USP DQI antimalarial sample delivery to Vietnam NIDQC from Thai-Cambodia cross-border study, and meetings with Cambodia DDF and USAID Vietnam

Phnom Penh, Cambodia and Hanoi, Vietnam
June 10-11, 2009

Trip Report

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About USP DQI

The United States Pharmacopeia Drug Quality and Information (USP DQI) Program, funded by the U.S. Agency for International Development (cooperative agreement HRN-A-00-00-00017-00), provides technical leadership to more than 30 developing countries to strengthen their drug quality assurance programs, ensure the quality of medicines and promote public health.
USP DQI helps build local, national and regional capacity to improve the standards of drug manufacturing and distribution, reduce the impact of infectious diseases, mitigate the effects of the HIV/AIDS epidemic, and advance the appropriate use of medicines. This document does not necessarily represent the views or opinions of USAID. It may be reproduced if credit is given to USP DQI.

Abstract

The United States Pharmacopeia Drug Quality and Information (USP DQI) Program conducted a field mission to collect and deliver antimalarial medicine samples from Cambodia and Thailand to the National Institute of Drug Quality Control (NIDQC) of the Ministry of Health (MOH) in Hanoi, Vietnam for confirmatory testing. The samples were collected during the Thai-Cambodia cross-border antimalarial medicine quality survey and included 20 samples from Thailand and 39 samples from Cambodia. The NIDQC generously agreed to accept the overflow samples to reduce the testing burden on the Thai Bureau of Drugs and Narcotics (BDN) laboratory and to complete the study within the agreed upon timeline. The USP DQI team also met with key partners in Cambodia and Vietnam during this visit.

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Key Words

Cambodia, Thailand, Vietnam, Pharmacovigilance, malaria medicine, cross border study, NIDQC, DDF, oseltamivir

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Special thanks also go to the USAID/Vietnam and USAID/Cambodia Missions for their continued support and to Mr. Anthony Boni and Ms. Veerle Coignez at USAID Washington for their advice and essential support for our activities in Southeast Asia.

ACRONYMS

ABT	Antibiotic
ACT	Artemisinin-based Combination Therapy
AI	Avian Influenza
AIDS	Acquired Immunodeficiency Syndrome
AML	Antimalarial
ATB	Anti-tuberculosis
BDN	Bureau of Drugs and Narcotics
BMGF	Bill and Melinda Gates Foundation
CNM	National Malaria Control Program
DDF	Department of Drugs and Food
HIV	Human Immunodeficiency Virus
MOH	Ministry of Health
MQM	Medicines Quality Monitoring
NIDQC	National Institute of Drug Quality Control
NLDQC	National Laboratory for Drug Quality Control
NMCP	National Malaria Control Program
PSA	Public Service Announcement
RDM/A	USAID Regional Development Mission for Asia
TB	Tuberculosis
USAID	United States Agency for International Development
USP DQI	United States Pharmacopeia Drug Quality and Information
WHO	World Health Organization

Background

With the financial support of the U.S. Agency for International Development's Regional Development Mission - Asia (USAID/RDM-A), the United States Pharmacopeia Drug Quality and Information (USP DQI) Program has been assisting countries in the Mekong Subregion – Cambodia, Laos, Thailand, Vietnam, and Yunnan Province of China (until mid-2005) – address the quality of essential medicines, including antimalarial (AML), antibiotic (ABT), anti-tuberculosis (ATB), and HIV/AIDS medicines, since early 2003.

In addition to the USAID/RDM-A funding, USP DQI received financial support from the Bill and Melinda Gates Foundation (BMGF) through the World Health Organization (WHO) to conduct a study on the quality of AMLs in the cross-border provinces of Cambodia and Thailand using a randomized sampling protocol. Due to recent changes in the infrastructure at the National Laboratory for Drug Quality Control (NLDQC) in Cambodia, samples collected during this study need to be sent to partner laboratories in Thailand and Vietnam for confirmation.

In addition to routine monitoring of the quality of infectious disease medicines in Vietnam, USP DQI is pioneering a regional strategy to establish monitoring of stockpiled and circulated *oseltamivir phosphate*, which is the principal antiviral medicine used to reduce mortality and morbidity resulting from avian influenza (AI) infection, caused by H5N1 virus, as well as preparedness for the new outbreaks of H1N1 recently.

Since the Vietnam Ministry of Health is highly concerned about AI (the country has had occasional AI transmission to humans), it is imperative that a routine protocol for sampling and ensuring good quality *oseltamivir phosphate* is established there. As part of regional pandemic preparedness for avian influenza, *oseltamivir phosphate* is often stored in stockpiles at both country and regional centers.

Purpose of Trip

Mr. Raymond transferred samples from the antimalarial medicine quality study from Cambodia to be tested with pharmacopeial methods at the National Institute of Drug Quality Control (NIDQC) in Hanoi, Vietnam. Some samples were also transferred from Thailand to Vietnam for confirmation due to the high work load of the Thailand Bureau of Drugs and Narcotic Lab. During this trip, Mr. Raymond met with key partners, including the Cambodia Department of Drugs and Food (DDF), Pharmacovigilance Center, and USAID/Vietnam staff.

Source of Funding

This trip was supported with funds from RDM/A and WHO/BMGF.

Overview of Activities

June 10, 2009

Meeting with DDF and PV staff, Department of Drugs and Foods Office
Participants: Chroeng Sokhan, Deputy Director of the Department of Drugs and Food and new President of the Pharmacists' Association of Cambodia; Dathara Mam, Cambodian Pharmacovigilance Center staff; Bunso Sok, Cambodian Pharmacovigilance Center staff; Christopher Raymond, USP DQI

Mr. Raymond, along with the PV staff, prepared 39 samples from three provinces (*see Annex 2*) to be brought for confirmatory testing to the NIDQC in Vietnam. Mr. Raymond also delivered a Dell Inspiron laptop computer to the PV staff – which was donated by a private individual to help the center's activities – and distributed copies of the "Pharmacide" public service announcement (PSA) to the DDF staff and for His Excellency, Undersecretary of State, Yim Yann.

