

## Visit to Binh Phuoc Province and Partner Meetings in Vietnam and Thailand

Hanoi, Ho Chi Minh City, and Binh Phuoc, Vietnam  
Bangkok, Thailand

January 21-28, 2013

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### *Trip Report*

Dr. Souly Phanouvong, Manager, Asia Programs

Dr. Vuong Tuan Anh, Vietnam Consultant

**Promoting the Quality of Medicines**  
Implemented by U.S. Pharmacopeia  
12601 Twinbrook Parkway  
Rockville, MD 20852 USA  
Tel: +66-83-122-6062; +1 301-816-8582  
Email: [exp@usp.org](mailto:exp@usp.org)

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PROMOTING THE QUALITY OF MEDICINES

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## **Executive Summary**

Dr. Souly Phanouvong and Dr. Vuong Tuan Anh traveled to Ho Chi Minh City, Vietnam to meet with current and potential program partners to brief them about upcoming workplan activities, develop action plans, and discuss roles and responsibilities for successful implementation. In addition, the PQM team traveled to Binh Phuoc province, where there has been increasing concern about artemisinin-resistant malaria. The team, with the assistance of local partners, collected antimalarials available in district and community health centers and retail pharmacy outlets. These samples will be analyzed in-country, and the results are expected in March 2013.

Following the Vietnam activities, the PQM staff went to Bangkok, Thailand to debrief the Regional Development Mission for Asia (RDMA) and meet with local program partners to discuss and plan for upcoming 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) and implemented by the United States Pharmacopeia (USP), is the successor of the Drug Quality and Information (DQI) program. PQM is USAID’s response to the growing challenge posed by the proliferation of counterfeit and substandard medicines. By providing technical assistance (TA) to developing countries, PQM helps build local capacity in medicines 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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## ACRONYMS

ADR&DI	Adverse Drug Reaction and Drug Information
ASEAN	Association of South-East Asian Nations
BREMERE	Build Regional Expertise in Medicines Regulation, Information Sharing, Joint Investigation and Enforcement
BVBD	Bureau of Vector Borne Disease, Thailand
DAV	Drug Administration of Vietnam
GF	Global Fund
GMP	Good Manufacturing Practices
GMS	Greater Mekong Sub-region
HUP	Hanoi University of Pharmacy
IDQC HCM	Institute of Drug Quality Control, Ho Chi Minh
IMPE HCM	Institute of Malariology, Parasitology and Entomology, Ho Chi Minh
MSH	Management Sciences for Health
MOU	Memorandum of Understanding
MQM	Medicines Quality Monitoring
NIMPE	National Institute of Malariology, Parasitology, and Entomology
NIDQC	National Institute of Drug Quality Control, Vietnam
NOMCOL	Network of Official Medicine Control Laboratories
NQCL	National Quality Control Lab
OI	Opportunistic Infection
PATH	Program for Appropriate Technology in Health
PEPFAR	President's Emergency Plan for AIDS Relief
PMI	President's Malaria Initiative
PQ	Prequalified
PQM	Promoting the Quality of Medicines Program
PV	Pharmacovigilance
QA	Quality Assurance
QC	Quality Control
RDMA	Regional Development Mission for Asia, USAID
TA	Technical Assistance
USAID	United States Agency for International Development
USP	United States Pharmacopeia
VAAC	Vietnam AIDS Administration Committee
WHO	World Health Organization

## **Background**

The Promoting the Quality of Medicines (PQM) program has been providing technical assistance (TA) to the Greater Mekong Sub-region (GMS), including Vietnam, since 2002. In the GMS, activities have focused on continuing and maintaining the effective medicines quality monitoring (MQM) program used to obtain evidence-based data to support decision-making and enforcement action; building the capacity of national quality control laboratories (NQCLs) in quality assurance/quality control (QA/QC) of medicines toward compliance with ISO 17025:2005 and/or World Health Organization (WHO) prequalification (PQ) standards; improving the practices of local pharmaceutical manufacturers for priority antimalarials; and raising awareness of poor-quality medicines among the general public, as well as among healthcare providers, the pharmaceutical industry, and retailers.

Medicine quality may have been one of the factors contributing to increasing malaria resistance to artemisinin-derivative medicines in Binh Phuoc province of Vietnam. To obtain relevant information on the supply and distribution of antimalarials circulating in “hot spots,” PQM and local partners agreed to travel to meet with local malaria control program staff and collect samples for quality analysis to better understand the situation and develop appropriate approaches to address problems related to medicines quality.

