

**Training Workshop on the Baseline Survey of Priority Opportunistic Infection Medicines' Quality in Selected Health Facilities in Vietnam; and follow-up on PQM Project Implementation**

**March 2-8, 2012**

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***Trip Report***

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**PROMOTING THE QUALITY OF MEDICINES**

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## **Executive Summary**

PQM conducted a one-day training workshop on the “Baseline Survey of Priority Opportunistic Infection Medicines’ Quality in Selected Health Facilities in Vietnam” at the National Institute of Drug Quality Control (NIDQC) in Hanoi, March 6, 2012. The purpose of the workshop was to provide training to participants from NIDQC, Ho Chi Minh Institute of Drug Quality Control (HCM IDQC), and provincial Drug Quality Control Centers (DQCCs) on sampling and testing methods for opportunistic infection (OI) medicines. A total of 29 representatives attended the workshop. The baseline survey will be conducted from May to September 2012.

The PQM team also paid visits to USAID/Vietnam, representatives from NIDQC, and the Chemical and Biological Institute (CBI – Ministry of Public Security) in order to follow up on the progress of activities.

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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 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, PMI or the United States Government. It may be reproduced if credit is given to PQM and USP.

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- Mr. Anthony Boni and Dr. Maria Miralles at USAID/Washington, D.C.
- Our local program partners:
  - Dr. Doan Cao Son, Director; Dr. Nguyen Viet Hung, Vice Director; and Ms. Nguyen Thi Phuong Thao, Assistant Quality Assurance Manager, at the National Institute of Drug Quality Control of Vietnam
  - Dr. Nguyen Manh Hung, Director, and Mr. Trinh Ngoc Hai, Chief Pharmaceuticals Division, at the National Institute of Malariology, Parasitology and Entomology of Vietnam
- Our PQM colleagues

## ACRONYMS

AIDS	Acquired Immunodeficiency Syndrome
API	Active Pharmaceutical Ingredient
ARV	Antiretroviral
CDC	U.S. Centers for Disease Control and Prevention
DAV	Drug Administration of Vietnam
DQI	Drug Quality and Information Program
GMP	Good Manufacturing Practices
HCM-IDQC	Ho Chi Minh Institute of Drug Quality Control
HIV	Human Immunodeficiency Virus
MQM	Medicine Quality Monitoring
NIMPE	National Institute of Malariology, Parasitology and Entomology, Vietnam
MOH	Ministry of Health
NIDQC	National Institute of Drug Quality Control, Vietnam
OI	Opportunistic Infection
PEPFAR	President's Emergency Plan for AIDS Relief
PQ	Prequalified
PQM	Promoting the Quality of Medicines Program
QA	Quality Assurance
QC	Quality Control
USAID	United States Agency for International Development
USP	United States Pharmacopeia
VAAC	Vietnam AIDS Administration Committee
WHO	World Health Organization

## **Background**

Under the national and President's Emergency Plan for AIDS Relief (PEPFAR)-supported projects in Vietnam, HIV/AIDS patients being treated with antiretrovirals (ARVs) also receive opportunistic infection (OI) medicines. Opportunistic infections occur in immune-compromised individuals infected with HIV. The OI medicines are procured through the U.S. Centers for Disease Control and Prevention (CDC)-funded LifeGap project. At the peripheral level, Provincial AIDS Centers locally purchase their OI products through provincial bidding. No quality control system has been established to assess the quality of these OI products during their storage or at distribution to patients. The current decentralized procurement practices make it difficult to ascertain OI product quality. It is apparent that poor quality medicines may harm patients, cause treatment failure, lead to drug resistance, waste scarce financial resources, and deteriorate trust in the government health care system.

In order to strengthen the quality assurance and quality control (QA/QC) of OI products produced and supplied in the PEPFAR program in Vietnam, PQM received financial support from USAID/Vietnam to conduct a survey of baseline data on the quality of OI products in national and PEPFAR-supported projects in Vietnam. After careful consultation with key partners, a workshop was organized at the National Institute of Drug Quality Control (NIDQC) to discuss the survey methodology and develop an implementation plan. Relevant technical staff members from PQM's key partners in Vietnam were invited to participate in the training.