In addition, Mr. Raymond and Dr. Sokhan met with the PV staff to discuss their concerns and requests for the next fiscal year's activities. Dr. Sokhan shared a document (in Khmer) with Mr. Raymond (*see Annex 3*) regarding actions taken against newly identified counterfeit amoxicillin 500mg capsules from Shujazhuang Ouyi Pharmaceuticals. He explained that the printed notice is a warning against the importer, Ocean Pharma, and that any further infraction or importation of this product would result in permanent revocation of their import license. A document (in Khmer) discussing the new policy on the artesunate monotherapy ban is included in *Annex 4*.

The PV staff continues to encounter delays in establishing an advisory committee because of high-level requirements in the MoH regarding nominating members to such a committee. Thus, the PV staff cannot select a specific individual for membership; rather, the MoH sends a letter to the university, hospital, or other organization from which a member will come, then allows that organization to select their own nominees. At the current time, a Pharmacy Board is being developed for Cambodia. This board would function as a licensing body with the authority to revoke licenses, accredit pharmacists, etc. It was suggested by the PV staff that the Pharmacy Board could act as an interim advisory committee for the PV center until such time that the internal issues at the MoH could be resolved.

During the USP DQI visit, His Excellency Yim Yann, Undersecretary of State, spoke with Dr. Sokhan to ask if USP DQI could support a final meeting to sign the subdecree that would effectively bring the Pharmacy Board into existence officially. This will need further discussion, but the timeline is very short (by end of the week June 19, 2009).

In discussions with the PV staff, it seems that the radio call-in program that was discussed previously has been put on hold indefinitely.

The PV staff, after debriefing Mr. Raymond on the recent, successful training that USP DQI sponsored at the Uppsala Monitoring Center (UMC) in Sweden, requested that a half-day workshop be organized in Siem Reap to educate local hospital staff on the reporting protocols to the PV Center. This could take place sometime during the next fiscal year. The reporting form for adverse drug reactions/events has been finalized and translated into Khmer, and they plan to begin accepting reports soon, for submission to the UMC.

Dr. Sokhan reiterated the desire for the DDF to expand sampling and testing to all drug classes into the 12 provinces in Cambodia that are not currently covered under the USP DQI/Global Fund monitoring network. He submitted the provincial budgets to Mr. Raymond (see *Annex 5*) for the previous quarter so that USP DQI could estimate costs if expansion into other provinces is deemed feasible. The DDF has expressed interest in expanding monitoring and would like further feedback from USAID/Cambodia regarding this.

Discussion also revolved around accounting for DDF budgets which USP DQI supports. There has been a recent change in structure at the MoH, and funding no longer goes directly to the DDF and to the USP DQI focal point (Mam Boravann), but rather goes through high ranking channels at the MoH. Thus, Dr. Sokhan requested that at the beginning of each year, USP DQI submit a letter which outlines each activity along with an "anticipated" budget that will be given to the DDF for USP DQI-related activities (even if this is not the "actual" budget). Thus, they can then account for any pipeline later in the year and increase their transparency to the higher levels of the MoH.

A national meeting will be held in Siem Reap June 15-16, 2009 (for the agenda, see *Annex 6*) to discuss the status of counterfeit medicines monitoring in Cambodia. This meeting will include presentations by Mr. Samuth of the Essential Drug Bureau on USP DQI's medicines quality monitoring (MQM) program as well as results from ongoing testing at the NLDQC by Tey Sovannarith. Ouk Rada, the USP DQI focal point at the national malaria program (CNM), will provide updates from the PV Center and the CNM. Mr. Raymond requested that USP DQI be made aware of such meetings so that they have the opportunity to attend, if necessary.

Next Steps

- Determine if USP DQI will fund signing of official subdecree to establish the Cambodia Pharmacy Board
- Continue discussions about expansion of MQM program into other provinces
- USP DQI to meet with His Excellency Secretary of State Chou Yin Sim, Director and Deputy Directors of DDF and other relevant stakeholders to follow up with pharmacovigilance activities, including defining the TOR and establishing the PV advisory committee to support the full operation of the PV center.
- Provide official letter (along with work plan) for "anticipated budget support" each year to the DDF after work plans are finalized

June 11, 2009

Meeting at the National Institute of Drug Quality Control, Hanoi, Vietnam
Participants: Associate Professor Dr. Trinh Van Lau, Director of the NIDQC; Dr. Bui Thi Hoa, Vice Director of the NIDQC; Christopher Raymond, USP DQI

Mr. Raymond met with Drs. Lau and Hoa to deliver the 39 samples from Cambodia (see *Annex 2*) and 20 from Thailand (see *Annex 1*) to be analyzed at the NIDQC according to the agreed upon protocol (see *Annex 7*). After discussing the probable three-week timeline for completion, to begin in July 2009, Dr. Lau mentioned recently meeting Dr. Roger Williams and Mr. Ed Zhao of USP in Ho Chi Minh City during the signing of a Memorandum of Understanding with the MoH . Dr. Lau expressed his appreciation of USP DQI's support to the NIDQC in the form of sending USP reference standards and for sponsoring two staff from the NIDQC (Ms. Le Thi Huong Hoa and Mr. Tran Thuy Thanh) and one from private industry (Mr. Phan Duc An) for the upcoming tuberculosis advanced methods training course at Chulalongkorn University in July 2009. Dr. Lau also mentioned his interest in pursuing a close relationship with USP for researching extraction methods for botanical products in Vietnam to develop reference standards for natural medicines.

Mr. Raymond also met briefly with Ms. Le Thi Huong Hoa to welcome her to the upcoming training in Thailand as she will be one of the participants.

Next Steps

- Follow up with the NIDQC to ensure timely completion of analysis of the confirmatory samples (by the end of the first week of July 2009)
- Send requested USP reference standards to NIDQC, as planned

Meeting at the USAID/Vietnam, Hanoi, Vietnam
Participants: Tim Meinke, Senior Avian Influenza Technical Advisor; Kim Thuy Oanh, Development Assistance Specialist (Avian Influenza); Richard Nyberg, Development Outreach and Communications Advisor; Christopher Raymond, USP DQI

Mr. Raymond distributed the "Pharmacide" PSAs to the USAID staff, who expressed interest in including links to the PSAs on the Mission's website. Dr. Meinke introduced Mr. Raymond to Mr. Richard Nyberg who is involved with media and outreach projects for the Mission and who will review the PSAs to determine how the Mission could use them in other outreach projects or in future media project development.

