

Introductory Course on Pharmacovigilance: building skills to implement activities with the Cambodian Pharmacovigilance Center

**Manila, Philippines
September 2-11, 2008**

Trip Report

Ms. Laura Krech, Program Manager, Southeast Asia

**U.S. Pharmacopeia Drug Quality
and Information Program**
12601 Twinbrook Parkway
Rockville, MD 20852 USA
Tel: (+1) 301-816-8160
Fax: (+1) 301-816-8374
Email: uspdqi@usp.org

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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 (USAID) 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

Ms. Krech and two Cambodian Ministry of Health/Department of Drugs and Food (DDF) staff participated in an introductory course on pharmacovigilance (PV) organized by the World Health Organization (WHO HQ) and WHO's Western Pacific Regional Office (WHO WPRO) in collaboration with the Bureau of Food and Drugs in Manila from Sept 2-11, 2008. Participants from 14 Asian and Western Pacific countries included officials in charge of medicines safety monitoring at their respective national health authority and/or representatives of national pharmacovigilance centers. USP DQI, with the support of USAID and in partnership with WHO and the Cambodian MOH/DDF, had recently established the Cambodian Pharmacovigilance Center. This training was essential for the Cambodian DDF staff and Ms. Krech to better understand the topic because they will be working very closely to implement pharmacovigilance activities in the USP DQI-USAID Cambodia Mission work plan.

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Key Words

Cambodia, pharmacovigilance, patient safety, World Health Organization, Western Pacific Regional Office, substandard medicines, counterfeit medicines, adverse drug events, adverse drug reactions, Bureau of Food and Drugs, Philippines.

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ACKNOWLEDGEMENTS

Ms. Krech would like to thank Dr. Mary Couper and Ms. Mitsuko Imai for allowing her to participate as an observer in this course. A special thanks as well goes to Mr. Bruce Hugman, Dr. Kenneth Hartigan-Go, Dr. Mary Couper, and Ms. Lovisa Sallstedt for their efforts as the main course lecturers/facilitators and patience in answering my many questions.

The Bureau of Food and Drugs (BFAD) and WPRO staff performed valuable work in organizing the course logistics; Ms. Pia Angelique Priagola, Ms. Nazarita Tacondong, and Dr. Kwang Soo Park deserve particular recognition.

Ms. Krech benefited not only from the content of the course but also from working closely with the Cambodian representatives, Ms. Mam Boravann and Mr. Huot Sengthong from the Cambodian Department of Drugs and Food, who also deserve recognition.

Finally, Ms. Krech sincerely thanks Dr. Patrick Lukulay and Dr. Souly Phanouvong from USP DQI, and Mr. Anthony Boni and Ms. Veerle Coignez from USAID, for their support and encouragement to take advantage of this valuable professional education experience.

ACRONYMS

ADR	Adverse Drug Reaction
BFAD	Bureau of Food and Drugs
CPC or “Center”	Cambodian Pharmacovigilance Center
DDF	Department of Drugs and Food
MOH	Ministry of Health
PV	Pharmacovigilance
UMC	Uppsala Monitoring Center
USAID	United States Agency for International Development
USP DQI	United States Pharmacopeia Drug Quality and Information
WHO	World Health Organization
WPRO	WHO Western Pacific Regional Office

Background

Pharmacovigilance (PV) is the key to monitoring and evaluating adverse reactions (ADRs) to medicines. It identifies and quantitatively assesses the risks related to the use of medicines in an entire population or in specific population groups. PV activities are imperative to improve public health and patient safety in relation to the use of medicines.

In 2008, 108 countries (84 full and 24 associate member countries) participate in the WHO Programme for International Drug Monitoring, run in conjunction with the WHO Collaborating Centre for International Drug Monitoring (UMC) in Uppsala, Sweden which holds the WHO global database of over 4 million spontaneous reports of ADRs. Australia, Brunei Darussalam, China, Fiji, Japan, Malaysia, New Zealand, Republic of Korea, Philippines, Singapore, and Vietnam are active members of the program from the WHO WPRO.

Whether or not PV systems or centers are established, current PV practice needs to be reviewed and developed in the areas of reporting, data quality, and assessment of ADRs and detection of signals, as well as training, prevention, communication, and crisis management. Training in these areas is therefore an important component of the WHO Program.

USP DQI, WHO, Cambodian MOH, and DDF recognize the importance of establishing a national PV program in Cambodia and subsequently organized a two-day workshop in Phnom Penh in May 2008 coordinated by PV experts with support from the USAID Cambodia Mission. The workshop brought together more than 40 representatives from international, non-governmental, and humanitarian organizations and universities to meet with members of the Cambodian MOH, hospital directors, and national and provincial public health leaders to create the structures needed for the Cambodian Pharmacovigilance Center (CPC). Participants formed working groups to address the logistics of establishing a PV center, determine what training is needed, and structure the ADR reporting system. PV experts from the Philippines and the Moroccan Poison Control and Pharmacovigilance Centre – a WHO Collaborating Center – facilitated the workshop. CPC activities for the current fiscal year are listed in *Annexes 3 and 4*.

