Comparative Study on Antimalarial Medicines’ Quality and Source in the Mekong Sub-region, and Follow up on Other Program Activities in Vietnam

Ho Chi Minh City, Vietnam
October 24-25, 2012

Trip Report

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Executive Summary

PQM held a training workshop entitled “Comparative Study on Antimalarial Medicines’ Quality and Source in Cambodia, Laos, Thailand, and Vietnam: Sampling Protocol, Testing Methodology, and Data Reporting” October 24-25, 2012 in Ho Chi Minh City, Vietnam. This workshop kicked off the comparative study between existing medicine quality monitoring (MQM) sites and non-MQM sites to obtain evidence-based data on the quality and source of antimalarials (and highly suspected essential antibiotics) in “hot spot” zones. This study aims to evaluate the progress and impact of MQM activities in the region.

Twenty trainees from national malaria control programs, official medicines quality control labs, and medicines regulatory agencies of Cambodia, Laos, Thailand, and Vietnam attended the workshop. Trainees participated actively in the workshop, provided insightful information for the successful implementation of the comparative study, and developed a protocol and detailed budgets for the study at country levels. The goals and objectives, study design and methods, roles and responsibilities of study teams, site selection, sampling, testing, reporting, and timelines of the study were agreed upon.

During the trip to Vietnam, the PQM team took the opportunity to hold meetings with key partners such as the Institute of Malariology, Parasitology, and Entomology, Ho Chi Minh (IMPE HCM), Institute of Drug Quality Control Ho Chi Minh (IDQC HCM), and National Institute of Drug Quality Control (NIDQC). Additionally, a teleconference with the World Bank, arc2lab, and National Health Product Quality Control Laboratory (NHQC) was arranged. Finally, meetings were held with the Thailand Bureau of Vector Borne Disease (BVBD), Kenan Institute Asia (K.I. Asia), and the Bureau of Drugs and Narcotics (BDN).
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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.
ACKNOWLEDGEMENTS

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- Staff of the Institute of Malariology, Parasitology, and Entomology, Ho Chi Minh (IMPE HCM), especially Dr. Lee Thanh Dong, Dr. Le Truong Son, Dr. Phung Duc Truyen, and Dr. Trinh Ngoc Hai for co-hosting the workshop and helping with its preparation

- Country participants from Cambodia, Laos, Thailand, and Vietnam for providing their invaluable insight throughout the workshop and agreeing to conduct the comparative study of antimalarials

- Dr. Wayne Stinson, Regional Malaria Advisor, President’s Malaria Initiative (PMI)-United States Agency for International Development (USAID)/Regional Development Mission for Asia (RDMA)

- Ms. Sharlene Bagga-Taves, Health Officer, Office of Public Health, USAID/RDMA

- Dr. Aye Aye Thwin, Director, Office of Public Health, USAID/RDMA

- Mr. Christopher Barrett, Deputy Director, Office of Public Health, USAID/RDMA

- Mr. Anthony Boni and Dr. Maria Miralles, USAID/Washington, for their guidance and support