The group then discussed possible strategies for USP DQI to assist the Mission in providing technical assistance to the MoH for ongoing monitoring and testing of any oseltamivir stockpile or circulating products. Mr. Raymond explained the sampling and testing protocol developed by USP DQI and the successful pilot project in Laos last year testing stockpiled public sector samples. It was reiterated that both WHO and USP DQI have met with difficulties getting details of Vietnamese oseltamivir stockpiles. A recent request was made by WHO-Vietnam for assistance in sampling protocols and recommendations for testing stockpiled WHO oseltamivir.

Dr. Meinke and Ms. Oanh, discussed possible appropriate strategies to begin the process of assisting the Vietnamese MOH in ensuring good quality oseltamivir drugs, especially in light of the H1N1 situation. Dr. Meinke mentioned that Mr. Jim Eberle, of the Deliver Project, will be in Hanoi looking at AI commodities distribution and procurement mechanisms July 6-15, 2009. He suggested that Mr. Eberle, during his analysis, could perhaps make some inquiries on the drug issues regarding oseltamivir stocks, including the pre-deployed ASEAN stockpiles in Vietnam.

In conclusion, the group agreed that USP DQI should send an official letter to two of the Vice Ministers of Health, as recommended by former MoH staff Ms. Oanh. The letter should outline USP DQI's offer to provide technical assistance regarding sampling and testing protocols, in addition to the assistance already given to the NIDQC, and should be addressed to Vice Minister Trinh Quan Huan and Vice Minister Cao Minh Quang. Each Vice Minister covers various aspects of drug procurement and regulation, including oseltamivir, and sending letters to them prior to Mr. Eberle's evaluation visit could be key to provide technical assistance to the Ministry.

Next Steps

- USP DQI to send official letter of offer of technical assistance to Vice Ministers Quang and Huan at the beginning of July 2009
- USP DQI to send finalize AI report from Thailand to the USAID/Vietnam AI staff

- USP DQI to send agenda and list of Vietnamese participants for the TB training at Chulalongkorn University scheduled for July 2009

Annex 1: List of samples from Thailand

Confirmation Antimalarial Medicine Samples Thai Ministry of Public Health, Bureau of Vector-borne Diesease

11-Jun-09

No	Code number	province collected from	Trade name	INN name
1	chan/Primaquine/soidow/R1/09/P001	Chanthaburi	Primaquine tablets	Primaquine phosphate
2	R1/Chan/watmai/ch002/chloroquine	Chanthaburi	Chloroquine tablets	chloroquine phosphate
3	R1/chan/patong/p002/primaquine	Chanthaburi	Primaquine tablets	Primaquine phosphate
4	Chan/primaquine/tongnong/R1/09/p004	Chanthaburi	Primaquine tablets	Primaquine phosphate
5	R1/chan/nayaiam/m004/mefloquine	Chanthaburi	Mequin	mefloquine HCL
6	R1/chan/pawa/p008/primaquine	Chanthaburi	Primaquine tablets	Primaquine phosphate
7	R1/chant/saikao/p014/primaquine	Chanthaburi	Primaquine tablets	Primaquine phosphate
8	surin/047/R2/09	Surin	Piomicin	tetracycline HCL
9	surin/011/R2/09	Surin	Chloroquine tablets	chloroquine phosphate
10	Ubon/nachaluay025/R2/09	Ubon ratchatani	Primaquine tablets	Primaquine phosphate
11	primaquine/012/R2/09	Srisaket	Primaquine tablets	Primaquine phosphate
12	Burerum/013/R2/09	Buriram	Quinine	Quinine sulphate
13	Burerum/005/R2/09	Buriram	Chloroquine tablets	chloroquine phosphate
14	Surin/027/R2/09	Surin	Primaquine tablets	Primaquine phosphate
15	Surin/002/R2/09	Surin	Chloroquine tablets	chloroquine phosphate
16	R1/chan/nayaiam/ch014/chloroquine	Chanthaburi	Chloroquine tablets	chloroquine phosphate
17	R1/chan/parknum/ch012/chloroquine	Chanthaburi	Chloroquine tablets	chloroquine phosphate
18	R1/chan/plung/ch022/chloroquine	Chanthaburi	Chloroquine tablets	chloroquine phosphate
19	R1/chan/tabsai/ar010/artesunate	Chanthaburi	Artesunate tablets	artesunate
20	chan/primaquine/songpeenong/p006/R1/09	Chanthaburi	Primaquine tablets	Primaquine phosphate

20 samples received for analysis
from Chanthaburi Province, USPDQI

Annex 2: List of samples from Cambodia

Confirmation Antimalarial Medicine Samples Cambodia Department of Drugs and Food, EDB, MoH