## **Purpose of Trip**

The main objectives of the trip were to:

- Meet with key local partners to develop implementation plans for the FY13 work plans
- Travel to Binh Phuoc province to review the presence and quality of antimalarials, with a focus on artemisinin-derivative combination therapies

## **Overview of Activities**

***January 22, 2013***

### **Meeting with National Institute of Drug Quality Control (NIDQC)**

Several topics were covered during the meeting, including:

Build Regional Expertise in Medicines Regulation, Information Sharing, Joint Investigation and Enforcement (BREMERE) and Network of Official Medicine Control Laboratories (NOMCOL)

Dr. Phanouvong briefed the NIDQC team about the BREMERE inaugural meeting held August 2012 in Bangkok, Thailand and invited NIDQC to participate in the February 18-19, 2013 implementation meeting in Siem Reap, Cambodia. NIDQC expressed its support for BREMERE as it will complement the existing Association of the South-East Asian Nations (ASEAN) post-marketing surveillance alert system for counterfeit medicines in the region.

Dr. Phanouvong also briefed the NIDQC about the NOMCOL-Asia Pacific Initiative, supported by the United States Pharmacopeia (USP), and invited NIDQC to participate in its inaugural meeting in Siem Reap February 20-22, 2013, just following the BREMERE meeting.

Updates on the Opportunistic Infections (OI) baseline study

A total of 101 samples were collected; 100 samples passed and one sample (Sufametroxazole-Trimetoprim 480 mg) failed the dissolution test under USP 34 specifications. The sample is being analyzed using the Vietnamese Pharmacopoeia.

### USP/ASEAN symposium

This symposium will be held during the week of June 10, 2013. PQM, NIDQC, and National Institute of Malariology, Parasitology, and Entomology (NIMPE) will discuss and select an MQM sentinel site (based on several factors: strategic location, close to Hanoi, having a full cycle of MQM) to hold a formal visit for PQM and Ministry of Health (MOH) leaders.

### WHO PQ re-qualification of NIDQC

Most deficiencies observed during the WHO PQ inspection visit in 2012 have been addressed, and NIDQC has submitted corrective and preventive action reports to the WHO PQ team. PQM will help to follow up on the status with WHO PQ.

### Reference standard development

PQM will coordinate with USP to consider holding a training workshop on reference standard development, in collaboration with USAID and Global Fund (GF). A joint training between Indonesia (USAID funding) and Vietnam (GF funding) could be held. The training will likely be held after June 2013. PQM will confirm with Indonesian partners in March 2013.

### Testing of samples from Myanmar

PQM requested assistance from NIDQC and the Institute of Drug Quality Control, Ho Chi Minh (IDQC HCM) to test samples collected from a baseline study in Myanmar. Both institutes are willing to assist in testing some 164 samples from Myanmar beginning in April 2013.

### Next Steps:

1. PQM will send formal invitations to NIDQC and IDQC HCM to participate in BREMERE and NOMCOL-Asia (completed)
2. PQM will follow up with the WHO PQ team regarding the status of NIDQC's re-qualification assessment (completed)
3. NIDQC and IDQC HCM to nominate and send representative to attend BREMERE and NOMCOL-Asia (completed)
4. NIDQC will submit to PQM a technical report on the OI product survey by mid-March 2013

### **Meeting with Dr. Socorro Escalante, WHO Technical Officer**

Dr. Escalante briefed the PQM team about the GF Round 10 plans for the national Adverse Drug Reaction and Drug Information (ADR&DI) Center with three main components: 1) Capacity building for junior center staff; 2) Establishment of sentinel sites; and 3) Building up active surveillance for HIV/AIDS, tuberculosis, and malaria. She suggests that PQM can help in building up the active surveillance system. Because there are many TA activities taking place, PQM recommended that the national center map existing TA activities to identify gaps and avoid duplication. PQM and WHO can identify what pharmacovigilance (PV) activities need to be supported. PQM briefed her on BREMERE and NOMCOL meetings that will take place in Cambodia in February and invited her to attend.