- PQM’s administrative and editorial staff for their assistance
<table>
<thead>
<tr>
<th>ACRONYMS</th>
<th>Description</th>
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<tr>
<td>BDN</td>
<td>Bureau of Drugs and Narcotics, Thailand</td>
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<tr>
<td>BA/BE</td>
<td>Bioequivalence/bioavailability</td>
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<tr>
<td>BVBD</td>
<td>Bureau of Vector Borne Disease, Thailand</td>
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<td>DQI</td>
<td>Drug Quality and Information Program</td>
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<td>GMS</td>
<td>Greater Mekong Subregion</td>
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<td>HSSP2</td>
<td>Second Health Sector Support Program</td>
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<tr>
<td>IDQC HCM</td>
<td>Institute of Drug Quality Control, Ho Chi Minh</td>
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<td>IMPE HCM</td>
<td>Institute of Malariology, Parasitology and Entomology, Ho Chi Minh</td>
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<tr>
<td>K.I. Asia</td>
<td>Kenan Institute Asia</td>
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<td>MQM</td>
<td>Medicines Quality Monitoring</td>
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<td>NIMPE</td>
<td>National Institute of Malariology, Parasitology, and Entomology</td>
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<td>NHQC</td>
<td>National Health Products Quality Control Laboratory, Cambodia</td>
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<tr>
<td>NIDQC</td>
<td>National Institute of Drug Quality Control, Vietnam</td>
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<td>NOMCOL</td>
<td>Network of Official Medicine Control Laboratories</td>
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<td>OI</td>
<td>Opportunistic Infection</td>
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<tr>
<td>PMI</td>
<td>President’s Malaria Initiative</td>
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<tr>
<td>PQM</td>
<td>Promoting the Quality of Medicines Program</td>
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<td>QA</td>
<td>Quality Assurance</td>
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<tr>
<td>QC</td>
<td>Quality Control</td>
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<tr>
<td>RDM/A</td>
<td>Regional Development Mission for Asia, USAID</td>
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<tr>
<td>TA</td>
<td>Technical Assistance</td>
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<tr>
<td>USAID</td>
<td>United States Agency for International Development</td>
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<td>USP</td>
<td>United States Pharmacopeia</td>
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<td>WB</td>
<td>World Bank</td>
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<td>WHO</td>
<td>World Health Organization</td>
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**Background**

The Promoting the Quality of Medicines (PQM) program has been providing technical assistance (TA) to the Greater Mekong Subregion (GMS) since 2002. In the GMS, activities have focused on continuing and maintaining the effective medicines quality monitoring (MQM) sampling and testing techniques 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 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.

In order to evaluate the progress and impact of MQM activities in the region, the PQM program aims to conduct a comparative study between existing MQM sites and areas not covered under the MQM program, using random sampling to obtain evidence-based data on the quality and source of antimalarials (and highly-suspected essential antibiotics) in “hot spot” zones. The main focus of this study will be in the areas along the borders between Cambodia and Thailand; between Cambodia and Vietnam; between Thailand and Myanmar; and in Laos. The sampling will focus on artemisinin-derivatives, monotherapy products, and some commonly found poor-quality antibiotics from health facilities, distributors/wholesalers, retail pharmacies, and clinics in both the public and private sectors.

**Purpose of Training Workshop**

The main objectives of the workshop “Comparative Study on Antimalarial Medicines’ Quality and Source in Cambodia, Laos, Thailand, and Vietnam: Sampling Protocol, Testing Methodology, and Data Reporting” were:

- Introduce relevant staff from Cambodia, Laos, Thailand, and Vietnam to the comparative study of availability, quality, and source of antimalarials
- Train relevant staff on survey sampling methods (random sampling in particular) and testing and reporting procedures
- Agree on a study protocol and procedures for successful implementation of the project
- Create study teams and agree on roles/responsibilities, implementation plan, and timeline

**Overview of Activities**

<table>
<thead>
<tr>
<th>Item</th>
<th>Description</th>
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<tbody>
<tr>
<td>Venue/Location</td>
<td>Renaissance Riverside Hotel Saigon, Ho Chi Minh City, Vietnam</td>
</tr>
<tr>
<td>Organizers</td>
<td>PQM and Institute of Malariology, Parasitology, and Entomology, Ho Chi Minh (IMPE HCM)</td>
</tr>
<tr>
<td>Sponsor</td>
<td>PMI through USAID/RDMA</td>
</tr>
</tbody>
</table>
| Trainers and Facilitators   | * Dr. Souly Phanouvong, PQM  
* Dr. Roman Perez Velasco, PQM  
* Dr. Vuong Tuan Anh, PQM  
* Ms. Siv Lang, PQM                                                                 |
| Agenda                      | See Agenda in Annex 1 for detailed information                                                                                               |
| Trainees                    | 20 trainees from national malaria control programs, official medicines quality control labs, and medicines regulatory agencies of Cambodia, Laos, Thailand, and Vietnam. See Participant List in Annex 2. |
| Opening Ceremony            | * Dr. Le Truong Son, IMPE HCM                                                                                                                  |
| **Modules** | • Study methodology, sampling methods and techniques  
• Medicines screening and testing protocols  
• Data reporting |
| **Closing Ceremony** | • Dr. Souly Phanouvong, PQM  
• Dr. Le Thanh Dong, IMPE HCM  
• Mr. Nguyen Anh Dao, USAID/Vietnam |
| **Equipment Provided** | See Annex 3 for a detailed list of supplies/reagents/equipment that are considered necessary to conduct the comparative study |
| **Conclusion** | The attendees actively participated in the workshop, provided insightful information for the successful implementation of the comparative study, and developed detailed budgets for the study at a country level. A draft study protocol was developed. |
| **Next Steps** | In the weeks following the workshop, all participants will report on the workshop outcomes to their superiors and help obtain buy-in and approval from their respective authorities. |

