality of Medicines Program





Promoting the Quality of Medicines Program

Questions?



USAID
FROM THE AMERICAN PEOPLE



Promoting the Quality of Medicines Program

Thank You

lwe@usp.org

www.pqm-usp.org

This presentation is made possible by the generous support of the American people through the United States Agency for International Development (USAID), under Cooperative Agreement number GHS-A-00-09-00003-00, in cooperation with the President's Malaria Initiative (PMI). The contents are the responsibility of the Promoting the Quality of Medicines Program and do not necessarily reflect the views of USAID, PMI or the United States Government.



USAID
FROM THE AMERICAN PEOPLE



USAID
FROM THE AMERICAN PEOPLE

President's Malaria Initiative



Kenya Pharmaceutical Society Conference
Mombasa, Kenya ♦ May 30, 2010

Promoting The Quality of Medicines Program

Kennedy Chibwe, Ph.D., MBA

Promoting the Quality of Medicines Program

Implemented by United States Pharmacopeia



USAID
FROM THE AMERICAN PEOPLE



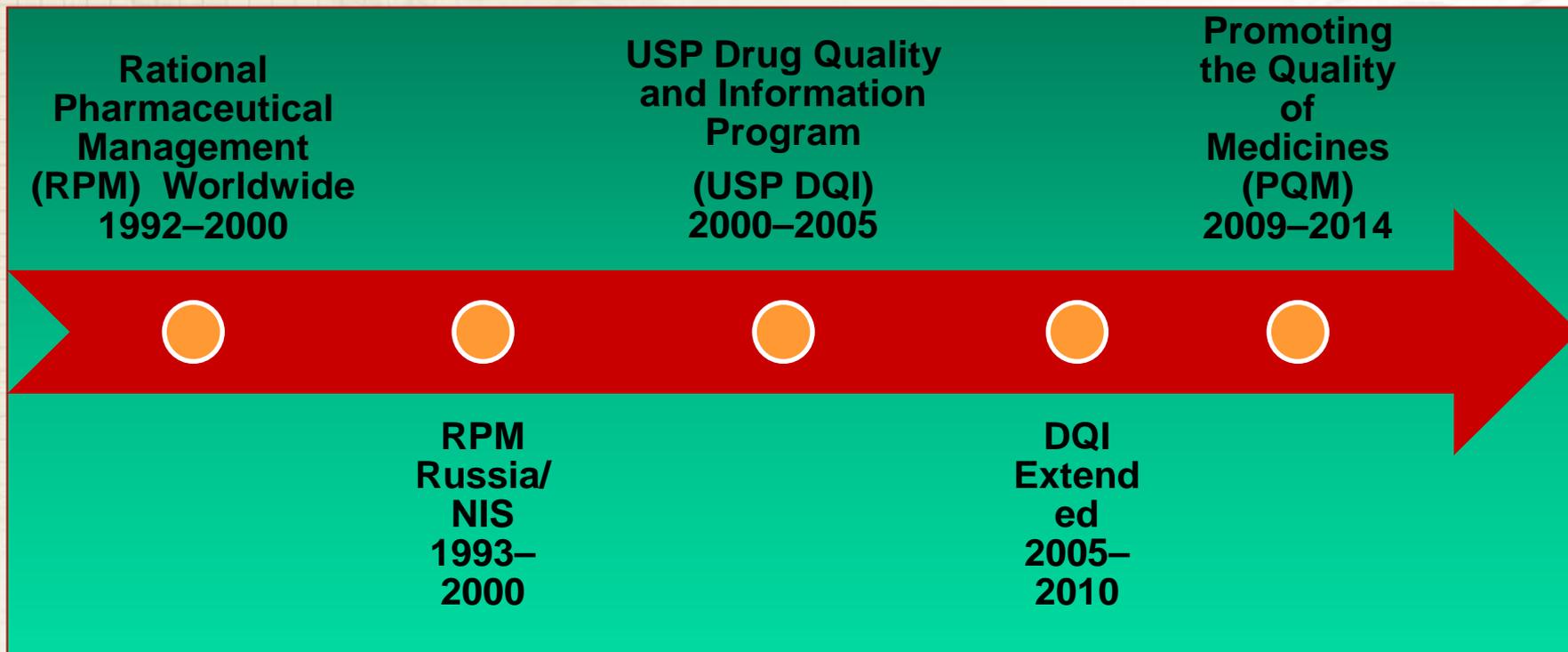
USP HQ, Rockville, MD



USAID
FROM THE AMERICAN PEOPLE



Promoting the Quality of Medicines Program



USAID
FROM THE AMERICAN PEOPLE



PQM Program Objectives

Promoting the Quality of Medicines Program



Build capacity & strengthen QA systems

- ▶ Train and educate in quality assurance
- ▶ Establish postmarketing surveillance programs