After the workshop, next steps to begin the implementation of PV activities included sending two staff from Cambodia (selected by the MOH) to attend the *Introductory Course on Pharmacovigilance*, from September 2-11 in Manila, Philippines, funded by WHO/WPRO. Ms. Krech also attended this course as part of her professional development activities to become more familiar with PV in order to better assist Cambodia in the development of the CPC.

Purpose of Trip

- Participate in an introductory course on PV organized by WHO HQ and WHO WPRO, in collaboration with the Bureau of Food and Drugs in Manila, Sept 2-11, 2008.
- Work with the Cambodian representatives from the DDF to better understand the topics and develop an action plan to implement the PV activities listed in the USP DQI-USAID Cambodia Mission work plan.

Source of Funding

This trip was funded by the USAID Missions in Cambodia and the Philippines.

Overview of Activities

September 2-11, 2008

*Introductory Course on Pharmacovigilance (please refer to **Annex 1** for the full course agenda)*

The target audience was Medicines Regulatory Authorities and Ministry of Health officials from 14 countries in Asia and the Western Pacific who have: a) recently commenced PV activities in their country; b) not begun PV activities but would like to start; or c) already established a PV center and conducted some activities, but have faced difficulty implementing activities, obtaining consistent funding, or encouraging health professionals to report ADRs. Ms. Krech was able to attend the course as an observer and worked closely with the Cambodian delegation. See **Annex 2** for a list of all country participants and their titles.

The first sections of the course addressed what pharmacovigilance is and why it is so important. The WHO definition of pharmacovigilance is “the science and activities relating to the detection, assessment, understanding, and prevention of adverse effects or any other drug-related problem.” Pharmacovigilance is about monitoring the safety of medicines, vaccines, anti-venoms, and herbal preparations in the population.

A medicines monitoring system is an essential and cost-efficient means of detecting and minimizing injury to patients. It also insures against the undetected use of ineffective, substandard, or counterfeit medicines. Furthermore, a medicines monitoring system assists in the promotion of rational drug use and the prevention of medication errors or inadvertent overdose.

The aims of pharmacovigilance are to enhance patient care and patient safety in relation to the use of medicines, especially with regard to the prevention of unintended harm from the use of drugs; to improve public health and safety in relation to the use of medicines by the provision of reliable, balanced information resulting in more rational use of drugs; and to contribute to the assessment of the risk-benefit profile of medicines, thus encouraging safer and more effective use of medicines and a resolution of the sometimes apparently conflicting interests of public health and individual patient welfare.

Ms. Krech participated in the course since she is the program manager for USP DQI activities in Cambodia and currently is working closely with the DDF, MOH, WHO, and pharmacovigilance experts to start a national PV program. As of July, the Cambodia Pharmacovigilance Center was up and running with two full-time staff. In order to better manage Cambodian pharmacovigilance activities, Ms. Krech wanted to learn as much as possible on this subject and obtain a solid understanding of: what pharmacovigilance is; the various components and staff needed to carry out necessary activities; how to create an excellent reporting form; how countries set up their own national programs and how they educate and train health professionals to report adverse drug reactions (ADRs); what to do with ADR reports once you have them; how they are analyzed; how countries and their PV centers interact with WHO and the Uppsala Monitoring Center; what the greatest challenges are to implementing PV activities; and country case studies detailing how to overcome the difficulties.

This training helped Ms. Krech to better implement the PV activities that are part of the USP DQI/USAID work plan in Cambodia. She is now able to work with the Cambodian

Pharmacovigilance Center staff and to understand what the Center wants to achieve and what steps to take. During the course, Ms. Krech worked with the Cambodia delegation to come up with a specific action plan that lists 5 pharmacovigilance activities that will be accomplished over the next year. After the course, Ms. Krech and the two Cambodian representatives went to Cambodia and jointly presented the action plan to other staff members of the DDF and the WHO country office. See *Annexes 3 and 4* to view the action plan for the next year.

Ms. Krech met with pharmacovigilance experts from WHO and the Uppsala Monitoring Center and can use these contacts to pose questions that will arise during the implementation of PV activities in Cambodia. Ms. Krech can also contact one of these experts (based in Asia) to do an on-site assessment of the Center and provide technical assistance to the two staff after it has been up and running for some time.

Among the many different topics covered over the 9-day course, the author found it of particular interest to learn why clinical trials do not provide enough information on the safety profile of a medicine, particularly regarding long-term effects and use in specific populations: pregnant women, children, the elderly, and different affects due to race (Asian versus Caucasian for rifampicin, chloroquine, etc). On average, there is only one ADR for every 30,000 patients using a particular medicine; this number is much larger than any clinical trial, therefore ADRs often do not show up until post-marketing surveillance.

Many ADRs currently happen because patients are not being managed properly by their doctor or pharmacist. Often, it is not the newer drugs that are of the greatest concern, but rather the older ones that have been on the market for a long time. For example, last year in Brazil a baby was born without limbs because the mother was prescribed thalidomide to relieve morning sickness symptoms.