11-Jun-09

No	Code number	provinces collected from	Trade name	INN name	Lot No
1	001PSXB/09	PURSAT	ARTEQUICK	ARTEMISININ/PIPERAQUINE	20070701
2	002PSXB/09	PURSAT	ARTEKIN	DIHYDROARTEMISININ/PIPERAQUINE	11206
3	003PSXB/09	PURSAT	COTECXIN	DIHYDROARTEMISININ	30406
4	004PSXB/09	PURSAT	ARTEQUICK	ARTEMISININ/PIPERAQUINE	20070701
5	005PSXB/09	PURSAT	DUO-COTECXIN	DIHYDROARTEMISININ/PIPERAQUINE	150107
6	006PSXB/09	PURSAT	DUO-COTECXIN	DIHYDROARTEMISININ/PIPERAQUINE	150107
7	007PSXB/09	PURSAT	DUO-COTECXIN	DIHYDROARTEMISININ/PIPERAQUINE	150107
8	008PSXB/09	PURSAT	DUO-COTECXIN	DIHYDROARTEMISININ/PIPERAQUINE	150107
9	009PSXB/09	PURSAT	ARTEQUICK	ARTEMISININ/PIPERAQUINE	20060801
10	010PSXB/09	PURSAT	DUO-COTECXIN	DIHYDROARTEMISININ/PIPERAQUINE	150107
11	011PSXB/09	PURSAT	DUO-COTECXIN	DIHYDROARTEMISININ/PIPERAQUINE	150107
12	012PSXB/09	PURSAT	DUO-COTECXIN	DIHYDROARTEMISININ/PIPERAQUINE	150107
13	013PSXB/09	PURSAT	DUO-COTECXIN	DIHYDROARTEMISININ/PIPERAQUINE	150107
14	014PSXB/09	PURSAT	DUO-COTECXIN	DIHYDROARTEMISININ/PIPERAQUINE	150107
15	010BBXB/09	BATTAMBANG	COTECXIN	DIHYDROARTEMISININ	30406
16	009BBXB/09	BATTAMBANG	ARTESUNATE	ARTESUNATE	80602
17	008BBXB/09	BATTAMBANG	TETRACYCLINE	TETRACYCLINE HCL	80201
18	007BBXB/09	BATTAMBANG	ARTESUNATE	ARTESUNATE	6508
19	006BBXB/09	BATTAMBANG	DUO-COTECXIN	DIHYDROARTEMISININ/PIPERAQUINE	60107
20	005BBXB/09	BATTAMBANG	ARTESIANE	ARTEMETHER INJECTION	70544
21	004BBXB/09	BATTAMBANG	MALARINE	ARTESUNATE/MEFLOQUINE	315116
22	003BBXB/09	BATTAMBANG	ARTHEMETHER	ARTEMETHER INJECTION	81201
23	002BBXB/09	BATTAMBANG	ARTESUNATE	ARTESUNATE	ZA 070406
24	001BBXB/09	BATTAMBANG	MALARINE	ARTESUNATE/MEFLOQUINE	315116
25	079USPX2009	BANTEY MEANCHEY	CHLOROQUINE	CHLOROQUINE PHOSPHATE	9350
26	082USPX2009	BANTEY MEANCHEY	CHLOROQUINE	CHLOROQUINE PHOSPHATE	9395
27	081USPX2009	BANTEY MEANCHEY	CHLOROQUINE	CHLOROQUINE PHOSPHATE	9396

37 samples received for analysis from Ch. St. plus Raymond, USP DQI

No	Code number	province collected from	Trade name	INN name	Lot No
28	080USPX2009	BANTEY MEANCHEY	CHLOROQUINE	CHLOROQUINE PHOSPHATE	9481
29	083USPX2009	BANTEY MEANCHEY	ARTESUNATE	ARTESUNATE	2908
30	084USPX2009	BANTEY MEANCHEY	MALARINE	ARTESUNATE/MEFLOQUINE	31198
31	085USPX2009	BANTEY MEANCHEY	TETRACYCLINE	TETRACYCLINE HCL	11608
32	086USPX2009	BANTEY MEANCHEY	CHLOROQUINE	CHLOROQUINE PHOSPHATE	18103
33	087USPX2009	BANTEY MEANCHEY	ARTESUNATE	ARTESUNATE	6508
34	088USPX2009	BANTEY MEANCHEY	TETRA CMP	TETRACYCLINE HCL	81009
35	089USPX2009	BANTEY MEANCHEY	TREX 250	TETRACYCLINE HCL	170912
36	090USPX2009	BANTEY MEANCHEY	CHLOROQUINE	CHLOROQUINE PHOSPHATE	9317
37	091USPX2009	BANTEY MEANCHEY	TREX 250	TETRACYCLINE HCL	170911
38	092USPX2009	BANTEY MEANCHEY	TETRAMAN	TETRACYCLINE HCL	7455108
39	078USPX2009	BANTEY MEANCHEY	ARTESUNATE	ARTESUNATE	6508

Annex 3: Official Notice of Counterfeit Amoxicillin in Cambodia

ព្រះរាជាណាចក្រកម្ពុជា

ជាតិ សាសនា ព្រះមហាក្សត្រ

ក្រសួងសុខាភិបាល

លេខ..០៤៥៥[illegible]....អបស/ទកបស

រាជធានីភ្នំពេញ, ថ្ងៃទី ២៥ ខែ កក្កដា ឆ្នាំ២០០៨

រដ្ឋមន្ត្រី ក្រសួងសុខាភិបាល

ជម្រាបមក

លោកប្រធានគ្រឹះស្ថានអាហរ័ណ នីហរ័ណឱសថ OCEAN Pharma

<u>កម្មវត្ថុ</u> : ករណី Amoxicillin 500 mg B/10-Blisters x 10 Capsules មានសារជាតិសកម្មមិនគ្រប់កំរិត ។

តបតាមដូចបានជម្រាបក្នុងកម្មវត្ថុខាងលើនេះ ខ្ញុំសូមជម្រាបលោកប្រធានថា : ក្រសួងសុខាភិបាលបានស្រាវជ្រាវឃើញថាឱសថ Amoxicillin 500mg B/10 Blister x 10 Capsules ដែលមានលេខឡូតិ៍ 0329 ខែឆ្នាំផលិត 05-2008 ខែឆ្នាំផុតកំណត់ 05-2011 និងមានលេខបញ្ជិកា CAM 798-07 ផលិតដោយរោងចក្រផលិតឱសថនៅប្រទេសចិន ឈ្មោះ SHUJAZHUANG OUYI PHARMACEUTICAL ដែលក្រុមហ៊ុន OCEAN Pharma របស់លោកបាន នាំចូល និង ចែកចាយ ក្នុងព្រះរាជាណាចក្រកម្ពុជាកន្លងមក មានសារជាតិសកម្មត្រឹមតែ 49,07 % តែប៉ុណ្ណោះ ។

ក្រសួងសុខាភិបាលបានសម្រេចដកឱសថ Amoxicillin 500 mg នេះ ចេញពីបញ្ជិកាឱសថរបស់ក្រសួងសុខាភិបាល ហើយក្រសួងសូមឱ្យលោកប្រធានបញ្ឈប់ការនាំចូល ការចែកចាយ និងចាត់ចែងប្រមូលមុខឱសថនេះឱ្យអស់ពីទីផ្សារក្នុងព្រះរាជាណាចក្រកម្ពុជាជាបន្ទាន់ ហើយធ្វើរបាយការណ៍ផ្ញើមកនាយកដ្ឋានឱសថ ចំណីអាហារ បរិក្ខារពេទ្យ និងគ្រឿងសំអាង ។