**Workshop Materials and Presentations**

The PQM workshop presentations, draft protocol, and other working documents from the workshop can be obtained by contacting Dr. Souly Phanouvong at sxp@usp.org.

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**Above: Overview of the workshop**

**Right: Closing remarks by Mr. Nguyen Anh Dao, USAID/Vietnam, with Dr. Le Thanh Dong, IMPE HCM, and Dr. Souly Phanouvong, PQM**
**Additional Activities**

*Meeting at IMPE HCM – October 22, 2012*

Participants: Dr. Dr. Le Thanh Dong, HCM IMPE; Dr. Trinh Ngoc Hai, HCM IMPE; Dr. Souly Phanouvong, PQM; Dr. Román Pérez Velasco, PQM

The PQM team gave updates on the PQM program in Vietnam, discussed the training workshop and comparative study, and received a guided tour of HCM IMPE labs.

PQM can help IMPE HCM with TA to intensify MQM activities of antimalarials in the border provinces with Cambodia, especially Binh Phuoc, where there has been great concern about resistance to artemisinin-derivative products. In addition, counterfeit artemate has been detected in this area. The PQM team recommended convening a face-to-face meeting among all relevant authorities and pharmacy outlets in Binh Phuoc to educate them on medicines quality. PQM and IMPE HCM will draft a strategy together and plan a joint visit to Binh Phuoc in the coming months (possibly January 2013) to assess the situation.

*Meeting at Institute of Drug Quality Control Ho Chi Minh (IDQC HCM) – October 22, 2012*

Participants: Ms. Truong Thi Thu Lan, Ms. Nguyen Thanh Ha, Ms. Nguyen Thi Anh, Ms. Tran Thi Thu Ha, Ms. Trinh Hoang Duong, and Ms. Vu Tran Viet Anh, IDQC HCM; Dr. Souly Phanouvong and Dr. Román Pérez Velasco, PQM

The objectives of this meeting were as follows:

- Introduce IDQC HCM, their quality management system, and development strategy
- Give updates on PQM program in Vietnam
- Tour IDQC HCM labs
- Discuss PQM TA to IDQC HCM towards WHO prequalification, including scope and potential expansion of ISO/IEC 17025 accreditation
- Discuss the Network of Official Medicine Control Laboratories (NOMCOL), a USP initiative

The PQM team proposed that IDQC HCM work towards being a partner in conducting bioavailability/bioequivalence (BA/BE) tests, especially of anti-tuberculosis medicines and antimalarials. PQM requested a list of the 35 products they already test and the testing protocol employed so as to assist the Institute in becoming WHO prequalified. Other areas for potential collaboration requested by the IDQC include:

- Enhancing IDQC HCM’s scope of ISO/IEC 17025
- IDQC HCM joining NOMCOL-Asia
- IDQC HCM testing antimalarial and antibiotic samples from other countries
- Involving IDQC HCM in Opportunistic Infection (OI) and comparative studies
- PQM training IDQC HCM staff in priority needs

Next Steps:

- USP will send invitation letters to IDQC HCM by the end of November 2012 to attend the inaugural NOMCOL-Asia meeting scheduled for February 2013
- PQM and IDQC will keep in touch on OI testing and comparative study samples and agree on fees for services
By December 2012, IDQC HCM will submit training needs to PQM for consideration

Teleconference with the World Bank – October 23, 2012
Participants: Ms. Pema Lhazom and Mr. Rajiv Aggarwal, World Bank (WB); Mr. Christian Schnitzer and Mr. Dirk Louw, Arc2lab; Mr. Prav Chheang Hor, National Health Product Quality Control Laboratory (NHQC); Dr. Souly Phanouvong, Dr. Elaine Yuan, Ms. Siv Lang, and Dr. Román Pérez Velasco, PQM

At USAID/Cambodia’s recommendation, PQM conducted a teleconference with the WB, Arc2lab, and NHQC to gain a clearer understanding of roles and responsibilities regarding the NHQC’s new building, specifically that it is constructed to comply with ISO 17025:2005 accreditation standards.

PQM explained that USAID is still finalizing the budget allocations; a decision should be reached by December. PQM also emphasized the need for not duplicating efforts and suggested clearly identifying each party’s responsibilities.

During the discussion, PQM obtained the commitment of the WB team to hold a face-to-face meeting among relevant stakeholders in the third week of December 2012 in order to discuss the WB’s funding assistance. The WB team indicated that they will not able to cover the cost of that meeting in December.

Next Steps:

- It was tentatively agreed that the Arc2lab consultant and PQM staff visits will take place in December 2012 in conjunction with the WB implementation support mission (this is subject to budget availability)
- PQM will keep WB informed on the budget so that the WB can help consult with the MOH on funding possibilities from the Second Health Sector Support Program (HSSP2).

Meeting with Vietnam National Institute of Drug Quality Control (NIDQC) at Renaissance Riverside Hotel Saigon – October 24, 2012
Participants: Dr. Nguyen Dang Lam, NIDQC; Dr. Souly Phanouvong, Dr. Vuong Tuan Anh, and Dr. Román Pérez Velasco, PQM

The PQM team provided an update on program activities in Vietnam and also described NOMCOL. NIDQC updated PQM on the advanced status of the OI survey and the interest of NIDQC’s Vice Director to be part of NOMCOL-Asia. In addition, Dr. Lam requested that NIDQC be informed of upcoming training workshops regarding medicines QA/QC.

Meeting with Thailand Bureau of Vector Borne Disease (BVBD) and Kenan Institute Asia (K.I. Asia) – October 26, 2012
Participants: Dr. Wichai Satimai, Ms. Sansanee Rojanapanas, and Ms. Suravadee Kitchakarn, BVBD; Ms. Jiranya Ratchinda, K.I. Asia; Dr. Souly Phanouvong and Dr. Roman Perez Velasco, PQM

The main issues discussed were:

- PQM program in the region, with a focus on Thailand
- PQM activities on Global Fund Round 10 antimalarial quality monitoring
- Regional anti-tuberculosis medicine manufacturers’ workshop in early 2013
- K.I. Asia’s proposal to request an extension from the Global Fund
BVBD showed their commitment to prioritize the antimalarial quality project and support its smooth implementation by hiring and dedicating a focal support person and exploring ways to complement the limited budget for confirmatory testing. With regard to second-line anti-tuberculosis medicine manufacturers, BVBD recommended contacting the Government Pharmaceutical Organization of Thailand. A new memorandum of collaboration could be signed, if needed.

Minilab® testing results conducted at the Office of Disease Prevention and Control were presented. As of October 23, a total of 572 samples have been tested (artesunate - 102 samples; mefloquine - 100 samples; chloroquine - 141 samples; primaquine 5 & 15 mg - 55 samples; quinine - 126 samples; and unknown - 3 samples).

Dr. Phanouvong raised a concern regarding the budget, since the Thailand Bureau of Drugs and Narcotics (BDN) increased their testing fees. PQM may need to request additional funding.