## **Objectives of Trip**

1. Conduct a training workshop on a baseline survey of OI product quality in selected health facilities in Vietnam
2. Follow up on project progress and provide technical guidance to address programmatic issues encountered at national and field levels

## **Source of Funding**

This trip was supported with funds from USAID/Vietnam.

## **Overview of Activities**

### Objective 1: Conduct a training workshop on a baseline survey of OI product quality in selected health facilities in Vietnam

On March 6, 2012, PQM, in collaboration with NIDQC, Vietnam AIDS Administration Committee (VAAC), and the Drug Administration of Vietnam (DAV), held a training workshop for 30 participants (see *Annex 1* for the Agenda and *Annex 2* for the list of participants).

Following opening remarks from Dr. Doan Cao Son, Director of NIDQC, and Mr. Jonathan Ross, Director of USAID/Vietnam's Office of Public Health, Dr. Souly Phanouvong explained the objectives of the training:

1. Explain the survey methodology and train on the sampling and testing protocol and procedures for the sampling and testing team members. In addition, the group will learn about data management and reporting of findings.
2. Establish a mechanism for effective communication and coordination between project management and local teams.

Highlights of the training are summarized below:

Sampling and testing protocols were clearly discussed and agreed on by all partners

- A random sampling of 46 (of 110) health facilities will be selected for the study.
- Some 380 samples of priority OI products will be collected, which include:
  - Sulfamethoxazole-trimethoprim (cotrimoxazole) (SUL-TRI) fixed dose combination tablets
  - Fluconazole (FLU) tablets
  - Acyclovir (ACY) capsules or tablets
  - Azithromycin (AZI) tablets
  - Cotrimoxazole (COT) pediatric syrup
  - Some provinces are asked to collect cotrimoxazol, cefaclor, and fluconazole tablets as well
- Compendial analysis will be used for evaluating the quality of OI products collected from 25 provinces which include:

1. An Giang	9. Da Nang	17. Long An
2. Bac Giang	10. Dien Bien	18. Nam Dinh
3. Bac Ninh	11. Ha Noi	19. Nghe An
4. Binh Duong	12. Hai Phong	20. Quang Ninh
5. Binh Thuan	13. Ho Chi Minh City	21. Quang Nam
6. Ba Ria - Vung Tau	14. Hoa Binh	22. Soc Trang
7. Can Tho	15. Khanh Hoa	23. Son La
8. Cao Bang	16. Lao Cai	24. Thai Binh
		25. Vinh Long

Samples collected will be tested at the following QC labs:

- Ho Chi Minh Institute of Drug Quality Control (HCM-IDQC) will be testing samples collected from Ho Chi Minh City, Bình Dương, Long An, Vinh Long, Cần Thơ, Sóc Trăng, and An Giang.
- The rest of the samples collected from other sites will be analyzed at NIDQC.

Timeline: April-September 2012 to complete the survey and produce a technical report

Next steps:

- NIDQC and partners (DAV, VAAC, LifeGap) will develop itemized budgets and submit them to PQM for review and approval – by mid April 2012 (completed)
- PQM will review the budget and wire funds once the budget is approved – by end of April 2012 (completed)
- NIDQC and PQM Country Consultant will lead the implementation of the survey – from May through September 2012

Objective 2: Follow up on project progress and provide technical guidance to address programmatic issues encountered

No progress has been made since the beginning of 2012 on supporting local methadone production partly due to lack of interest by some of the key stakeholders in methadone local production.