ក្នុងករណីមានឱសថផ្សេងទៀតដែលក្រុមហ៊ុនលោកនាំចូលមកមានបញ្ហាគុណភាពដូចគ្នានេះ ក្រសួងសុខាភិបាលនឹងធ្វើការបញ្ឈប់ក្រុមហ៊ុន OCEAN Pharma មិនឱ្យបន្តអាជីវកម្មឱសថតទៅទៀតបានទេ ។ ដោយឡែករោងចក្រផលិតដែលបានបញ្ជូនឱសថគ្មានគុណភាពមកទីផ្សារកម្ពុជាក៏នឹងត្រូវហាមឃាត់ជាស្ថាពរ លែងឱ្យធ្វើអាជីវកម្មផលិតផលរបស់ខ្លួននៅលើទីផ្សារកម្ពុជាផងដែរ ។

សូមលោកប្រធានជ្រាប និងចាត់ចែងតាមសំណូមពររបស់ក្រសួងសុខាភិបាលឱ្យមានប្រសិទ្ធភាព ។

<u>ចម្លងជូន</u> :

- ខុទ្ទកាល័យក្រសួងសុខាភិបាល
- អគ្គនាយកដ្ឋានបច្ចេកទេសសុខាភិបាល
- នាយកដ្ឋានឱសថ-ចំណីអាហារ-បរិក្ខារពេទ្យ និងគ្រឿងសំអាង
- គ្រប់មន្ទីរសុខាភិបាលរាជធានី-ខេត្ត
- គ្រប់ក្រុមហ៊ុនអាហរ័ណ-នីហរ័ណឱសថ
- គ្រប់សហគ្រាសផលិតឱសថ
- គ្រប់ឱសថស្ថាន-ឱសថស្ថានរង
- ឯកសារ - កាលប្បវត្តិ

ជ.រដ្ឋមន្ត្រី

រដ្ឋលេខាធិការ

ឱសថការី ជូ-យិនស៊ីម

ទីស្តីការក្រសួងសុខាភិបាល,លេខ ១៥១-១៥៣ វិថីកម្ពុជាក្រោម ភ្នំពេញ ទូរស័ព្ទ-ទូរសារ: (៨៥៥-២៣) ៨២៦ ០៣៤/៨២៦ ៨៤១ ទូរស័ព្ទ: (៨៥៥-២៣) ៧២២ ៨៧៣

Annex 4: Official Notice of Artesunate Monotherapy Ban in Cambodia

ព្រះរាជាណាចក្រកម្ពុជា

ជាតិ សាសនា ព្រះមហាក្សត្រ

ក្រសួងសុខាភិបាល

លេខ ០២៩៤ អបក ថ្មី អបក

រាជធានីភ្នំពេញ, ថ្ងៃទី ២៣ ខែ មិនា ឆ្នាំ២០០៩

សេចក្ដីប្រកាសពត៌មាន

ក្រសួងសុខាភិបាល មានកិត្តិយសសូមជំរាបជូនអស់លោក-លោកស្រី ជាវេជ្ជបណ្ឌិតដែលចេញវេជ្ជបញ្ជា និង ឱសថការីទាំងអស់ ដែលទទួលខុសត្រូវគ្រឹះស្ថានផលិតឱសថ , គ្រឹះស្ថានអាហរ័ណ-នីហរ័ណឱសថ , ឱសថស្ថាន-ឱសថស្ថានរង , អាជីវករ និង ប្រជាពលរដ្ឋទាំងអស់ ឱ្យបានជ្រាបថា :

-យោងលិខិតលេខ ០៩០៥ អបស/ឱអបស ចុះថ្ងៃទី ២៣ ខែ កញ្ញា ឆ្នាំ ២០០៨ របស់ក្រសួងសុខាភិបាល ស្តីពីការ បញ្ឈប់នូវការផលិត ការនាំចូល ការចុះបញ្ជិកាឱសថ ការលុបចេញពីបញ្ជីឱសថដែលបានចុះបញ្ជិកា នូវឱសថគ្រុនចាញ់ ប្រភេទជាថ្នាំគ្រាប់សំរាប់លេបមួយចំនួន ផលិតដោយជាតិសកម្ម Artemisinin ឬ Artsesunate ឬ Artemether ឬ Dihydroartemisin តែមួយមុខ ដែលបណ្ដាលឱ្យមានភាពស៊ាំក្នុងការព្យាបាលជម្ងឺគ្រុនចាញ់ និងដោយពិនិត្យឃើញនៅ លើទីផ្សារកម្ពុជាបច្ចុប្បន្ននៅមានចរាចរឱសថគ្រុនចាញ់ខាងលើ ដែលក្រសួងបានហាមឃាត់ ។

អាស្រ័យហេតុនេះ អនុលោមតាមច្បាប់ ស្តីពីការគ្រប់គ្រងឱសថ ក្រសួងសូមមានវិធានការ ដូចតទៅ :

១.គ្រឹះស្ថានផលិតឱសថ និងគ្រឹះស្ថានអាហរ័ណ នីហរ័ណឱសថ ដែលធ្វើប្រតិបត្តិការផលិត នាំចូល ឬចែកចាយឱសថ ខាងលើ ត្រូវចាត់តាំងការប្រមូលឱសថទាំងនោះ ពីឱសថស្ថាន-ឱសថស្ថានរងនានា ក្នុងព្រះរាជាណាចក្រកម្ពុជា

២.គ្រឹះស្ថានលក់ឱសថទាំងអស់ត្រូវបញ្ឈប់ការតាំងលក់ឱសថខាងលើ ចាប់ពីថ្ងៃចេញសេចក្ដីជូនដំណឹងនេះតទៅ

៣.គ្រប់មន្ទីរសុខាភិបាលរាជធានី-ខេត្ត ត្រូវមានវិធានការ ធ្វើការណែនាំ ដល់គ្រប់សាខាគ្រឹះស្ថានអាហរ័ណ នីហរ័ណឱសថ-ឱសថស្ថាន-ឱសថស្ថានរង ដូចមានក្នុងចំណុច១ខាងលើ

