

Antimalarial Supply Management Workshop and Meetings with the Guyana Food and Drug Department

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Trip Report

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PROMOTING THE QUALITY OF MEDICINES

Executive Summary

Dr. Evans travelled to Guyana to participate in the Antimalarial Supply Chain Management Workshop, sponsored by Management Sciences for Health (MSH)/Systems for Improved Access to Pharmaceuticals and Services (SIAPS). The workshop convened the Food and Drug Department (FDD), Vector Control Services (VCS), Material Management Unit (MMU), Regional Health Services (RHS), and the Pan American Health Organization (PAHO). The objective of the workshop was to provide guidance to the country on improving access to and the supply of quality assured medicines throughout the supply chain as well as the flow of information among departments within the Ministry of Health (MOH). Healthcare workers from each of the ten regions in Guyana participated in the workshop, which was led by MSH/SIAPS and PQM.

Dr. Evans also met with FDD, VCS, and PAHO to discuss their roles and responsibilities in the implementation of the Three-Level Approach for ensuring medicine quality detailed in the memorandum of understanding (MOU) between these organizations and the RHS and MMU. Discussions were held with the new directors of VCS and the FDD to provide information on leveraging resources from other country programs to support medicine quality assurance programs.

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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, and is 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.

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- Ms. Jewel Sears, FDD Acting Director, and her staff for allocating time to meet during the visit.
- All of the stakeholders who attended and participated in the workshop.
- PQM administrative staff and editors for their assistance with logistical arrangements and for editing the trip report.
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ACRONYMS

AMI	Amazon Malaria Initiative
DQI	Drug Quality and Information Program
FDD	Food and Drug Department
MOH	Ministry of Health
MMU	Materials Management Unit
MOU	Memorandum of Understanding
MQM	Medicine Quality Monitoring
MSH/SIAPS	Management Sciences for Health/Systems for Improved Access to Pharmaceuticals and Services
PAHO	Pan American Health Organization
PQM	Promoting the Quality of Medicines Program
QA	Quality Assurance
QC	Quality Control
QMS	Quality Management Systems
RHS	Regional Health Services
TAP	Technical Assistance Program
USAID	United States Agency for International Development
USP	United States Pharmacopeia
VCS	Vector Control Services (national malaria program)
WHO	World Health Organization

Background

The Promoting the Quality of Medicines (PQM) Program provides technical assistance to the Guyanese Ministry of Health (MOH)'s Food and Drug Department (FDD) and Vector Control Services (VCS), in collaborative efforts to improve the quality of medicines in Guyana. PQM activities have been focused on strengthening the FDD lab's technical capabilities and assisting VCS to establish a functional medicine quality monitoring (MQM) program throughout the country. In 2012, PQM supported a training workshop for regional pharmacy assistants to increase the workforce assigned for MQM in Guyana's malaria endemic regions.

PQM's work in Guyana is supported under the Amazon Malaria Initiative (AMI), funded by the United States Agency for International Development (USAID). AMI offers a multidisciplinary approach where international partners and country stakeholders provide support to prevent and control malaria in Bolivia, Brazil, Colombia, Ecuador, Guyana, Peru, and Suriname. During the last several years, assistance has also been provided to selected countries in Central America. PQM provides assistance to ensure the availability of good quality medicines and strengthen quality assurance and quality control (QA/QC) systems in the participating countries.

Purpose of Trip

- Participate in the Antimalarial Supply Chain Management workshop and present the Three-level Approach for medicine quality (See *Annex 1* for the Meeting Agenda).
- Meet with national stakeholders to advance the completion of a memorandum of understanding (MOU) that assigns roles and responsibilities for medicine QA/QC throughout the supply chain.
- Meet with the new head of the FDD to discuss the status of the lab and its role in the implementation of the "Three-level Approach."

Overview of Activities

Highlights of the meeting with FDD

Dr. Evans met with: Ms Jewell Sears (Acting Director), Ms. Aletha Quintyn (Analytical Scientific Officer), Ms. Erica Ward (Analytical Scientific Officer), and Mr. Vishna Ramlagan (Analytical Scientific Officer).

- Ms. Sears assumed the Acting Director position in October 2012.
- The FDD supports the implementation of the Three-Level Approach, but due to the limited number of inspectors, assistance is needed to conduct medicines sampling in the field. Dr. Evans pointed out that the objective of training the pharmacy assistants in July 2012 was to address this human resources issue. In the MOU being prepared by national stakeholders (FDD, VCS, MMU, RHS, and PAHO), field sampling and testing responsibilities describing the MQM process will need to be explicitly defined.
- The lab expressed interest in attaining World Health Organization (WHO) Prequalification and ISO 17025 accreditation. The lab has limited resources, thus making the endeavor very challenging at this time. A teleconference with the PQM Quality Management Systems (QMS) team will be convened to provide guidance.
- The lab's capability to perform key tests continues to be hindered by maintenance issues with essential lab equipment. Consequently, full implementation of the Three-Level

Approach is severely impacted due to the inability of performing tests according to registration procedures and specifications (level 3 analysis).

