USP DQI Report on Cambodian-Thai Cross-border Antimalarial Medicines Quality Study Planning Meeting; Establishing an Anti-infective Medicines Quality Monitoring Program in Thailand; and Program Partners' Meeting in Laos on Oseltamivir and HIV/AIDS Activities.

Thailand
May 6 – 16, 2008

Laos
May 23 – 27, 2008

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 USP DQI team (S. Phanouvong, L. Krech, and C. Raymond) organized a planning workshop on May 8-9, 2008 in Bangkok for the *Thai-Cambodia Cross-border Study on Antimalarial Medicines Quality Using a Randomized Sampling Protocol* under the auspices of the Bill and Melinda Gates Foundation (BMGF) through the World Health Organization (WHO) grant. The meeting was held in collaboration with the Bureau of Vector-Borne Diseases Control (BVD), Department of Disease Control, Ministry of Public Health of Thailand.

Between May 12-16, 2008, USP DQI also organized a 5-day training workshop entitled *Establishing an Anti-infective Medicines Quality Monitoring in Thailand* in collaboration with the Bureau of Drugs and Narcotics (BDN), Department of Medical Sciences, Food and Drug Administration and the Bureau of Vector-Borne Diseases (BVBD), Department of Disease Control, Ministry of Public Health of Thailand, and the Kenan Institute Asia (K.I.Asia). The training course was conducted by the USP DQI team, Dr. R. Jahnke of Global Pharma Health Fund Minilab® Project and selected facilitators from the BDN.

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Key Words

Cross-border, anti-malarial medicines, Thailand, Cambodia, malaria resistance, Minilab, medicines quality monitoring, study protocol, sampling, testing and Mekong Sub-region.

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Acknowledgements

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Thanks also go to Dr. Pascal Ringwald, Medical Officer, Case Management and Research of WHO HQ; Mr. Paul Wedel, Executive Managing Director, K.I.Asia; and Mr. James Hopkins, Director, Borderless Action Against Microbes, for their support of the USP DQI program in the Mekong Region, and in Thailand in particular.

Special thanks go to Dr. Manit Terratantikanont, Director General, Medical Sciences Department; Ms. Rojana Kovithvattanaphong, Director, Bureau of Drug and Narcotics, Department of Medical Sciences; Dr. Wichai Satimai, Director; and Ms. Saowanit Vijaykadga, Senior Technical Officer, Bureau of Vector-Borne Diseases, Department of Disease Control; and Mr. Prapol Angtrakol, Representative from Thai FDA for their collaboration and support to this successful workshop.

Acronyms

ACT	Artemisinin-based Combination Therapy
AIDS	Acquired Immunodeficiency Syndrome
ARV	Antiretroviral medication
ANEQAM	Asian Network of Excellence in Quality Assurance of Medicines
BAAM	Borderless Action Against Microbes
BDN	Bureau of Drugs and Narcotics
BMGF	Bill & Melinda Gates Foundation
BVD	Bureau of Vector-Borne Disease of Thailand
CHAD	Center for HIV/AIDS and Sexually Transmitted Infections of Laos
CNM	National Centre for Parasitology, Entomology, and Malaria Control Programme
DCD	Department of Disease Control of Thailand
DMS	Department of Medical Sciences
FDA	Thailand Food and Drug Administration
FDQCC	Food and Drug Quality Control Center of Laos
HIV	Human Immunodeficiency Virus
MPSC	Medical Product Supply Center of Laos
QA	Quality Assurance
QC	Quality Control
RDM-A	USAID Regional Development Mission for Asia
SEARO	WHO South East Asia Regional Office
TLC	Thin Layer Chromatography
USAID	United States Agency for International Development
USP DQI	United States Pharmacopeia Drug Quality and Information
USP-NF	United States Pharmacopeia National Formulary
WHO	World Health Organization
WPRO	WHO Western Pacific Regional Office