៤.ក្រសួងនឹងមានវិធានការតឹងរឹងតាមផ្លូវច្បាប់ ចំពោះគ្រឹះស្ថានផលិតឱសថ គ្រឹះស្ថានអាហរ័ណ នីហរ័ណឱសថ ឱសថស្ថាន-ឱសថស្ថានរងទាំងឡាយណា ដែលនៅតែបន្តការផលិត ការនាំចូល ឬចែកចាយ និងការតាំងលក់ ឱសថខាងលើនេះ ។

ជ.រដ្ឋមន្ត្រី

រដ្ឋលេខាធិការ

ឱសថការី ជូ.យិនស៊ីម

ចម្លងជូន :

- ក្រសួងពត៌មាន "ដើម្បីជួយផ្សព្វផ្សាយ"
- លេខាធិការដ្ឋាន នៃគណៈកម្មការអន្តរក្រសួង និងគណៈកម្មការរាជធានី-ខេត្ត លុបបំបាត់ឱសថក្លែងក្លាយ និងសេវាសុខាភិបាលខុសច្បាប់
- គ្រប់មន្ទីរពេទ្យជាតិ
- គ្រប់មន្ទីរសុខាភិបាលរាជធានី-ខេត្ត
- នាយកដ្ឋានឱសថ ចំណីអាហារ បរិក្ខារពេទ្យ និងគ្រឿងសំអាង
- គ្រប់ស្ថានីយវិទ្យុ-ទូរទស្សន៍ "ដើម្បីជួយផ្សព្វផ្សាយ"
- គ្រប់សារព័ត៌មាន "ដើម្បីជួយផ្សព្វផ្សាយ"
- ឯកសារ-កាលប្បវត្តិ

Annex 5: Cambodian budget for quarter 6

Detail of TLC Activities for Provincial Level

Global Fund: R6 Malaria (Quarter 6)

N	Province	Perdiem for Colecting Sample(cat. 4.8)			Perdiem for Testing (Basic test TLC) Cat. 4.10			Sample cost (Cat. 4.12)			TOTAL
		Within Town								Communication Cost (Cat 6.4)	
		Time	Perd.	Total	People	#days	Perdiem	Total	N.of Sample	Sample Cost	Total		
a	b	d	e	A=d*e	f	g	h	B=f*g*h	i	j	C=i*j	D	A+B+C+D
1	Kg.Cham	3	$5	$15	2	16	$5	$160	50	$3	$150	$50	$375
2	Battambang	3	$5	$15	2	16	$5	$160	50	$3	$150	$50	$375
3	Banteaymeanchey	3	$5	$15	2	15	$5	$150	45	$3	$135	$50	$350
4	Pursat	3	$5	$15	2	14	$5	$140	40	$3	$120	$50	$325
5	Kratie	3	$5	$15	2	12	$5	$120	40	$3	$120	$50	$305
6	Rattanakiri	3	$5	$15	2	12	$5	$120	40	$3	$120	$50	$305
7	Stung treng	2	$5	$10	2	12	$5	$120	35	$3	$105	$50	$285
8	Pailin	2	$5	$10	2	12	$5	$120	35	$3	$105	$50	$285
9	Odormeanchey	2	$5	$10	2	12	$5	$120	35	$3	$105	$50	$285
10	Koh Kong	2	$5	$10	2	10	$5	$100	30	$3	$90	$50	$250
11	Preah Vihear	2	$5	$10	2	10	$5	$100	30	$3	$90	$50	$250
12	Mondulkiri	2	$5	$10	2	10	$5	$100	30	$3	$90	$50	$250
	TOTAL :	30		$150	24	151		$1,510	460		$1,380	$600	$3,640

Approved by:

Dr.Chroeng Sokhan
Project Manager
Date: 04 . May . 09

Prepaired by:

Ph. Hun Huong
Programm Coodinator
Date: 04 . May . 09

*Note : ជារូបិយប័ណ្ណដុល្លារអាមេរិក

Det of IMC Activities for Provincial level

Global Fund: R6 Malaria (Quarter 6)