He also recommended that, although antimalarials may be produced by the same manufacturer or distributed with the same lot number, there are many factors which affect medicine quality, including storage systems. Therefore, he recommended testing all 55 primaquine samples at BDN. If the budget does not allow for this, it would be acceptable to do grouping/customization of these samples, selecting proportionally at each level (e.g., warehouse, malaria clinic, etc.) where the samples were collected from. The criteria for triage are as follows: physical damage, then non-uniformity of shape, color, and other observations. A rough estimate of the number of primaquine samples triaged using this method would be 15/17. Taking this into account and estimating from the 30% of samples that remain to be collected, the total number of samples to be sent to BDN for testing would be in the range of 140–160.

Due to delays in sample collection, Minilab® testing in some districts, and BDN’s overloaded work schedule, PQM asked that K.I. Asia request an extension of the implementing period and prepare the financial commitment report for this period.

Finally, the dissemination workshop will be postponed to early 2013.

Meeting with BDN – October 26, 2012
Participants: Ms. Nidapan Ruangrittinon, Dr. Wiyada Akarawut, Ms. Yaowalak Wattanapisit, Dr. Supanee Duangteraprecha, Ms. Sasida Yoosook, Ms. Witinee Kongsuk, and Dr. Boontarika Boonyapiwat, BDN; Dr. Souly Phanouvong and Dr. Roman Perez Velasco, PQM

The following points were addressed in this meeting:

- Test plan for Global Fund Round 10 in Thailand
- Test plan for comparative study samples from Thailand
- Potential cooperation to test samples from other countries (e.g. Myanmar)
- PQM support to BDN towards achieving WHO prequalification
- NOMCOL

After being informed that samples from the Global Fund Round 10 project would be sent to them for testing, BDN stated that they could accept a maximum of 140 samples, which could be analyzed by March 2013. PQM told BDN that a cut-off approach for the testing can be used. Also, it will be
sufficient to know if some active pharmaceutical ingredient is lacking; it will not be necessary to determine the actual content.

The pricing for this testing would be reduced from approximately USD $216/sample test to a flat rate of approximately USD $160/sample test, since USP will provide the reference standards and columns needed. BDN showed interest in helping to test samples for the comparative study of antimalarials and a limited number of samples from Myanmar.

On another note, BDN is about to achieve WHO prequalification and is already ISO-accredited for High Performance Liquid Chromatography methods for both raw materials and finished products.

Also discussed were the possibility of signing a new memorandum of collaboration, extending the lab’s ISO 17025 accreditation to other methods (such as dissolution or gas chromatography), and BDN’s participation in NOMCOL-Asia.

Next Steps:

- BDN will test samples from Global Fund Round 10 by March 2013
- PQM will draft a memorandum of collaboration and send it to BDN to review by November 2012
- BDN will contact the PQM Quality Management Systems manager for continued support on BDN’s pursuance of WHO prequalification
## Training Workshop Tentative Agenda

**Comparative Study on Antimalarial Medicines’ Quality and Source in Cambodia, Laos, Thailand, and Vietnam: Sampling Protocol, Testing Methodology, and Data Reporting**