Background

With the financial support of the USAID/RDM-A, USP DQI has been assisting countries in the area of drug quality, including antimalarials, in the Mekong Sub-region since early 2003, as part of the regional effort of containing drug-resistant malaria. USP DQI's key assistance areas include: 1) strengthening the medicines regulatory agencies' (MRAs) capacity for post-marketing surveillance through establishment of a network for monitoring and early detection of poor quality anti-infective medicines; 2) capacity building of national laboratories for medicines quality control through provision of essential lab equipment and training of lab analytical and field staff; 3) assisting with good manufacturing practices and regulatory enforcement; and 4) creating a regional network of "Centers of Excellence" in quality assurance of medicines. USP DQI uses a collaborative approach and works with national and international partners active in the region. These include, but are not limited to, USAID regional and country missions, WHO regional and country offices, ministries of health (MoH), national MRAs, medicines quality control laboratories, national malaria, HIV/AIDS, and TB programs, and others.

In response to increasing concerns about failure rates of *P. falciparum* malaria and drug resistance, USP DQI has developed a randomized study sampling protocol being conducted at Cambodian-Thai cross-border provinces looking at the quality of antimalarial medicines. Funding for this study comes from USAID/RDM-A and BMGF through WHO.

Purpose of Trip

To organize two workshops 1) a planning workshop for the Thai-Cambodia Cross-border Study on Antimalarial Medicines Quality; 2) a 5-day training course entitled *Establishing an Anti-infective Medicines Quality Monitoring in Thailand*; and 3) meeting with program partners to provide updates on USP DQI's work in the region and planning for the next steps.

Source of Funding

This trip was supported with funds from the USAID/RDM-A and the BMGF grant.

Overview of Activities

<u>May 8-9, 2008: Cross-border Study Planning Workshop</u>

In collaboration with BVBD, Department of Disease Control, MoH of Thailand, USP DQI organized a planning workshop on the *Thai-Cambodia Cross-border Study on Antimalarial Medicines Quality Using a Randomized Sampling Protocol.* The workshop was held in Bangkok, Thailand and funded by BMGF through a WHO grant. Participants were representatives from Cambodia (National Malaria Center, Food and Drugs Department, National Laboratory for Drug Quality Control, Banteay Meanchey, Oddar Meanchey and Preah Vihear Provincial Health Department staff) and Thailand (BVBD, BDN, and Regional Office of Disease Prevention and Control and the Provincial Health Office staff of Sakaeo, Sisaket, Surin, and Buri Ram provinces). The agenda of the workshop is attached in **Annex 1** and the list of participants is in **Annex 2**.

Key discussion points included: 1) selection of outlets for sampling; 2) obtaining sample information if using the "mystery shopper" technique; 3) concern about the limited availability of the units of samples in certain remote areas; 4) the sample size per medicines to be collected; and 5) the proportion of the number of outlets between various sectors.

Next steps:

1. The country study investigation team translates the protocol into their respective languages by June 30, 2008.
2. The country study investigation team – in collaboration with the provincial investigators – completes the sampling mapping by June 30, 2008.
3. The country study investigation team submits an itemized budget to USP DQI for approval by June 15, 2008.
4. USP DQI reviews the budgets, approves and transfers the money to the country for implementation two weeks after receiving the country submission.
5. Sample collection starts July 1, 2008.

May 12-16, 2008: Establishing medicines quality monitoring in Thailand

The USP DQI team organized a 5-day joint training workshop entitled *Establishing Anti-infective Medicines Quality Monitoring in Thailand* in collaboration with the BDN, Department of Medical Sciences, FDA and the BVBD, Department of Disease Control, Ministry of Public Health of Thailand, and K.I.Asia. This training course was conducted jointly by the USP DQI team and Dr. R. Jahnke of Global Pharma Health Fund Minilab® Project with four qualified facilitators from the BDN. The training agenda is attached in **Annex 3** and list of participants in **Annex 4**. The evaluation of the training is attached in **Annex 5**. The training was conducted in Thai and English and was considered an overall success. No major technical issues were encountered. Operational and logistical issues were raised by some of the participants, including: mapping sampling locations, traveling to collect samples in remote areas, and the availability of medicines.

After the training, the USP DQI team and program partners conducted inventory control to make sure that every Minilab® kit contained all items as described in the content list and was ready for shipping to the selected site.