### Next Steps:

1. PQM and WHO will communicate with each other on areas of TA for the Center
2. PQM will share the mapping results with WHO Vietnam

### **Meeting with Vietnam AIDS Administration Committee (VAAC)**

Dr. Tam, Head of the Harm Reduction Unit of VAAC, briefed the PQM team on the national Methadone Maintenance Therapy program and requested that PQM provide TA to procure methadone finished product. In 2013, funding will be allocated to procure methadone for about 3,000 patients, in addition to the 15,000 patients currently supported by the President's Emergency Plan for AIDS Relief (PEPFAR). She requested that PQM provide templates for international procurement to help VAAC in developing product specifications, including quality and other technical aspects and reviewing technical requirements of tender documents. Dr. Phanouvong indicated that procurement and tender organization are not part of PQM's mandate, but he will communicate with appropriate agencies such as Management Science for Health (MSH) and Program for Appropriate Technology in Health (PATH). Dr. Tam also provided updates of the final inspections of six local manufacturers for methadone production. PQM requested a copy of the report when it becomes available as PQM plans to assist the selected manufacturers towards compliance with WHO Good Manufacturing Practices (GMP).

#### **Next Steps:**

- PQM will communicate with MSH and PATH by mid-February (completed)
- VAAC will share the inspection report with PQM, when available
- VAAC will share the tender document with PQM for feedback by February 2013
- PQM will send technical specifications of methadone finished products (10mg/ml) and dispensing pump to VAAC for tendering (completed)

### **Meeting with CPC1**

Mr. Tho, Head of the Export Unit, introduced CPC1 to the PQM team. CPC1 was established in 1956, and at present, has seven branches and two warehouses (one in Hanoi, one in Ho Chi Minh City). CPC1 has more than 420 staff and a QC lab to test basic pharmaceutical product quality properties. CPC1 is one of six local importers and is distributing methadone for PEPFAR and GF. CPC1 distributes methadone to 60 clinics (GF and PEPFAR) at the rate of 3,000 bottles of methadone HCL 10mg/ml per month.

#### **Next Step:**

- PQM will be in touch with CPC1 should it win the bid for methadone supply under the VAAC project (as discussed above) for any technical assistance CPC1 may need

### ***January 23, 2013***

#### **Meeting with USAID/PEPFAR Vietnam**

Dr. Phanouvong briefed the USAID Activity Manager for PQM, Mr. Nguyen Anh Dao, on the outcomes of the previous meetings and invited USAID representatives to attend the two upcoming BREMERE and NOMCOL meetings in Siem Riep, Cambodia.

#### **Next Step:**

- PQM will send a formal invitation to USAID/Vietnam to attend the meetings

#### **Meeting with the national ADR&DI Center**

Dr. Nguyen Dang Hoa—Rector of Hanoi University of Pharmacy (HUP) and Director of the national ADR&DI Center—and his team briefed PQM about the status and progress of the GF

Round 10 project, “Strengthening the national PV system in Vietnam.” The PQM team discussed PQM’s program in Vietnam, potential TA to the national PV system within the GF Round 10 project, and experience in PV activities in the region and in Africa. The PQM team requested that the national ADR&DI center share previous assessment reports by other agencies to help identify gaps where PQM TA might be needed. In addition, the PQM team recommended that the center map all relevant TA activities to-date. PQM will help the center to do this mapping.

PQM and HUP also discussed how to collaborate in other sectors, such as in training and education for medicine QA/QC. HUP will send their curriculum and syllabus on QA/QC to for review. USP and HUP may collaborate in doing research to develop monographs and exchanging fellows. PQM can financially support some HUP representatives to attend the USP/ASEAN symposium.

Next Steps:

- The HUP ADR&DI team will map the current TA areas by March 2013
- PQM will assist in the mapping and determine where PQM TA might be useful
- HUP will send PQM the existing curriculum for final pharmacy students on medicines QA/QC by March 2013.

### **Meeting with NIMPE**

Dr. Phanouvong also briefed the NIMPE team on potential TA to artemisinin-product producers in Vietnam to achieve WHO PQ. In order to implement this activity, PQM and NIMPE will assess the quality of antimalarials in Vietnam. Ms. Thu, Head of the Pharmaceutical Department for Malaria Research and Training, reported where hotspots of artemisinin-resistance have been observed (Binh Phuoc, Dak Nong, Quang Nam, and Quang Tri provinces). Pilot sampling will be done in Binh Phuoc in the coming days. Ms Thu also provided information about local manufacturers of artemisinins. The MOH does not ban antimalarial monotherapies; it only recommends that clinicians not use them.

Next Step:

- NIMPE will lead the comparative study as soon as it receives funds from PQM.