Pharmacovigilance saves lives; withdrawing a medicine from the market that is doing more harm than good is critical.

Next Steps

- Send the two PV staff (Dr. Mam Dathara and Dr. Sok Bunso) to a fully-functioning PV center for hands-on training. Examine other nearby country options – including Malaysia and Indonesia – since there are some political tensions currently between Thailand and Cambodia which have caused the original plan to change. Dr. Bruce Hugman, UMC consultant, will be able to provide guidance in finding an institution that would work well to facilitate the hands-on training experience.
- Purchase the necessary equipment for the Center (computers, printers, fax machine).
- For the future, think about how the CPC can be combined with the activities of the poison control facilities at Calumet Hospital and drug information.
- Set up the pharmacovigilance technical committee.
- Dr. Sokhan from the DDF will write to Dr. Mary Couper at WHO headquarters to become a provisional member of the WHO Programme for International Drug Monitoring to participate in global PV activities. After the CPC submits at least 20 ADR reports that they have collected to the Uppsala Monitoring Center they will become full members.



Organized by the
World Health Organization
in collaboration with the
Bureau of Food and Drugs, Department of Health

Training Course on **PHARMACOVIGILANCE**



**Renaissance Hotel
Makati City, Philippines**

02 to 11 September 2008

Background Information

Pharmacovigilance is the key to monitoring and evaluating adverse reactions to medicines. It identifies and quantitatively assesses the risks related to the use of medicines in an entire population or in specific population groups. Pharmacovigilance activities are imperative to improve public health and patient care in relation to the safe use of medicines.



Whether or not Pharmacovigilance centres are established, current Pharmacovigilance systems need to be reviewed and developed further in the areas of reporting, detection and assessment of ADRs as well as prevention and communication. Training is therefore an important component of the activities of the programme.



Objectives:

- Raise awareness about overall public health concern in relation to medicines safety.
 - Demonstrate the importance of pharmacovigilance activities in improving patients treatment outcomes.
-
- Provide the latest tools on basic ADR reporting mechanisms to enhance reporting of adverse drug reactions (ADRs) at all levels of health services and the pharmaceutical industry
 - Build or reinforce capacity of national Pharmacovigilance centres
 - Share experience and challenges faced to establish or strengthen pharmacovigilance programmes
 - Establish networking between regulatory agencies, pharmacovigilance centers and WHO for information sharing and providing assistance in identifying signals and making judgments based on sound science.

Dates and Site

The meeting will be held from
02 to 11 September 2008

Renaissance Makati City Hotel

Esperanza St. corner
Makati Avenue

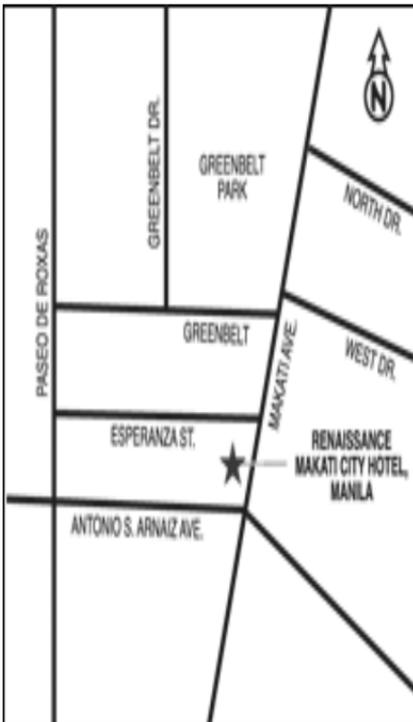
Language

English only.



Participants

Officials in charge of medicines safety monitoring at national health authorities, and/or representatives of national pharmacovigilance centres of the Western Pacific countries.



Visa

All travellers are responsible for having in their possession a passport valid for at least six months from date of departure for the Philippines. Participants from China should apply with the diplomatic representations of the Philippines abroad for visa. Other participants are permitted to stay in the Philippines for 21 days without a visa provided they are holding onward or return air tickets. Chinese participants holding a British passport issued in Hong Kong may enter the Philippines without a visa for a maximum stay of seven (7) days; this can be extended for another seven (7) days.

Hotel Accommodation

A block booking (for the participants) has been arranged at the Oxford Suites Makati which is just a five minutes drive from the training venue. The hotel rate is US \$ 53-55 (inclusive of breakfast)

Oxford Suites Makati

Durban cor. P. Burgos Streets

Makati City

Tel No. (632) 895-4801

Fax No. (632)895-4805

Reservations: (632) 895-4803



A shuttle will transport the participants daily to the training venue and back to the hotel.

Accommodations for the speakers have been arranged with the Renaissance Hotel. The hotel rate is US\$ 125++ inclusive of breakfast.