Help increase supply of QA medicines

- ▶ Improve manufacturers' GMP compliance
- ▶ Test procurement agency samples (UNICEF)



Combat availability of counterfeit meds

- ▶ Provide technical assistance to IMPACT, INTERPOL and other initiatives
- ▶ Raise awareness w/PSAs, campaigns

Provide technical leadership

- ▶ Advocate globally for medicine quality
- ▶ Promote new detection technologies





Promoting the Quality of Medicines Program

Promoting the Quality of Medicines Program

Building capacity for medicine quality assurance systems	Conducting research and providing technical leadership globally	Raising awareness on counterfeit and substandard medicines
Medicine Regulatory Authorities	<ul style="list-style-type: none"> ▶ Develop monographs for essential medicines 	<ul style="list-style-type: none"> ▶ Create PSAs about the dangers of substandard and counterfeit medicines
<ul style="list-style-type: none"> ▶ Establish medicine quality monitoring program 	<ul style="list-style-type: none"> ▶ Conduct collaborative research to provide data on medicine quality 	<ul style="list-style-type: none"> ▶ Publish articles, reports, and promotional materials on medicine quality issues
<ul style="list-style-type: none"> ▶ Provide technical assistance (TA) in drug registration and dossier evaluation 	<ul style="list-style-type: none"> ▶ Advocate the importance of medicine quality in international health programs 	<ul style="list-style-type: none"> ▶ Produce Matrix of Drug Quality Reports Affecting USAID-assisted Countries
<ul style="list-style-type: none"> ▶ Establish pharmacovigilance and medicine information centers 	<ul style="list-style-type: none"> ▶ Promote development of new technologies to detect counterfeits 	<ul style="list-style-type: none"> ▶ Advocate for good quality medicines at national and international forums
Manufacturers	<ul style="list-style-type: none"> ▶ Serve as technical resource for int'l organizations (UNICEF, WHO, GDF, etc.) 	<ul style="list-style-type: none"> ▶ Create communication campaign materials advocating medicine quality
<ul style="list-style-type: none"> ▶ Build capacity to reach WHO Prequalification for products 		
<ul style="list-style-type: none"> ▶ Provide TA in dossier preparation for WHO prequalification 		
National QC Laboratories		
<ul style="list-style-type: none"> ▶ Train in basic laboratory techniques for quality control 		
<ul style="list-style-type: none"> ▶ Provide TA toward ISO 17025 accreditation and WHO Prequalification 		



PQM Countries

Promoting the Quality of Medicines Program

◆ Africa

- ▶ Benin, Ethiopia, Ghana, Kenya, Liberia, Mali, Rwanda, Senegal, Tanzania, Uganda

◆ Asia

- ▶ Cambodia, India, Laos, Myanmar/Burma, Nepal, Philippines, Thailand, Vietnam, Yunnan Province of China

◆ Latin America and Caribbean

- ▶ Bolivia, Brazil, Colombia, Ecuador, Guyana, Guatemala, Jamaica, Panamá, Paraguay, Peru, Suriname

◆ Europe/Eurasia

- ▶ Russia



African Reference Standards System

Promoting the Quality of Medicines Program

- ◆ **NAMCOL** (Network of African Medicines Control Labs).
- ◆ Establish a system for reference standards for Africa.
- ◆ The Kenya National Quality Control Lab being assessed.
- ◆ **African Reference Standards System** packaging facility assessment FY10.



2nd Line TB Technical Assistance

Promoting the Quality of Medicines Program

◆ Focus on Manufacturer

- ▶ Provide technical assistance in GMP
 - Conduct on-site assessment of facilities
 - Review processes prior to Prequal audits
- ▶ Expedite WHO Prequal process by increasing company readiness for inspection
- ▶ Review and provide input to strengthen quality of submitted dossiers

◆ PQM as your Broker

We do not approve your application but we facilitate the approval by WHO Prequalification Programme.



Summary

Promoting the Quality of Medicines Program

- ◆ **African Reference Standards System** will assist in providing primary reference standards.
- ◆ PQM provides technical assistance toward WHO prequalification of medicines for 2nd Line TB medicines.



Promoting the Quality of Medicines Program

Questions?



USAID
FROM THE AMERICAN PEOPLE



Promoting the Quality of Medicines Program

Thank You

lwe@usp.org

www.pqm-usp.org

This presentation is made possible by the generous support of the American people through the United States Agency for International Development (USAID), under Cooperative Agreement number GHS-A-00-09-00003-00, in cooperation with the President's Malaria Initiative (PMI). The contents are the responsibility of the Promoting the Quality of Medicines Program and do not necessarily reflect the views of USAID, PMI or the United States Government.



USAID
FROM THE AMERICAN PEOPLE



President's Malaria Initiative