In mid-2011, USP hosted two visiting scientists from DAV and NIDQC to help them gain experience on methadone production and methods to address counterfeit and substandard medicines. On this current trip, the PQM team had a meeting with Ms. Tran Thuy Hanh from NIDQC, one of the visiting scientists who participated in the 2011 USP training. The group discussed what could be done to help further the progress of local methadone production and concluded that unless the Ministry and/or DAV Director General take the first step, nothing will progress. Ms. Tran Thuy Hanh is ready to contribute her technical experience and skills to support the project.

NIDQC has received \$7.7 million over five years (2011-2015) from the Global Fund Round 10. Among other activities, NIDQC will expand the Medicines Quality Monitoring (MQM) project, from 9 PQM-supported sentinel sites to 50 total sites; strengthen NIDQC provincial QC lab networks' capacity; and improve the quality systems of the NIDQC itself. The PQM team met with the NIDQC Global Fund implementation team to discuss the possibility of USP providing technical assistance to NIDQC.

Next Steps:

- NIDQC will send the scope of work to PQM for review and consideration – by April 2102 (completed, under consideration)

The PQM team met with representatives from the Ministry of Public Security, the Chemical and Biological Institute (CBI), USAID/Vietnam, and NIDQC. The meeting was held to gain understanding of the CBI, which has been experimenting with the production of methadone active pharmaceutical ingredient (API). CBI will finish the experimentation phase in June 2012 and will produce a pilot batch of 0.5 kg by 2013, scaling up to 2 kg/batch. NIDQC is helping conduct the CBI methadone API stability study. CBI would like PQM to provide technical assistance on methadone API production with respect to the following key areas:

- Improve route of synthesis
- Improve purity (and make sure the impurities meet the specifications)
- Build the quality system per World Health Organization (WHO) standards
- Help develop and compile key documents

On March 5, the PQM team briefed the USAID team on ongoing activities in Vietnam and the region and on recent accomplishments. After the meeting, PQM submitted the revised 2012 workplan for approval.

Next Steps:

- USAID/Vietnam will inform PQM if PQM can reprogram funds to help CBI

## **Conclusion**

The training workshop on OI medicines sampling and testing was successful, and PQM and NIDQC partners are ready to collect and test samples. For the most part, PQM activities in Vietnam are progressing as planned.

## Agenda 1

### *Training Workshop Baseline Survey on Priority Opportunistic Infection Medicines' Quality in Selected Health Facilities in Vietnam*

In collaboration with the  
National Institute of Drug Quality Control Laboratory  
Date: March 6<sup>th</sup>, 2012 – Hanoi, Vietnam

#### TENTATIVE AGENDA

Time	Activity	Responsible
08:30-09:00	Registration	
09:00-09:15	Opening Remarks	NIDQC representative USAID representative USP/PQM representative
09:15-09:30	<ul style="list-style-type: none"> <li>Introduction of Participants</li> <li>Introduction to the training</li> </ul>	Nguyen Thi Phuong Thao (NIDQC)/ Vuong Tuan Anh (USP-PQM)
09:30-12:00	<ul style="list-style-type: none"> <li>Overview of the Project</li> <li>Sampling Protocol</li> <li>Sample handling, storage and documentation</li> <li>Project monitoring and supervision</li> <li>Data reporting and management</li> <li>Technical report</li> </ul>	Souly Phanouvong
12:00-13:00	<b>Lunch</b>	ALL
13:00-14:30	<ul style="list-style-type: none"> <li>Identify and agree on analytical methods for samples</li> <li>Discussion on methods and procedures</li> </ul>	Asawin Likhitsup
14:30-15:00	<ul style="list-style-type: none"> <li>Set up survey team(s) and define responsibilities/assignments</li> <li>Financial arrangement (receiving, dispatching, expense report)</li> </ul>	Souly Phanouvong
15:00-15:30	<b>Coffee/Tea Break</b>	ALL
15:30-16:30	Action items: implementation plan and timeline	Souly Phanouvong
16:30-17:00	Wrap up and closing	PQM

#### **US Pharmacopeia (USP) - Promoting the Quality of Medicines (PQM) program:**

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Date: March 6, 2012

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