Participants are therefore requested to send their travel itineraries as soon as they have booked their flights to:

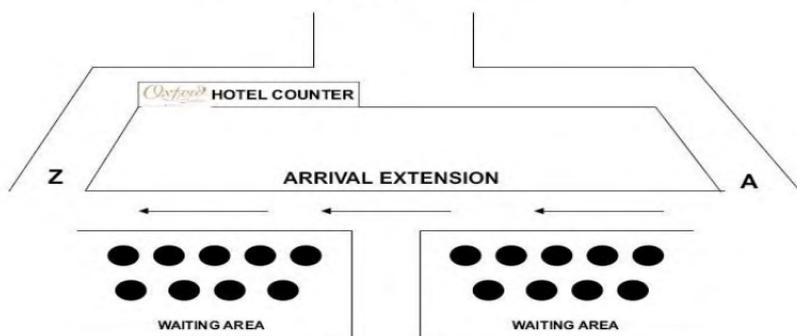
Ms. Pia Angelique Priagola
Bureau of Food and Drugs, Philippines
Tel: (63 2) 8424538; (63 2) 8070700
Fax (63 2) 8070700
Email: piaangelique@yahoo.com

Travel arrangements

Arrangements has been made for Airport – Hotel – Airport transfers which is charge against the participants personal account. Participants are to proceed to the Oxford Suites front desk at the arrival area.

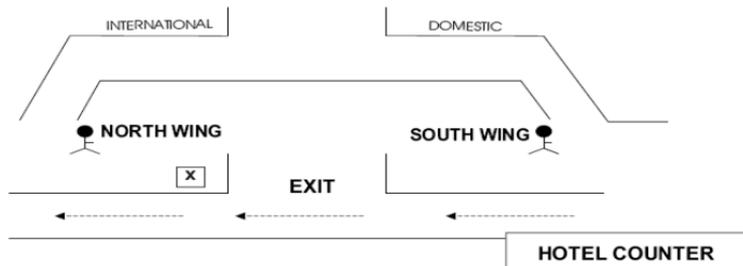
NINYO AQUINO INTERNATIONAL AIRPORT (NAIA 1)

ARRIVAL AREA



CENTENNIAL AIRPORT – TERMINAL 2

ARRIVAL AREA



Legend:

 Oxford Airport Representative

 Pick-up point





Currency

The monetary unit in Manila is the Peso.

The exchange rate is currently at P 44.00 to US\$1.00 (subject to change).

Airport tax

P750 for international departure and P200 for local departure (paid in Philippine pesos only) are charge as Airport tax. Departing passengers for international destinations are advised to check with airport or tourist information counters (Tel. Nos. 524-1703; 832-2964) the departure fees which may change without notice.

Documents for the workshop

Each participant will be given a bag containing the materials for the training.

Climate

March to May is hot and dry. June to October is rainy. November to February is cool. Average temperatures: 78oF/25oC to 90oF/32oC; humidity: 77%.

Postal, e-mail and fax no.

Participants may use the following address for personal mail for the duration of the workshop:

Name of Participant
Attending the
Introductory Course On Pharmacovigilance
Oxford Suites Makati
Durban cor. P. Burgos Streets
Makati City 1200, Philippines
Tel. no. (632) 895-4801
Email: cynchdiza@yahoo.com



Tuesday, September 2: Day 1

09.00 - 09.30	Opening ceremony Welcome remarks	Prof. Leticia B.Gutierrez, MS Director, Bureau of Food and Drugs
	Opening remarks	Dr Soe Nyunt U WR Philippines
09.30 - 10.15	Introduction of participants and faculty	WHO/HQ
10.15 - 10.30	Photo session	
10.30 - 11.00	Coffee Break	
11.00 - 11.15	Introduction of the course and objective	
11.15 - 12.00	The need for Pharmacovigilance including key definitions	Dr Mary Couper WHO/HQ
12.00 - 12.30	Discussion	
12.30 - 13.30	Lunch	
13.30 - 13.45	Pharmacovigilance - regional perspective	Ms Nazarita T. Tacandong WPRO
13.45 - 14.15	Discussion	
14.15 - 15.00	Country presentation: Pharmacovigilance activities and experiences (Philippines, China)	
15.00 - 15.30	Coffee break	
15.30 - 17.00	Country presentation: Pharmacovigilance activities and experiences (Fiji, Republic of Korea, Viet Nam, Mongolia)	

Welcome Dinner

Wednesday, September 3: Day 2

09.00 - 09.15	Feedback from the previous day	WHO/HQ
09.15 - 10.00	ADR surveillance: methods of reporting	Dr Mary Couper
10.00 - 10.15	Questions and discussion	
10.15 - 10.45	Coffee break	
10.45 - 12.15	Establishing a Pharmacovigilance centre - general principles (WHO Uppsala Monitoring Centre guidelines)	Mr Bruce Hugman
12.15 - 13.15	Lunch	
13.15 - 13.45	How to conduct effective workshops and meetings	Mr. B. Hugman
13.45 - 14.45	Working Groups (4 groups): Establishing an adverse reaction monitoring system - the practicalities	Mr Bruce Hugman Dr Kenneth Hartigan Go Ms Lovisa Sällstedt, UMC Dr Mary Couper
14.45 - 15.45	Report back from groups	
15.45 - 16.15	Coffee break	
16.15 - 17.00	Working Groups (4 groups): Discussion on the following points; 1. Who should report? 2. What should be reported? 3. How should we promote reporting?	Mr Bruce Hugman Dr Kenneth Hartigan Go Ms Lovisa Sällstedt, UMC Dr Mary Couper
17.00 - 17.30	Presentation of results of discussion	