N	Province	Meeting (Cat 4.13)					Control at Check Points (Cat 4.13)													Seisure & Destruction (Cat 4.13)						Outreach Education (Cat 4.13)																			Transportation (Cat 4.13)	Admin Cost(Cat 4.14)	Communication Cost (Cat 6.3)	TOTAL
							Province to district < 40km						Province to district > 40km													Province to district < 40km									Province to district > 40km													
		Person	Perdiem	Refreshment	Time	Total	Person	Perdiem	Day/Night	Time	Transportation	Total	Person	Perdiem	Day/Night	Time	Transportation	Total	Sub TOTAL	Person	Perdiem	Day/Night	Time	Material	Total	Person	Perdiem	Day/Night	Refreshment	Material	Picture	Time	Transportation	Total	Person	Perdiem	Day/Night	Refreshment	Material	Picture	Time	Transportation	Total	Sub TOTAL				
1	2	3	4	5	6	A	7	8	9	10	11	a	12	13	14	15	16	b	B=a+b	17	18	19	20	21	C	22	23	24	25	26	27	28	29	c	30	31	32	33	34	35	36	37	d	D=c+d	E	F	G	A+B+C+D+E+F+G
1	Kg. Cham	10	$5	$1	3	$180	4	$5	1	6	**	$120	4	$15	2	1	**	$120	$240	10	$5	1	1	$10	$60	4	$5	1	$30	$30	$5	1	***	$85	4	$15	1	$20	$25	$5	1	***	$110	$195	$200	$45	$50	$970
2	B. Bang	10	$5	$1	3	$180	4	$5	1	6	**	$120	4	$15	2	1	**	$120	$240	10	$5	1	1	$10	$60	4	$5	1	$30	$30	$5	1	***	$85	4	$15	1	$20	$25	$5	1	***	$110	$195	$200	$43	$50	$968
3	B.Mean Chey	10	$5	$1	3	$180	4	$5	1	6	**	$120	4	$15	2	1	**	$120	$240	10	$5	1	1	$10	$60	4	$5	1	$30	$30	$5	1	***	$85	4	$15	1	$20	$25	$5	1	***	$110	$195	$200	$43	$50	$968
4	Pursat	10	$5	$1	3	$180	4	$5	1	6	**	$120	4	$15	2	1	**	$120	$240	10	$5	1	1	$10	$60	4	$5	1	$30	$30	$5	1	***	$85	4	$15	1	$20	$25	$5	1	***	$110	$195	$200	$42	$50	$967
5	Kratié	10	$5	$1	3	$180	4	$5	1	6	**	$120	4	$15	2	1	**	$120	$240	10	$5	1	1	$10	$60	4	$5	1	$30	$30	$5	1	***	$85	4	$15	1	$20	$25	$5	1	***	$110	$195	$200	$42	$50	$967
6	RattanaKiri	10	$5	$1	3	$180	4	$5	1	6	**	$120	4	$15	2	1	**	$120	$240	10	$5	1	1	$10	$60	4	$5	1	$30	$30	$5	1	***	$85	4	$15	1	$20	$25	$5	1	***	$110	$195	$200	$42	$50	$967
7	St. Treng	10	$5	$1	3	$180	4	$5	1	6	**	$120	4	$15	2	1	**	$120	$240	10	$5	1	1	$10	$60	4	$5	1	$30	$30	$5	1	***	$85	4	$15	1	$20	$25	$5	1	***	$110	$195	$200	$40	$50	$965
8	Pailin	10	$5	$1	3	$180	4	$5	1	6	**	$120	4	$15	2	1	**	$120	$240	10	$5	1	1	$10	$60	4	$5	1	$30	$30	$5	1	***	$85	4	$15	1	$20	$25	$5	1	***	$110	$195	$200	$40	$50	$965
9	Od.Mean Chey	10	$5	$1	3	$180	4	$5	1	6	**	$120	4	$15	2	1	**	$120	$240	10	$5	1	1	$10	$60	4	$5	1	$30	$30	$5	1	***	$85	4	$15	1	$20	$25	$5	1	***	$110	$195	$200	$40	$50	$965
10	Kah Kong	10	$5	$1	3	$180	4	$5	1	6	**	$120	4	$15	2	1	**	$120	$240	10	$5	1	1	$10	$60	4	$5	1	$30	$30	$5	1	***	$85	4	$15	1	$20	$25	$5	1	***	$110	$195	$200	$40	$50	$965
11	Preah Vihear	10	$5	$1	3	$180	4	$5	1	6	**	$120	4	$15	2	1	**	$120	$240	10	$5	1	1	$10	$60	4	$5	1	$30	$30	$5	1	***	$85	4	$15	1	$20	$25	$5	1	***	$110	$195	$200	$40	$50	$965
12	Mond. Kiri	10	$5	$1	3	$180	4	$5	1	6	**	$120	4	$15	2	1	**	$120	$240	10	$5	1	1	$10	$60	4	$5	1	$30	$30	$5	1	***	$85	4	$15	1	$20	$25	$5	1	***	$110	$195	$200	$40	$50	$965
	TOTAL	120	$60	$12	36	$2,160	48		12	72		$1,440	48		24	12		$0	$2,880	120		12	12		$720	48		12	$360	$360	$60				48	$180	12	$240	$300	$60	12	$0		$2,340	$2,400	$500	$600	$11,600

TOTAL Cat. 4.13	$10,500
TOTAL Cat. 4.14	$500
TOTAL Cat. 6.3	$600
Grand Total	$11,600

Approved by:

Dr.Chroeng Sokhan
Project Manager
Date: 04- May. 09

*Note : តំលៃសោហ៊ុយធ្វើដំណើរប្រែប្រួលតាមចំណាយជាក់ស្តែង

Prepaired by:

Ph. Hun Huong
Programm Coodinator
Date: 04. May. 09

Annex 6: Agenda of Cambodia National Meeting on Counterfeit Medicines Monitoring

កម្មវិធីសិក្ខាសាលា

កិច្ចប្រជុំពិគ្រោះយោបល់ស្តីពីយុទ្ធសាស្ត្រនៃការលុបបំបាត់និង ជំរុញឱសថក្លែងក្លាយពីទីផ្សារកម្ពុជា

ទីកន្លែង: ខេត្ត សៀមរាប (សណ្ឋាគារ អប្សរាអង្គរ)