- Dr. Evans informed Ms. Sears that PQM has budgeted for one scientist to participate in the regional training on compendial analysis of Coartem, to be held in Bogota, Colombia in May/June 2013.
- The FDD requested assistance in developing sampling guidelines for post-market surveillance.
- The FDD also indicated that the country's lengthy procurement processes have made it difficult to purchase supplies and reference standards via the USP Technical Alliances Program (TAP).
- The FDD requested hard copies of the latest USP documentary standards (i.e., *USP/NF*)

Antimalarial Supply Chain Management Workshop

The Antimalarial Supply Chain Management Workshop in Guyana was sponsored by Management Sciences for Health (MSH)/Systems for Improved Access to Pharmaceuticals and Services (SIAPS) and convened the FDD, VCS, Materials Management Unit (MMU), Regional Health Services (RHS), and Pan American Health Organization (PAHO). RHS health workers from both the malaria endemic and non-endemic regions participated in the workshop. The objective of the workshop was to gather information to improve both access to and supply of quality assured medicines throughout the supply chain as well as the flow of information among the various MOH departments.

Presentations by the SIAPS team focused on supply chain interventions successful in other AMI countries. As part of the workshop, stakeholders developed interventions to improve the supervision system and antimalarial information flow. Dr. Evans presented the Three-Level Approach and its incorporation into the supply chain along with descriptions of the role and responsibilities of each of the stakeholders. The Guyana MOH presented data on national malaria cases and the increase that has been observed over the last two years.

During the workshop, Dr. Evans met informally with Dr. Rahman, Director of VCS, to brief him on the status of the MOU for MQM. A conference call among the directors of the FDD, MMU, VCS, and the RHS was recommended to update all of the stakeholders on the status of the MOU. Dr. Rahman noted that he is the new director of the country's Global Fund malaria program. He was advised of the Global Fund's quality assurance policy requirements, and PQM offered to provide assistance to ensure compliance.

Conclusion

The workshop in Guyana was successful; PQM was able to present a concise description of the implementation of the Three-Level Approach to the MOH. In addition, discussions with the new directors of the FDD and VCS provided updates on the status of the laboratory and current medicine quality monitoring that will aid in planning future technical assistance and finalizing the MOU.

Next Steps

By the end of March 2013, PQM will:

- Provide FDD with information detailing the resources needed and path to WHO Prequalification/ISO 17025 accreditation
- Arrange and host a conference call with the VCS, FDD, MMU, RHS and PAHO regarding the MOU for MQM
- Request USP to ship hard copies of all the latest versions of USP documentary standards to the FDD
- Send an invitation letter for a FDD staff member to participate in the Coartem training in Colombia in May/June 2013
- Initiate south-south collaboration from a regional medicines regulatory authority to assist the FDD in developing sampling guidelines for post-market surveillance
- Arrange and host a conference call with the VCS to discuss technical assistance for compliance with the Global Fund quality assurance policy for pharmaceutical products

Annex 1

Meeting Agenda		
Time	Activity	Presenter/Facilitator
Friday, February 8th		
8:30-9:00	Registration	
9:00-9:15	Welcome and introduction to the meeting	National representative/ PAHO representative
9:15-9:30	Presentation of participants and workshop methodology	John Marmion
9:30-9:45	Presentation of malaria situation in Americas and Guyana.	5' Nicolas Ceron 10' Guyana- Krishnalall
9:45-10:15	Situation of supply management of antimalarials and MSH frameworks	20' John Marmion 10' Discussion
10:15-10:45	Break	
10:45-11:45	Three level approach	Lawrence Evans
11:45-12:15	Present regional MSH interventions <ul style="list-style-type: none"> • Regional monitoring system • Supervision systems • Guidelines for first line treatment • Programming in low incidence areas 	20' John Marmion 10' Discussion
12:15-12:45	Lunch	
12:45-1:45	Presentation of pharmaceutical situation in Guyana (Guide 1- national level)	Guyana 20' Krishnalall 10' Discussion
1:45- 2:30	Presentation of Guyana's AMI work plan for MSH and USP components	Guyana
2:30-3:30	Round table to discuss interventions and implementation (Guide 2)	John Marmion
3:30-4:00	Break	
4:00-5:00	Round table to discuss interventions and implementation (Guide 2) Presentation of plan by representatives.	John Marmion
Saturday, February 9th		
9:00-9:30	MIS function and background	John Marmion
9:30-10:00	MIS function in Guyana context and information system for monthly report	Nicolas/Colette
10:30-11:00	Regional Monitoring system theory and history.	John Marmion
11:00-11:30	Break	
11:30-12:00	Report 4 th quarter data for Guyana information system and Regional Monitoring Report and presentation of National data. (Guide 1 national/ regional levels, regions complete slide 1,2 and 3 only)	20' Group work. 10' Presentation of national data
12:00-12:30	Closure and Final agreements	
12:30- 1:30	Lunch	