Thursday, September 4: Day 3

09.00 - 09.15	Feedback from the previous day	WHO/HQ
09.15 - 09.45	WHO Adverse Drug Reaction Monitoring Programme	Dr Mary Couper
09.45 – 10.00	Questions and discussion	
10.00 - 10.45	Constructing an ADR reporting form-design issues	Mr Bruce Hugman
10.45 - 11.15	Coffee break	
11.15 - 12.30	Working groups (by country): Development of monitoring system and reporting forms: What needs to be done?	
12.30 - 13.30	Lunch	
13.30 - 14.00	Terminologies for coding of adverse reactions and diseases	Ms Lovisa Sällstedt
14.00 - 15.00	Working groups (4 groups): Discussion on traditional medicines	Dr Cynthia Diza,
15.00 - 15.30	Coffee break	
15.30 - 16.00	Feedback from working groups	
16.00 - 16.45	Literature sources for ADR information	Dr Klara Tisocki,
17.00 -	Medico-legal aspects of pharmacovigilance (Optional)	Dr Kenneth Hartigan Go

Friday, September 5: Day 4

09.00 - 09.15	Feedback from the previous day	WHO/HQ
09.15 - 09.45	Principles of causality assessment	Dr Kenneth Hartigan Go
09.45 - 10.45	Working groups (4 groups): Case causality assessments	Dr Kennethh Hartigan Go
10.45 - 11.15	Coffee break	
11.15 - 12.30	Case causality assessments: Discussion	
12.30 - 13.30	Lunch	
13.30 - 14.00	VigiFlow - Computer software for management of ADR case data	Ms Lovisa Sällstedt
14.00 - 15.00	Practical recording of case information -hands on practice	Ms Lovisa Sällstedt Dr Klara Tisocki
15.00 - 15.30	Coffee break	
15.30 - 16.30	Practical recording of case information -hands on practice (cont.)	
16.30 - 17.15	Diagnosis and management of ADR and mechanisms of ADR	Dr Kenneth Hartigan Go
17.15 - 17.30	Discussion	

Saturday, September 6: Day 5 (half day)

09.00 - 09.15	Feedback from the previous day	WHO/HQ
09.15 - 10.15	Good communications practice in Pharmacovigilance	Mr Bruce Hugman
10.15 - 10.45	Coffee break	
10.45 - 12.30	Good communications practice in Pharmacovigilance a case study	Mr Bruce Hugman
12.30 – 13.00	Review of the week	

Monday, September 8: Day 6

09.00 - 09.15	Feedback from Saturday	WHO/HQ
09.15 - 10.15	Identifying early signals of suspected drug problems and principles of data mining techniques used in signal detection	Dr Kenneth Hartigan Go
10.15 - 10.30	Discussion	
10.30 - 11.00	Coffee break	
11.00 - 12.30	Pharmacovigilance in vaccines	Dr Kenneth Hartigan Go
12.30 - 13.30	Lunch	
13.30 - 15.00	Crisis management	Mr Bruce Hugman
15.00 - 15.30	Coffee break	
15.30 - 17.00	Crisis management	Mr Bruce Hugman

Tuesday, September 9: Day 7

09.00 - 09.15	Feedback from the previous day	WHO/HQ
09.15 - 10.00	Pharmacovigilance and rational use of drugs	Dr Kenneth Hartigan Go
10.00 - 10.30	Discussion	
10.30 - 11.00	Coffee break	
11.00 - 12.00	Role of Regulators in Pharmacovigilance including the translational process from signal identification to regulatory decision making	Dr Cynthia Diza
12.00 - 12.30	Discussion	
12.30 - 13.30	Lunch	
13.30 - 14.00	Pharmacovigilance involving consumer reporting	Ms. Nazarita T. Tacandong
14.00 - 14.30	Discussion	
14.30 - 15.00	Individual work: Development of country-specific action plan for Pharmacovigilance for the next year	
15.00 - 15.30	Coffee break	
15.30 - 16.30	Individual work: Development of country-specific action plan for Pharmacovigilance for the next year	
16.30 – 17.00	Report back from some volunteers on their work	