Next steps:

1. BVBD and BDN to arrange the transport of Minilab® kits to the field at selected sites by June 15.
2. BVBD to follow up with all regional sites on sampling location selection and provide further guidance on sample collection and testing as appropriate.
3. BVBD to translate the sampling and testing forms into Thai by June 30.
4. BVBD and the regional staff to start collecting samples from June 30 –Aug 15 and submit report.

May 26, 2008: Meeting with Lao Program Partners – Program updates

Souly met with Lao program partners at the Food and Drugs Department (FDD), Ministry of Health for updates from each main partner on activities being implemented in Laos. He also provided instructions on quality control (sampling and testing) of oseltamivir capsules to be collected from WHO warehouses and stocks from 4 main hospitals in Vientiane and 16 provincial hospitals for basic quality evaluation. Present at the meeting were representatives from the FDD, FDQCC, MPSC, Curative Department, and Hygiene & Disease Prevention Department. A list of participants is in **Annex 6**. The meeting participants agreed to form a working group on oseltamivir quality testing, which consists of one representative each, from the FDD, FDQCC, and the Curative Medicine Department. The group is responsible for managing the sample collecting, testing, and reporting of the results to appropriate agencies, including USP DQI and WHO.

The FDQCC reported that, for the most recent round of medicines quality monitoring between May and mid-June 2008, 197 samples of anti-infective drug samples were collected and tested. Three artesunate 50 mg tablet samples – all of the same lot No. 060207 – were found to be counterfeit (no active pharmaceutical ingredient (API)). These samples were collected from 3 separate locations (Savanh Pharmacy Center, Phitsamai Pharmacy, and Bounsy Pharmacy in Bachieng District, Champasack Province). The FDD reported that a warning notice was issued to the Champasack provincial authority to confiscate all remaining stocks from these outlets. The warning notice was also sent to all other provinces in the country. The FDD recommended that a specific budget (for swift additional investigation and, if needed, transport and allowance) should be made available to support the provincial authority. Dr. Phanouvong suggested to the FDD to include this activity in the future budget request.

Next steps:

1. The FDD is to compile accomplishments from other partners and submit an update report to USP DQI by June 30, 2008.
2. The FDQCC is to submit a report on the latest round of sample collection and testing to USP DQI by June 20, 2008.
3. The oseltamivir working group is to submit a proposed budget for USP DQI approval and fund transfer by June 20, 2008.
4. The oseltamivir working group is to conduct sampling and testing immediately after receiving funds from USP DQI and provide a report of findings by August 15, 2008.

May 26, 2008: Meeting with Dr. Tsuyuoka and Mrs. Nakhonesid of WHO Office

In the afternoon, Dr. Phanouvong met with Dr. Tsuyuoka and Mrs. Nakhonesid to update them on USP DQI's activities in Laos, including oseltamivir quality testing. Currently, WHO has some oseltamivir stock that expired in February 2008. WHO has expressed concern about its existing stock, which will expire in October 2008. Dr. Tsuyuoka fully supports the USP DQI initiative to check the quality of this product and said that the findings could potentially be used for policy recommendations in terms of procurement, distribution, and storage of oseltamivir products.

Next steps:

1. WHO will coordinate with Curative Department, and Hygiene & Disease Prevention Departments to obtain the exact figure of oseltamivir products distributed to each of the hospitals.
2. Dr. Phanouvong will share the meeting minutes with the Lao Partners on oseltamivir with Dr. Tsuyuoka.

May 27, 2008: Meeting Lao Program partners on HIV/AIDS medicines information, quality and safety

Dr. Phanouvong met with representatives - whose names are listed in **Annex 7**- from the FDD, FDQCC, MPSC, Center for HIV/AIDS and STIs (CHAD), the University of Health Sciences Faculty of Pharmacy, Setthathirat Hospital, and Mahosot Hospital to discuss developing and conducting a training program on HIV/AIDS medications information, quality, and safety for selected hospital and community pharmacists in Laos. Currently, most antiretroviral medications (ARVs) are strictly controlled and are available only in public health facilities. Opportunistic infections medications are, however, available in the private sector as well. Representatives from CHAD – Dr. Phongphet, and Dr. Thanom of the MPSC – brought up a salient point that the trained pharmacists from rural areas involved with this project could play a key role in increasing access to ARV and opportunistic infectionss medicines. They will be able to provide appropriate information for patients living in rural and remote areas since public health facilities are not easily accessible. The meeting participants recommended that the training materials of this project be adapted and used as a curriculum for medical and pharmacy students at the University of Health Sciences.