### Day 1 October 24

<table>
<thead>
<tr>
<th>Time</th>
<th>Activity</th>
<th>Responsible</th>
</tr>
</thead>
<tbody>
<tr>
<td>08:30-09:00</td>
<td>Registration</td>
<td>Representative from IMPE HCM Souly Phanouvong, Manager Asia Programs, USP PQM</td>
</tr>
<tr>
<td>09:00-09:15</td>
<td>Opening Remarks</td>
<td>Souly Phanouvong, USP PQM</td>
</tr>
<tr>
<td>09:15-09:30</td>
<td>• Introduction of Participants&lt;br&gt;• Introduction to the training: objectives, expected outcomes and agenda</td>
<td>ALL/Román Perez Velasco, USP PQM</td>
</tr>
<tr>
<td>09:30-10:00</td>
<td>Group Photo &amp; Coffee/Tea Break</td>
<td>ALL</td>
</tr>
<tr>
<td>10:00-10:30</td>
<td>• Current Medicines Quality Monitoring: strengths and weaknesses</td>
<td>Souly Phanouvong, USP PQM</td>
</tr>
<tr>
<td>10:30-12:00</td>
<td>• Overview of the Comparative Study&lt;br&gt;• Sampling Protocol&lt;br&gt;• Sample handling, storage and documentation</td>
<td>Souly Phanouvong, USP PQM</td>
</tr>
<tr>
<td>12:00-13:00</td>
<td>Lunch</td>
<td>ALL</td>
</tr>
<tr>
<td>13:00-14:00</td>
<td>Testing methods and procedures:&lt;br&gt;• Agree on pharmacopeial monographs to be used&lt;br&gt;• Essential supplies needed to be used in the analysis&lt;br&gt;• Tests results reporting</td>
<td>Souly Phanouvong, USP PQM</td>
</tr>
<tr>
<td>14:00-15:00</td>
<td>• Project monitoring and supervision&lt;br&gt;• Data reporting and management&lt;br&gt;• Technical report</td>
<td>Souly Phanouvong, USP PQM</td>
</tr>
<tr>
<td>15:00-15:30</td>
<td>• Identify and agree on non-MQM sites, number of samples to be collected, analytical methods for samples, and lab supplies needed&lt;br&gt;• Discussion on methods and procedures</td>
<td>ALL</td>
</tr>
<tr>
<td>15:30-16:00</td>
<td>Coffee/Tea Break</td>
<td>ALL</td>
</tr>
<tr>
<td>16:00-16:45</td>
<td>• Set up survey team(s) and define responsibilities/assignments&lt;br&gt;• Each country discuss schedule for sample collection.</td>
<td>ALL</td>
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<tr>
<td>16:45-17:00</td>
<td>Wrap-up of Day 1</td>
<td>USP PQM</td>
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### Day 2 October 25