Wednesday, September 10: Day 8

09.00 - 09.15	Feedback from the previous day	WHO/HQ
09.15 - 10.15	Developing training material and in-country pool of speakers and trainers	Mr Bruce Hugman
10.15 - 11.00	Interacting with the media	Mr Bruce Hugman
11.00 - 11.30	Coffee break	
11.30 - 12.15	Pharmacovigilance in Public Health Programmes	Dr Mary Couper
12.15 - 12.30	Discussion	
12.30 - 13.30	Lunch	
13.30 - 14.00	Patient safety - medication errors	Dr Kenneth Hartigan Go
14.00 - 14.20	Discussion	
14.20 - 14.50	Quality assurance, WHO Prequalification Programme and safety problems related to drug counterfeiting	Dr Mary Couper
14.50 - 15.20	Coffee break	
15.20 - 17.00	Individual work: Preparation for action plans	

Thursday, September 11: Day 9

09.00 - 09.15	Feedback from the previous day	WHO/HQ
09.15 - 12.30	Presentation of country action plans (including Coffee break)	
12.30 - 13.30	Lunch	
13.30 - 14.00	Lessons and questions from the country action plans	
14.00 - 14.30	Lessons and questions from the whole course	
14.30 - 15.00	Networking, agreeing on a way forward and evaluation	
15.00	Thanks and closure	

Other useful information

Smoking is prohibited in public areas.

Electricity - 220 volts, A.C. 60 cycles. Most hotels have 110-volt outlets.

Customs -Visitors are advised to fill in the Baggage Declaration Form before disembarking to facilitate Customs examination. Visitors carrying more than US\$ 3,000 are to declare the amount at the Central Bank of the Philippines counter situated at the Customs area. Foreign currency taken out upon departure must not exceed the amount brought in.

Local Transport

Metered and fixed rate taxis are widely available in key cities nationwide. Jeepneys and buses are inexpensive ways of getting around most places.

In Metro Manila the fastest way of commuting is via the railway system. LRT connects Monumento on the north to Baclaran on the south. MRT traverses the length of EDSA from North Avenue to Taft Avenue.



Health Regulations

A certificate of vaccination against yellow fever is required for travelers coming from infected areas. Children less than one year old are exempted but may be subject to isolation when necessary.

[Hospitals](#) are listed in the "Yellow Pages" of the local telephone directory.

Business and Banking Hours -Private and government offices are open either from 8:00 a.m. to 5:00 p.m. or from 9:00 a.m. to 6:00 p.m. from Mondays to Fridays. Most commercial establishments are open from 10:00 a.m. to 8:00 p.m. daily. Banks are open from 9:00 a.m. to 3:00 p.m., Mondays to Fridays, with automated teller machines (ATM) operating 24 hours.

Credit Cards - International credit cards such as Visa, Diners Club, MasterCard, and American Express Card are accepted in major establishments.

Dining Out

Filipino food is an exotic, tasteful blend of Oriental, European, and American culinary influences. There is a wide variety of fresh seafood and delectable fruits. First class restaurants offer gourmet specialties as well as Filipino cuisine.



Entertainment and Culture

Metro Manila is the center of entertainment and cultural activities. The premier venue for the performing arts is the Cultural Center of the Philippines. The hubs of nightlife activities are the Remedios Circle in Malate, Ayala Center and The Fort at Bonifacio Global City in Makati, Timog and Tomas Morato Avenues in Quezon City, and Eastwood in Libis, Quezon City.



What To Wear - Light, casual clothes are recommended. When visiting churches and temples, propriety dictates that shorts and scanty clothing be avoided.



Communication Facilities - Most national dailies are in English. There are 7 national television stations. which broadcast mainly in Filipino. Cable TV is available as well



Front cover design by



WORLD HEALTH
ORGANIZATION



ORGANISATION MONDIALE
DE LA SANTÉ

REGIONAL OFFICE FOR THE WESTERN PACIFIC
BUREAU RÉGIONAL DU PACIFIQUE OCCIDENTAL

INTRODUCTORY TRAINING COURSE
ON PHARMACOVIGILANCE

WP/2008/DHS/08/PHA/2008/IB/2
29 August 2008

Manila, Philippines
2-11 September 2008

ENGLISH ONLY

INFORMATION BULLETIN NO. 2

PROVISIONAL LIST OF PARTICIPANTS, TEMPORARY ADVISERS, CONSULTANTS
REPRESENTATIVES/OBSERVERS, AND SECRETARIAT

1. PARTICIPANTS

BRUNEI DARUSSALAM

Dk HjH Siti Zarinah Pg Hj Zainal
Pharmaceutical Chemist
Department of Pharmaceutical Services
Ministry of Health
Commonwealth Drive
Bandar Seri Begawan BB3910
Tel: 673 3335331 Ext 5005
Fax: 673 3340424
E-mail: zarinahzainal@yahoo.com

Ms Ellys Mohammed
Pharmaceutical Chemist
Drugs Administration Section
Ministry of Health
2G8:03, Block 2G, Ong Sum Ping Condominium
Bandar Seri Begawan BB 1111
Tel/Fax: 673 2 230001
Email: ellys_718@yahoo.co.uk

CAMBODIA

Ms Mam Boravann
Deputy Chief
Essential Drug Bureau
Department of Drugs and Food
Ministry of Health
151-153 Kampuchea Krom Road
Phnom Penh
Tel./Fax: (855) 23 880969
Email: edb.ddf@online.com.kh