### ***January 24, 2013***

### **Meeting with Institute of Malariology, Parasitology and Entomology, Ho Chi Minh (IMPE HCM)**

Dr. Phanouvong briefed Mr. Trinh Ngoc Hai, Head of Drug Efficacy Testing and the Molecular Unit, about the outcomes of the meeting with NIMPE, the status of the MOU amendment, and discussed logistics for sampling antimalarials in Binh Phuoc province.

### **Meeting with VIDIPHA**

Mr. Nguyen Ngoc Tuan introduced the PQM team to VIDIPHA, a state-owned manufacturer and registered joint-stock company. In 2010, VIDIPHA built a new manufacturing plant in Binh Duong, which received a GMP license from the MOH. VIDIPHA produces narcotics such as morphine, diazepam, and codeine. At the end of 2012, the MOH inspected potential local methadone manufacturers, which included VIDIPHA.

### ***January 24-25, 2013***

#### **Field trip to Binh Phuoc**

The PQM team and IMPE HCM staff traveled to meet with local malaria control program staff to gain a better understanding of the supply and distribution of antimalarials in the public and private sectors. In the public sector, all antimalarials are supplied to the Binh Phuoc province by IMPE HCM. The provincial malaria control program then dispatches them to the district level which further distributes to community health centers semi-annually. In the private sector, antimalarials, especially artemisinin-derivatives, were not available in high quantities or volume. No solid dosage forms of artesunate were available in the public sector, while this product still can be found in private sector retail pharmacies.

The team, with assistance from the local malaria control staff, collected 25 antimalarial samples from different districts and communities where there is much concern about artemisinin-resistant malaria. These samples will be analyzed at IDQC HCM; results are expected in March 2013.

Next Steps:

- IMPE HCM will send samples to IDQC HCM for analysis (completed)
- PQM will follow up the tests results with a written technical report

### ***January 28, 2013***

#### **Meeting with President's Malaria Initiative (PMI) and Regional Development Mission for Asia (RDMA) teams**

Dr. Phanouvong traveled to Bangkok, Thailand to brief PMI/RDMA on the Vietnam trip and discuss other PQM activities in the region. PMI/RDMA alerted PQM to upcoming meetings: PMI partners' meeting in Bangkok in February and PMI partners' meeting and CAP-Malaria Cross-Border Meeting in Yangon in April.

#### **Meeting with Thailand Bureau of Vector Borne Disease (BVBD)**

Ms. Sansanee Rojanapanas and Ms. Suravadee Kitchakarn updated Dr. Phanouvong on sample collection progress in 22 provincial malaria clinics under GF Round 10. BVBD is preparing to submit the samples to the Bureau of Drugs and Narcotics lab for analysis beginning in February.

#### **Conclusion**

This was a successful trip, with the PQM team able to meet current and potential partners to discuss work plans for the coming year. Additionally, the team helped collect antimalarial samples in Binh Phuoc province to help monitor the quality of medicines on the market.