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<th>Time</th>
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<tbody>
<tr>
<td>09:00-09:30</td>
<td>• Financial arrangements (receiving, dispatching, expense report)</td>
<td>Souly Phanouvong, USP PQM</td>
</tr>
<tr>
<td>09:30-10:00</td>
<td>Coffee/Tea Break</td>
<td>ALL</td>
</tr>
<tr>
<td>10:00-11:30</td>
<td>• Action items: implementation plan and timeline</td>
<td>ALL</td>
</tr>
<tr>
<td>11:30-11:55</td>
<td>• Wrap up of Day 2, next steps</td>
<td>USP PQM</td>
</tr>
<tr>
<td>11:55-12:05</td>
<td>• Closing remarks</td>
<td>Representative from IMPE HCM and USP PQM</td>
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<td>12:05-13:30</td>
<td>Farewell Lunch</td>
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<tr>
<td>Full name</td>
<td>Position</td>
<td>Organization</td>
</tr>
<tr>
<td>-----------------------</td>
<td>--------------------------------------------------------------------------</td>
<td>-------------------------------------------------------------------------------</td>
</tr>
<tr>
<td>Ms. Suravadee Kitchakarn</td>
<td>Public Health Technical Officer, Practitioner Level</td>
<td>Bureau of Vector Borne Disease, Thailand</td>
</tr>
<tr>
<td>Ms. Witinee Kongsuk</td>
<td>Pharmacist, Professional Level</td>
<td>Bureau of Drug and Narcotic, Thailand</td>
</tr>
<tr>
<td>Ms. Mam Boravann</td>
<td>Chief of PPM Unit</td>
<td>National Center for Malaria Control, Parasitology and Entomology (CNM), MoH-Cambodia</td>
</tr>
<tr>
<td>Mr. Prav Chheang Hor</td>
<td>Deputy Director</td>
<td>National Health Products Quality Control lab (NHQC), MoH-Cambodia</td>
</tr>
<tr>
<td>Mr. Hun Huong</td>
<td>Drug Inspector</td>
<td>Department of Drugs and Food (DDF), MoH-Cambodia</td>
</tr>
<tr>
<td>Mrs. Keobouppaphone Chindavongsa</td>
<td>Deputy Chief</td>
<td>Laboratory and Treatment Unit, Center for Malariaology, Parasitology and Entomology (CMPE), Lao PDR</td>
</tr>
<tr>
<td>Mr. Chansapha Pamanivong</td>
<td>Technical Staff</td>
<td>Drug and Cosmetic Division, Food and Drug Quality Control Centre (FDQCC), MoH, Lao PDR</td>
</tr>
<tr>
<td>Dr. Bouxou Keohavong</td>
<td>Deputy Chief</td>
<td>Drug Control Division, Food and Drug Department (FDD), MoH, Lao PDR</td>
</tr>
<tr>
<td>Associate Prof Ta Thi Tinh</td>
<td>Department of Malaria Treatment and Research</td>
<td>National Institute of Malariaology, Parasitology and Entomology (NIMPE), Vietnam</td>
</tr>
<tr>
<td>Dr. Bui Quang Phuc</td>
<td>Head of Department of Malaria Treatment and Research</td>
<td>NIMPE</td>
</tr>
<tr>
<td>Mr. Nguyen Tuan Anh</td>
<td>Head of Laboratory of Herbal Medicines and Materials</td>
<td>National Institute for Drug Quality Control (NIDQC), Vietnam</td>
</tr>
<tr>
<td>Ms Tran Thi Phuong Thanh</td>
<td>The Quality Management Div.</td>
<td>Drug Administration of Vietnam (DAV)</td>
</tr>
<tr>
<td>Mr. Pham Chi Thanh</td>
<td>Department of Planning and General Affairs</td>
<td>Institute for Drug Quality Control, Ho Chi Minh City (HCM IDQC), Vietnam</td>
</tr>
<tr>
<td>Mr. Pham Van Toi</td>
<td>Senior Research Pharmacist, Pharmacology Department,</td>
<td>Centre for Tropical Medicine, Oxford University Clinical Research Unit, Ho Chi Minh City, Vietnam</td>
</tr>
<tr>
<td>Mr. Nguyen Anh Dao</td>
<td>Care and Treatment Specialist</td>
<td>USAID Vietnam</td>
</tr>
<tr>
<td>Dr. Trinh Ngoc Hai</td>
<td>Chief - organisation board</td>
<td>Department Molecular Biology and Immunology, Institute of Malariaology, Parasitology and Entomology, Ho Chi Minh (HCM IMPE)</td>
</tr>
<tr>
<td>Dr. La Hoang Yen</td>
<td>Head - Organisation Board</td>
<td>HCM IMPE</td>
</tr>
<tr>
<td>Ms. Pham Nguyen Thuy Vy</td>
<td>Research staff</td>
<td>HCM IMPE</td>
</tr>
<tr>
<td>Ms. Pham Giang Anh</td>
<td>Deputy Head - Workshop Administration Support</td>
<td>HCM IMPE</td>
</tr>
<tr>
<td>Ms. Hoang Mai Anh</td>
<td>Research staff - Workshop Administration Support</td>
<td>HCM IMPE</td>
</tr>
</tbody>
</table>
REFERENCE STANDARDS NEEDED FOR THE COMPENDIAL ANALYSIS
These are the reference standards (and the related compounds, where applicable) that are available, their prices and where they are from. Note that for the BP and CP monographs, we would be using USP and IP reference standards as there is no BP Chloroquine reference standard or CP reference standards available.