Mr Huot Sengthong
EBD Officer
Department of Drugs and Food
Ministry of Health
151 - 153 Kampuchea Krom Road
Phnom Penh
Tel./Fax: (855) 23 880969
Email:

CHINA

Dr Wang Gang
Project Officer
Division of Medical Service Supervision and
Management
Department of Medical Administration
Ministry of Health
No. 1 Nanlu, Xizhimenwai
Beijing 100044
Tel.: (8610) 68792209
Fax: (8610) 68792513
Email: wanggang_dfh@hotmail.com

Dr Wang Yali
Doctor, National Center for ADR Monitoring
Center for Drug Reevaluation
State Food and Drug Administration
Building 6, No. 3 Yard, San Li He Yi Qu
Xicheng District
Beijing
Tel.: (8610) 68586283
Fax: (8610) 68586295
Email: Wangyali@cdr.gov.cn

Mr Xuan Qingsheng
Deputy Director-General
Anhui Food and Drug Administration
96 East Wangjiang Road
Hefei, Anhui
Tel.: (865) 51 3677657
Fax: (865) 51 3677618
Email: xgs@ndn.gov.cn

CHINA (Cont.)

Ms Zhang Shufang
President
China Licensed Pharmacist Association
1001 Tower B-1, No.9 Chegongzhuang Road
Beijing 10004
Tel.: (8610) 88312158
Fax: (8610) 88312155
Email: dq_8256@hotmail.com

FIJI

Ms Mary Kama
Pharmacist (Regional Procurement Unit)
Fiji Pharmaceutical Services
Ministry of Health
Lot 1, Jerusalem Road Nabua
Suva
Tel.: (679) 338 8000
Fax: (679) 338 8003
Email: mary.kama@govnet.gov.fj

**LAO PEOPLE'S DEMOCRATIC
REPUBLIC, THE**

Mr Vongtavanh Chiemsisourath
Director, Narcotic Drug
Chemical & Cosmetic Control Division
Food and Drug Department
Ministry of Health
Simuang Road, Vientiane Capital
Tel.: (856-21) 214013-14
Fax: (856 21) 214015
Email: drug@laotel.com; cosmetic_laos@yahoo.com

Ms Soulyvanh Keokinnaly
Senior Officer, Drug Control Division
Food and Drug Department
Ministry of Health
Simuang Road, Vientiane Capital
Tel.: (8555556-21) 214013-14
Fax: (856-21) 214015
Email: drug@laotel.com; keokinnaly@yahoo.com

MONGOLIA

Ms Chojjoo Amarjargal
Officer-in-Charge
Pharmaceutical and Medical Devices Department
Ministry of Health
210648 Zasgiin gazriin VIII bair
Olympiin gudamj2Sukhbaatar duureg
Ulaanbaatar
Tel.: (976) 11 263786
Fax: (976) 11 323541
Email: ajarjargal_ch@yahoo.com

MONGOLIA (Cont.)

Mr Ulziikhutag Bayaraa
Officer-in-Charge
Registration of ADR and Poisoning
National Center for Health Development
210648 Jamyas Street 13
Sukhbaatar duureg
Ulaanbaatar
Tel.: (976) 11 70110894
Fax: (976) 11 320633
Email: bayarpic@yahoo.com

PAPUA NEW GUINEA

Dr Phillip Kigodi
Discipline of Pharmacy,
School of Medicine and Health Sciences
P.O. Box 5623 Boroko
Tel.: (675) 3233263
Fax: (675) 3250809
Email: kikovele@daltron.com.pg

PHILIPPINES, THE

Dr Cynthia Diza
Medical Specialist III
Bureau of Food and Drugs
Civic Drive, Filinvest Corporate City
Alabang, Muntinlupa City
Tel: (632) 807 07 00
Fax (632) 807 0751
Email : cynchdiza@yahoo.com

Ms Cynthia Lim
Food – Drug Regulation Officer III
Bureau of Food and Drugs
Civic Drive, Filinvest Corporate City
Alabang, Muntinlupa City
Tel.: (632) 807 8275
Fax: (632) 807 8511
Email: cynthlim@yahoo.com

Dr Robert Louie P. So
Program Manager, Pharmaceutical Management Unit
Department of Health, Bureau of International Health
Cooperation
OSEC Bldg 1, San Lazaro Compound
Sta. Cruz, Metro Manila
Tel./Fax: (632) 7438301 local 1101
Email: rlpsomd@yahoo.com

PHILIPPINES

Dr Dennis S. Quiambao
Project Management Operating Officer & Coordinator
Pharmaceutical Management Unit
Bureau of Int'l Health Cooperation
OSEC Bldg. 1, San Lazaro Compound, Manila
Tel/Fax: (632) 7438301 local 1102
Email:

Ms Beulah F. Villanueva
Pharmacist II
Quirino Memorial Medical Center
Quezon City, Philippines
Tel.: (632) 4212250
Fax: (632) 4219289
Email: bhe_fv@yahoo.com