ថ្ងៃទី១: ថ្ងៃច័ន្ទទី ១៥ ខែ មិថុនា ឆ្នាំ ២០០៩

ពេលវេលា	កម្មវិធី	អ្នកទទួលបន្ទុក	ផ្សេងៗ
០៨:០០-៨:២០	១- ចុះឈ្មោះអ្នកចូលរួម	ក្រុមការងារ	
០៨:២០-៨:៣៥	២- ប្រកាសកម្មវិធី	លោកស្រី វណ្ណ មុនី	
០៨:៣៥-៨:៥០	៣- មតិស្វាគមន៍អង្គសិក្ខាសាលា	ប្រធានមន្ទីរសុខាភិបាលខេត្តសៀមរាប	
០៨:៥០-៩:១០	៤- បង្ហាញគោលបំណងអង្គសិក្ខាសាលា	លោកបណ្ឌិត ច្រឹង សុខន អនុប្រធាននាយកដ្ឋានឱសថ ចំណីអាហារបរិក្ខារពេទ្យ និងគ្រឿងសំអាង	
០៩:១០-០៩:៣០	៥- សន្ទរកថា បើកកម្មវិធី	ឯកឧត្តម ជូ យិនស៊ីម រដ្ឋលេខាធិការក្រសួងសុខាភិបាល	
០៩:៣០-០៩:៤៥	សំរាកពិសារភេសជ្ជៈ		
០៩:៤៥-១០:១៥	៦- បង្ហាញពីសកម្មភាពរបស់ភ្នាក់ងារត្រួតពិនិត្យឱសថ	លោកឱសថការី ប្រេម ណូរ៉ុន អនុប្រធាននាយកដ្ឋានឱសថ ចំណីអាហារបរិក្ខារពេទ្យ និងគ្រឿងសំអាង	
១០:១៥-១០:៣៥	៧- សកម្មភាពត្រួតពិនិត្យគុណភាពឱសថក្រោម គំរោង USP-DQI (USAID)	លោក អឿន សាមុត	
១០:៣៥-១១:០០	៨- របាយការណ៍សរុបសកម្មភាព គណៈកម្មការលុបបំបាត់ឱសថ ក្លែងក្លាយ សេវាខុសច្បាប់ និងប្រព័ន្ធតាម ដានគុណភាពឱសថលើទី ផ្សារសំរាប់ឱសថគ្រុនចាញ់	លោក ហ៊ុន ហួង	
១១:០០-១២:០០	៩-ពិភាក្សាក្រុមធំ	ឯកឧត្តម ជូ យិនស៊ីម រដ្ឋលេខាធិការក្រសួងសុខាភិបាល	
១២:០០-១៤:០០	សំរាកពិសារបាយ		
១៤:០០-១៤:៣០	១០-ប្រតិបត្តិការខ្យល់ព្យុះ	លោក វរៈសេនីយ៍ទោ សួន ណារ៉ា នាយការិយាល័យនៃនាយកដ្ឋានប្រឆាំងបទល្មើសសេដ្ឋកិច្ច	
១៤:៣០-១៥:១០	១១-ការបង្ហាញពីលទ្ធផលវិភាគគុណភាពឱសថរបស់ NLDQCសហការ ជាមួយ DDF ក្រោម គំរោង GFR6& USP-DQI (USAID)	លោក តី សុវណ្ណរិទ្ធ	
១៥:១០-១៥:៤០	សំរាកពិសារភេសជ្ជៈ		
១៥:៤០-១៦:១៥	១២-របាយការណ៍សកម្មភាពរបស់កម្មវិធី Pharmacovigilanceនិងទិសដៅ បន្ត	លោក សុខ ប៊ុនស្វ និង លោក ម៉មជាត្តារ៉ា	
១៦:១៥-១៧:០០	១៣- ផែនការសកម្មភាពលើសេវាឯកជនរបស់ CNM	លោក អ៊ុក វ៉ាដា	

ថ្ងៃទី២: ថ្ងៃអង្គារទី ១៦ ខែ មិថុនា ឆ្នាំ ២០០៩

០៨:០០-០៨:២០	១៤- សង្ខេបសកម្មភាពថ្ងៃទី១	លោក ហួត សេងធុង	
០៨:២០-១០:០០	១៥- របាយការណ៍សកម្មភាពគណៈកម្មការលុបបំបាត់ឱសថក្លែងក្លាយសេវាខុសច្បាប់ និងប្រព័ន្ធតាមដានគុណភាពឱសថលើទីផ្សារសំរាប់ឱសថគ្រុនចាញ់របស់ខេត្តនីមួយៗ	ខេត្តកំពង់ចាម, ព្រះវិហារ, បាត់ដំបង, កំពង់ឆ្នាំង	
១០:០០-១០:២០	សំរាកពិសារភេសជ្ជៈ		
១០:២០-១២:០០	១៦-ការបង្ហាញលទ្ធផលរបស់ក្រុមនីមួយៗ	តំណាងក្រុមពិភាក្សា	
១២:០០-១៤:០០	សំរាកពិសារបាយ		
១៤:០០-១៤:៣០	១៧- បង្ហាញពីគោលការណ៍ទូទាត់ថវិកា សំរាប់គំរោងមូលនិធិសកល	លោកស្រី ដួង ដារី	
១៤:៣០-១៦:២០	១៨-ពិភាក្សាក្រុមធំ	លោកបណ្ឌិត ច្រឹង សុខន លោកឱសថការី ប្រេម ណូរ៉ុន	
១៦:២០-១៦:៤០	សំរាកពិសារភេសជ្ជៈ		
១៦:៤០-១៧:០០	១៩- អនុសាសន៍ សំណូមពរ និងប្រកាសបិទវគ្គសិក្ខាសាលា	លោកបណ្ឌិត ច្រឹង សុខន	

◆ សូមរក្សាសិទ្ធក្នុងការកែប្រែកម្មវិធី

Annex 7: Protocol for samples testing

U.S. PHARMACOPEIA
DRUG QUALITY AND INFORMATION PROGRAM

USAID
FROM THE AMERICAN PEOPLE

8 June, 2009

Assoc. Prof. **TRINH VAN LAU**, PhD
Director of National Institute of Drug Quality Control (NIDQC)
No 48 Hai Ba Trung Str, Hoan Kiem Dist
Hanoi, Vietnam

Dear Dr Lau,

It is with great appreciation that the NIDQC has agreed to accept the antimalarial medicine samples for confirmatory testing, according to pharmacopeial methods, from our specialized study on the Thailand-Cambodia border. We are pleased to have the collaboration of your institute, a highly recognized laboratory and a long history of successful cooperation with United States Pharmacopeia Drug Quality and Information Program projects in Vietnam.
Since we began our joint activities with NIMPE, the DAV, and the NIDQC in 2003, USPDQI is encouraged by the efforts made in monitoring the medicines supply in Vietnam. Additionally, we are pleased to provide support as needed in the form of reference standards and advanced methods training for your lab staff as has been done in previous years.
Please find enclosed all of the relevant paperwork, sample data sheets, and antimalarial medicine samples for confirmatory testing at the NIDQC laboratory. We very much appreciate timely completion of analysis, especially due to time constraints to submit the final report of this special study.
In addition, find attached to this letter the required tests to be performed as well as the recommended pharmacopeias and the reporting forms to be included in the final report.

Test protocol:

1. Appearance,
2. Identity of API(s)
    a. *if passed* – continue with the Assay (Test 3)
    b. *If failed* – no need to do Assay, nor other tests
3. Assay for content of API(s)
    a. *if passed* – continue with dissolution test (Test 4)
    b. *if failed* – no need to do dissolution test, nor other tests
4. Dissolution

Note for some additional tests:

1. artesunate test for related substance
2. Tetracycline test for impurity (4-epianhydrotetracycline)

Please separate the results according to country, i.e. one separate report for Thailand, and one report for Cambodia.
Thank you in advance for your vital assistance in this endeavor in making our study a success.

Regards,
Christopher Raymond
Christopher Raymond
Project Coordinator for Southeast Asia
US Pharmacopeia
Drug Quality and Information Program
Bangkok, Thailand

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