### USP

<table>
<thead>
<tr>
<th>Reference Standard</th>
<th>Monograph</th>
<th>Price (USD)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Chloroquine Phosphate (500 mg)</td>
<td>Chloroquine Phosphate tablets/HCl injection</td>
<td>$204.00</td>
</tr>
<tr>
<td>Amodiaquine Hydrochloride (500 mg)</td>
<td>Chloroquine Phosphate tablets</td>
<td>$204.00</td>
</tr>
<tr>
<td>Chloroquine Sulfate (500 mg)</td>
<td></td>
<td>$204.00</td>
</tr>
<tr>
<td>Chloroquine Related Compound A (25 mg)</td>
<td></td>
<td>$636.00</td>
</tr>
<tr>
<td>Endotoxin (10,000 units)</td>
<td>Chloroquine HCl Injection</td>
<td>$204.00</td>
</tr>
<tr>
<td>Amoxicillin (200 mg)</td>
<td>Amoxicillin capsules</td>
<td>$204.00</td>
</tr>
<tr>
<td>Artesunate (200 mg)</td>
<td>Artesunate tablets</td>
<td>$204.00</td>
</tr>
<tr>
<td>Artemether (100 mg)</td>
<td></td>
<td>$204.00</td>
</tr>
<tr>
<td>Artemether Related Compound A (15 mg)</td>
<td>Artemether/Lumefantrine tablets</td>
<td>$636.00</td>
</tr>
<tr>
<td>Artemether Related Compound B (15 mg)</td>
<td>Lumefantrine related tablets</td>
<td>$636.00</td>
</tr>
<tr>
<td>Lumefantrine (100 mg)</td>
<td></td>
<td>$204.00</td>
</tr>
<tr>
<td>Lumefantrine Related Compound A (25 mg)</td>
<td></td>
<td>$636.00</td>
</tr>
<tr>
<td>Cloxacillin Sodium (200 mg)</td>
<td>Cloxacillin Sodium tablets</td>
<td>$204.00</td>
</tr>
<tr>
<td>Mefloquine HCl (100 mg)</td>
<td>Mefloquine HCl tablets</td>
<td>$204.00</td>
</tr>
<tr>
<td>Primaquine Phosphate (200 mg)</td>
<td>Primaquine Phosphate tablets</td>
<td>$204.00</td>
</tr>
<tr>
<td>Primaquine Related Compound A (15 mg)</td>
<td></td>
<td>$636.00</td>
</tr>
<tr>
<td>Sulfadoxine (200 mg)</td>
<td>Sulfadoxine Pyrimethamine tablets</td>
<td>$204.00</td>
</tr>
<tr>
<td>Pyrimethamine (200 mg)</td>
<td></td>
<td>$204.00</td>
</tr>
</tbody>
</table>

### International Pharmacopeia

<table>
<thead>
<tr>
<th>Reference Standard</th>
<th>Monograph</th>
<th>Price (USD)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Artemether (100 mg)</td>
<td>Artemether injection</td>
<td>$158.10</td>
</tr>
<tr>
<td>Artemether tablets</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Artenimol (100 mg)</td>
<td>Artenimol (DHA) tablets</td>
<td>$158.10</td>
</tr>
<tr>
<td>Artesunate (100 mg)</td>
<td>Artesunate tablets</td>
<td>$158.10</td>
</tr>
</tbody>
</table>

### British Pharmacopeia

<table>
<thead>
<tr>
<th>Reference Standard</th>
<th>Monograph</th>
<th>Price (USD)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Chloroquine Sulfate (200 mg) – IP</td>
<td>Chloroquine Sulfate injection/tablets</td>
<td>$198.90</td>
</tr>
<tr>
<td>Chloroquine Sulfate (500 mg) – USP</td>
<td></td>
<td>$204.00</td>
</tr>
</tbody>
</table>

### Chinese Pharmacopeia

<table>
<thead>
<tr>
<th>Reference Standard</th>
<th>Monograph</th>
<th>Price (USD)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Quinine HCl Dihydrate (1 g) (USP)</td>
<td>Quinine 2HCl injection</td>
<td>$204.00</td>
</tr>
<tr>
<td>Sulfadoxine (200 mg) (USP)</td>
<td>Sulfadoxine tablets</td>
<td>$204.00</td>
</tr>
</tbody>
</table>