The FDD and CHAD recommended that the training program include a brief session on the HIV/AIDS situation and treatment practices in Laos using two examples from Mahosot (Central level) and Savannakhet (Provincial level) hospitals. Also included should be discussion on the current regulations concerning HIV/AIDS medicines from the registration, procurement, storage, and distribution perspectives. Participants agreed on this recommendation and were enthusiastic about the project.

Next steps:

1. USP DQI will send the draft outlines of the training materials to Lao counterparts for comments by June 15, 2008.
2. Lao counterparts will provide feedback by June 30, 2008.
3. USP DQI will send a formal letter to the Director of the FDD with copies to other key partners for approval from the MoH by July 10, 2008.

Annex 1: Planning Meeting Agenda on Cross-Border Study, Bangkok May 8-9, 2008

Day One:

8:30 – 9:00	Registration
9:00 – 9:30	Welcome address Self-introduction Objectives and expected outcomes of the meeting
9:30 – 10:00	Overview of USP DQI Program in Mekong Sub-region
10:00 – 10:30	Coffee/Tea break
10:30 – 12:00	Country presentation on antimalarial drugs supply and distribution situation in their respective countries, with emphasis on the study provinces. 30 Minutes each country and 10 minutes for Q&A
12:00 – 13:00	Lunch break
13:00 – 14:00	Overview of the current "final" draft study protocol
14:00 – 15:00	Discussion with focus on sampling methodology/techniques
15:00 – 15:30	Coffee/tea break
15:30 – 17:00	Discussion continues

Day Two:

8:30 – 10:00	Consolidation of comments from Day One discussion
10:00 – 10:30	Coffee/tea break
10:30 – 11:30	Adoption of the study protocol
11:30 – 12:00	Assignment of study team/investigation; roles and responsibilities
12:00 – 13:00	Lunch break
13:00 – 15:00	Study implementation planning
15:00 – 15:30	Coffee/Tea break
15:30 – 16:30	Study implementation planning continues
16:30 – 17:00	Next steps and wrap up

Annex 2: Cross-Border Study Workshop Participant List

Thailand:

Bureau of VBD, MOH:

1. Mrs.Saowanit Vijaykadga, Senior Technical Officer
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2. Miss Arpakorn Teacharat, Technical Officer, VBD Malaria Cluster
3. Mrs.Puangtip Butrak, Technical Officer, VBD Malaria Cluster

Provincial Representatives:

4. Miss Kannika Wisoottiwan, DC Region 3 Chonburi Province
   E-mail: Kannika_v2550@gmail.com
5. Mr.Wijit Kosalakit, DC Region 5 Nakornratchasima Province
6. Mr. Wuttipong Tong-On, Provincial Health Srisaket Province, Kuntararak Hospital
7. Mrs. Janya Pongnan, Provincial Health Surin Province
8. Mrs. Petcharat Chae Eng, Provincial Health Sakheaw Province

BDN - Department of Medical Sciences:

9. Ms. Yaowalak Wattanapisit, Senior Staff

Administrative Support Staff from VBD:

10. Mrs.Yupin Peangkatok
11. Miss Supaporn Piromkit
12. Mr. Prapun Luang-A-ram

Cambodia:

National Malaria Center:

1. Mr. Ouk Rada, Pharmacist

Essential Drugs Bureau, DDF:

2. Mam Boravann, Technical Officer and Project Manager
3. Oeurn Samuth, Assistant Project Manger

National Laboratory for Drug Quality Control:

4. Tey Sovannarith, Senior Technical Officer

Provincial Health Staff:

Banteay Meanchey:

5. Mr. Pikun Bunnara, Chief of Drug Bureau (Pharmacist)
6. Mr. Yam Chifoan, Drug Bureau officer (Pharmacist)

Oddar Meanchey:

7. Mr. Hean Kimseat, Chief of Drug Bureau (Pharmacist)
8. Mr. Bun Channa, Officer of Drug Bureau (Pharmacist)

Preah Vihear:

9. Mr. So Lain, Chief of Drug Bureau
10. Dr. Kong Sakal, Officer of Drug Bureau

ANNEX: 3 Establishing Anti-Infective Medicines Quality Monitoring Training Agenda

8:30-9:30	1. Welcome speech by Director of BDN 2. Reps from USAID, WHO, BAAM, USP DQI brief opening remarks (5 mn each) 3. Short presentation of FDA on the current situation of counterfeit and substandard medicines in Thailand (10 mn) 4. Short presentation of USP DQI-supported activities in Thailand (10mn) 5. Opening speech of Representative from Thailand MOPH
9:30 -10:00	6. Tea/Coffee Break
From 10 AM, follow USP DQI Training program, described below	

Proposed Training Program Agenda

Day 1	**Topic/Activity**
10.00 – 11:30	Brief opening of the training workshop
	Introduction of facilitators and participants
	Workshop objectives and expected outcomes
	Overview of Agenda
	Introduction to medicines quality issues
11:30-12:30	Lunch break
12:30 – 15:00	Principles of Good Laboratory Practice –focus on Minilab®
15:00– 15:30	Tea/coffee break
15:30 – 16:30	Sampling Procedures and demonstration on sampling techniques
16:30 – 17:00	Sample Collection – Sharing lessons learned from the field
Day 2	
8:00 – 8:15	Housekeeping and review of previous day
8:15 – 9:30	Review of Basic Tests – Theory and discussion
9:30 – 10:00	Tea/coffee break
10:00 – 12:00	Group work: practical work – pipetting and spotting practice
12:00-13:00	Lunch Break
13:00 – 14:30	Basic tests: Physical/Visual Inspection – theory and practice
14:30 – 15:00	Tea/coffee beak
15:00 – 17:00	Basic tests: Simple Disintegration – theory and practice
Day 3	
8:00 – 8:15	Housekeeping and review of previous day
8:15 – 9:30	Basic tests: TLC theory and practices – Video on TLC
9:30 – 10:00	Tea/coffee beak
10:00 – 12:00	Group work: TLC standard solution and sample preparation – and run one TLC: antibiotics (ampicillin or chloramphenicol)
12:00 – 13:00	Lunch break
13:00 – 14:30	Group work: practice - continued with antibiotics
14:30 – 15:00	Tea/coffee beak
15:00 – 17:00	Group work: practice with anti-TBs
Day 4	
8:00 – 8:15	Housekeeping and review of previous day
8:15 – 10:00	Group work: practice continued with anti-TBs
10:00 – 10:30	Tea/coffee beak
10:30 – 12:00	Group work: practice with HIV/AIDS medicines
12:00 – 13:00	Lunch break

13:30 – 15:00	Group work: practice continued with HIV/AIDS medicines
15:00 – 15:30	Tea/coffee beak
15:30 – 17:00	Group work: practice with antimalarials
Day 5	
8:00 – 8:15	Housekeeping and review of previous day
8:15 – 10:00	Group work: practice continued with antimalarials
10:00– 10:30	Tea/coffee beak
10:30 – 12:00	Group work: practice with oseltamivir
12:00 – 13:00	Lunch break
13:00 – 15:00	Data management and reporting, Action Plan Development and next steps
15:00 – 15:30	Tea/coffee beak
15:30 – 17:00	Data management and reporting, Action Plan Development and next steps - continues
17:00-17:30	Hand over certificates and closing ceremony

Annex 4: Establishment of Anti-Infective Medicines Quality Monitoring in Thailand
Join Training Workshop (USP DQI, GPHF, BAAM and WHO) in collaboration with Thailand Ministry of Public Health
Bangkok, Thailand, May 12-16, 2008
Participant list

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ANNEX 5: Evaluation by Participants

Participants are given evaluation forms at the beginning of each module of the training workshop and, after the course, asked to rate its educational materials and associated activities. Participants are asked to rate all categories that apply and return the completed form to the instructor.