## Annex1

<b>Program Agenda - Vietnam</b>			
<b>Date &amp; Time</b>	<b>Issues to be discussed/purposes</b>	<b>Partner/place</b>	<b>Key persons met</b>
21 Jan 9-10:30 AM	<ul style="list-style-type: none"> <li>• BREMERE &amp; NOMCOL</li> <li>• Updates of OI baseline survey</li> <li>• USP/ASEAN symposium</li> <li>• WHO PQ re-assessment of national QC lab</li> <li>• Technical Assistance Program</li> </ul>	NIDQC	<ul style="list-style-type: none"> <li>• Dr. Doan Cao Son, Director</li> <li>• Dr. Tran Viet Hung, Vice Director</li> <li>• Ms. Nguyen Phuong Thao, Head of Depart of Planning</li> <li>• Mr. Pham Van Kien, Staff of Depart of Planning</li> <li>• Ms. Tran Thuy Hanh, Vice Head, Lab for Control APIs (expert of methadone API and finished product control)</li> <li>• Ms. Le Thi Thu, Head, Lab for Establishing of Standards and Reference Substances</li> </ul>
21 Jan 12-13:30	<ul style="list-style-type: none"> <li>• Technical Assistance to the GFR 10 "Strengthening the national PV system in Vietnam"</li> </ul>	WHO	<ul style="list-style-type: none"> <li>• Dr. Socorro Escalante, Technical Officer, Pharmaceutical Sector</li> </ul>
21 Jan 14-15:00	<ul style="list-style-type: none"> <li>• Technical Assistance to the procurement of methadone finished products</li> </ul>	VAAC	<ul style="list-style-type: none"> <li>• Ms. Nguyen Minh Tam, Head of Harm Reduction Unit</li> <li>• Ms. Tran Thu Hien, staff of Harm Reduction Unit</li> <li>• Tran Thuy Hanh (NIDQC)</li> </ul>
15:30-16:30	<ul style="list-style-type: none"> <li>• Understanding the procurement procedure for methadone in Vietnam</li> </ul>	CPC1	<ul style="list-style-type: none"> <li>• Mr. Nguyen Van Tho, Head of Export Unit</li> <li>• Ms. Tran Thuy Hanh (NIDQC)</li> </ul>
22 Jan 9:00 AM	<ul style="list-style-type: none"> <li>• PQM Workplan 2013</li> <li>• Updates for PQM activities</li> </ul>	USAID/PEPFAR	<ul style="list-style-type: none"> <li>• Mr. Nguyen Anh Dao, Activites Manager – HIV/AIDS Care &amp; Treatment Specialist</li> </ul>
22 Jan 14-15:30	<ul style="list-style-type: none"> <li>• TA to the GF round 10 " Strenthening the national PV system"</li> <li>• Collaboration in the phase II 2014-2016</li> <li>• Collaboration in education and training on drug QA/QC</li> </ul>	HUP	<ul style="list-style-type: none"> <li>• Dr. Nguyen Dang Hoa (Associate Prof), Rector of the HUP and Director of the national ADR&amp;DI center</li> <li>• Dr. Nguyen Hoang Anh, Vice Director of the national ADR&amp;DI center</li> <li>• Ms. Dinh Thi Hien Van, Head of Department of International Relations</li> <li>• Ms. Tran Le My, staff of the Department of International Relations</li> </ul>
22 Jan 16-17:30	<ul style="list-style-type: none"> <li>• Updates about the Amendment of the MOU</li> <li>• QA/QC for Antimalarial medicines</li> <li>• Capacity building for local manufacturers on</li> </ul>	NIMPE	<ul style="list-style-type: none"> <li>• Dr. Nguyen Van Huong, Vice Head of the Department for Malaria Research and Training</li> <li>• Dr. Nguyen Van Hong, Vice Head of the Department for Malaria Research and Training</li> </ul>

	Antimalarial medicines (Arteminisine based Combined Therapy)		<ul style="list-style-type: none"> <li>Dr. Nguyen Thi Minh Thu, Head of pharmaceutical team - Department for Malaria Research and Training</li> </ul>
23 Jan 16:00	<ul style="list-style-type: none"> <li>Flight to HCMC</li> </ul>		<ul style="list-style-type: none"> <li>PQM team</li> </ul>
24 Jan 8-9:30 AM	<ul style="list-style-type: none"> <li>Updates about the Amendment of the MOU</li> <li>Planning for Antimalarial medicine sampling in Binh Phuoc</li> </ul>	IMPE HCM	<ul style="list-style-type: none"> <li>Mr. Trinh Ngoc Hai, Head of Drug Efficacy Test and Molecular Department</li> </ul>
24 Jan 10-11 AM	<ul style="list-style-type: none"> <li>Briefing with VIDIPHA the TA for local methadone production</li> <li>Understanding the production capacity of VIDIPHA</li> </ul>	VIDIPHA	<ul style="list-style-type: none"> <li>Mr. Nguyen Ngoc Tuan, Head of the Department of Planning</li> </ul>
Lunch time	<ul style="list-style-type: none"> <li>Depart for Binh Phuoc</li> </ul>		<ul style="list-style-type: none"> <li>PQM team</li> <li>Mr. Trinh Ngoc Hai</li> </ul>
24 Jan PM	<ul style="list-style-type: none"> <li>Sampling of Antimalarial medicines</li> </ul>	<ul style="list-style-type: none"> <li>Binh Phuoc Provincial center for Malarial Control</li> <li>Dong Soai town</li> </ul>	<ul style="list-style-type: none"> <li>PQM team</li> <li>Mr. Trinh Ngoc Hai</li> </ul>
25 Jan	<ul style="list-style-type: none"> <li>Sampling of Antimalarial medicines</li> </ul>	<ul style="list-style-type: none"> <li>Bu Dang District</li> <li>Phuong Long District</li> <li>Phuoc Long town</li> <li>Dak Nheu Commune Health Station</li> <li>Dak O Commune Health Station</li> </ul>	<ul style="list-style-type: none"> <li>PQM team</li> <li>Mr. Trinh Ngoc Hai</li> </ul>