Name of session: Introduction to Medicine Quality Issues (May 12, 2008)

Indicator	Strongly Agree	Agree	Disagree Somewhat
1. Course objectives were relevant to my needs.	18	8	
2. I was able to understand the content of the materials presented.	8	18	
3. Overall the course was useful and will help me do my job better.			
4. There were enough practical exercises to facilitate understanding of the course.			
5. The pacing of the sessions was appropriate for my understanding of course materials.	13	12	1
6. The instructors were knowledgeable on the subject	23	3	
7. The instructors allowed an appropriate level of participation in the class.	24	5	

Name of session: Good Laboratory Practices (May 12, 2008 afternoon)

Indicator	Strongly Agree	Agree	Disagree Somewhat
8. Course objectives were relevant to my needs.	20	7	
9. I was able to understand the content of the materials presented.	13	13	
10. Overall the course was useful and will help me do my job better.			
11. There were enough practical exercises to facilitate understanding of the course.			
12. The pacing of the sessions was appropriate for my understanding of course materials.	14	12	
13. The instructors were knowledgeable on the subject	20	7	
14. The instructors allowed an appropriate level of participation in the class.	15	12	

Name of session: Sampling Procedures-Lecture/Practical Exercise (May 12-13, 2008)

Indicator	Strongly Agree	Agree	Disagree Somewhat
15. Course objectives were relevant to my needs.	11	11	1
16. I was able to understand the content of the materials presented.	6	17	
17. Overall the course was useful and will help me do my job better.			
18. There were enough practical exercises to facilitate understanding of the course.	4	12	4
19. The pacing of the sessions was appropriate for my understanding of course materials.	8	12	
20. The instructors were knowledgeable on the subject	11	12	
21. The instructors allowed an appropriate level of participation in the class.	11	12	

Name of session: Basic Tests (May 13, 2008 afternoon)

Indicator	Strongly Agree	Agree	Disagree Somewhat
22. Course objectives were relevant to my needs.	16	8	
23. I was able to understand the content of the materials presented.	13	12	
24. Overall the course was useful and will help me do my job better.		1	
25. There were enough practical exercises to facilitate understanding of the course.	13	11	
26. The pacing of the sessions was appropriate for my understanding of course materials.	13	11	
27. The instructors were knowledgeable on the subject	14	10	
28. The instructors allowed an appropriate level of participation in the class.	17	7	

ສາທາລະນະລັດ ປະຊາທິປະໄຕ ປະຊາຊົນລາວ

ສັນຕິພາບ ເອກະລາດ ປະຊາທິປະໄຕ ເອກະພາບ ວັດທະນະຖາວອນ

ກົມອາຫານ ແລະ ຢາ

ໂທ 214014

ລາຍຊື່ຜູ້ເຂົ້າຮ່ວມ

ກອງປະຊຸມປຶກສາຫາລືວຽກງານໂຄງການຂອງ USP DQI

ວັນທີ 27/05/2008

ລ/ດ	ຊື່ ແລະ ນາມສະກຸນ	ໜ້າທີ່ຮັບຜິດຊອບ	ບ່ອນປະຈຳການ	ໂທລະສັບ	Email	ເຊັນ
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ສັນຕິພາບ ເອກະລາດ ປະຊາທິປະໄຕ ເອກະພາບ ວັດທະນະຖາວອນ

ກົມອາຫານ ແລະ ຢາ

ໂທ 214014

ລາຍຊື່ຜູ້ເຂົ້າຮ່ວມ

ກອງປະຊຸມປຶກສາຫາລືວຽກງານໂຄງການຂອງ USP DQI

ວັນທີ 26/05/2008

ລ/ດ	ຊື່ ແລະ ນາມສະກຸນ	ໜ້າທີ່ຮັບຜິດຊອບ	ບ່ອນປະຈຳການ	ໂທລະສັບ	Email	ເຊັນສັນຍາ
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