REPUBLIC OF KOREA, THE

Ms Ha Jihe
Scientific Officer, Pharmacist
Risk Assessment Team
National Institute of Toxicological Research
Korea Food and Drug Administration
194 Tongil-ro, Eunpyung-gu
Seoul
Tel.: (822) 3801826
Fax: (822) 3886393
Email: jihyeha@kfda.go.kr

Mr Jin Byungjo
Assistant Director, Pharmacist
Pharmaceutical Management Division
Pharmaceutical Safety Bureau
Korea Food and Drug Administration
Yurim Building 38-29
Nokbeon-dong, Eunpyung-gu
Seoul
Tel.: (822) 31568063
Fax: (822) 31568071
Email: bjjin@kfda.go.kr

SOLOMON ISLANDS

Ms Erin Mitchell
Training Pharmacist
Ministry of Health and Medical Services
P.O. Box 349
Honiara
Tel.: (677) 91945
Fax: (677) 20085
E-mail: emitchell@nrh.com.sb; eza44@hotmail.com

VIET NAM

Dr Hoang Thanh Mai
Officer-in-Charge of ADR Monitoring
ADR Centre of Drug Administration
138 A Giang Vo – Badminh
Ha Noi
Tel.: (844) 8235812
Fax: (844) 8234758
Email: hoangthanmai@hotmail.com

Ms NguyenThi Phuong Cham
Senior Expert of Medical Administration
Ministry of Health
138A GiangVo Street
Ha Noi
Tel.: (84-4)2732273 - 1703
Fax: (84-4)273228
Email: ntpcham@gmail.com

2. TEMPORARY ADVISERS / FACILITATORS

Dr Kenneth Yu Hartigan-Go
Consultant for Health Technology Assessment,
Quality Assurance and Reference Drug Pricing,
Philippine Health Insurance Corporation (PHIC)
Executive Director, The Zuellig Foundation
The Zuellig Foundation
8/F Equitable Card Center, 203 Salcedo St.
Legaspi Village, Makati City,
Tel.: (632) 8931449
Fax: (632) 8922871
Email hartigan@zuelligfoundation.org

Mr Bruce John Hugman
International Communication Consultant
426/39 Moo3, Koggalae T. Rimkok
A. Muang, Chiang Rai 57100
P.O. Box 246, Amphur Muang, Chiang Rai 57000
Bangkok
Tel.:(66) 896 35 35 94
Fax: (66) 53 750876
E-mail: mail@brucehugman.net

Ms Lovisa Sallstedt
MSc Pharm
Safety Support & Services
The Uppsala Monitoring Centre
WHO Collaborating Centre for Intl. Drug Monitoring
Box 1051, S-751 40 Uppsala
Sweden
Tel.: (461) 8656060
Fax: (461) 8656088
E-mail: Lovisa.sallstedt@who-umc.org

Ms Nazarita Tacandong
Unit 908 Providence Tower
Leon Guinto corner Estrada Sts.,
Malate, Manila
Mobile: 09164387165
Email : nazarita_tacandong@yahoo.com

Dr Klara Tisocki
EU Technical Assistance for Health Sector
Policy(TA4HSP)
Bureau of Food and Drugs
Civic Drive, Alabang, Muntinlupa City
Tel./Fax: (632) 807-8285;
Mobile: 63(0)920-9076956
Email: klara.tisocki@gtz.de, ktisocki@yahoo.ie

4. OBSERVERS

BUREAU OF FOOD AND DRUGS (BFAD)

Ms Lanette Lee A. Querubin
Food and Drugs Regulation Officer III, Bureau of Food
and Drugs
Civic Drive, Filinvest Corporate City
Alabang, Muntinlupa City
Tel.: (632) 8070725
Fax: (632) 8078275
E-mail: lanettelee@gmail.com

**BUREAU OF FOOD AND DRUGS (Cont.)
(BFAD)**

Ms Nida Alfaro Mangmang
Food and Drugs Regulation Officer III
Bureau of Food and Drugs
Civic Drive, Filinvest Corporate City
Alabang, Muntinlupa City
Tel.: (632) 807 0726 or 8070700
Fax: (632) 8070700
Email:

Ms Arlyn G. Magno
Food-Regulation Officer I, Product Services Division
Bureau of Food and Drugs
Civic Drive, Filinvest Corporate City
Alabang, Metro Manila
Tel.: (632) 8070725
Fax: (632) 8078275
Email: arlyn_magno@yahoo.com

UNITED STATES PHARMACOPEIA

Ms Laura Krech, MPH
Program Manager, Southeast Asia
United States Pharmacopeia
Drug Quality and Information Program (USP DQI)
International Technical Alliances Program (ITAP)
12601 Twinbrook Parkway
Rockville, MD 20852-1790 USA
Tel: (1 301) 816-8167
Fax: (1 301) 816-8374
Email: lk@usp.org
<http://www.uspdqi.org>

5. SECRETARIAT

WHO/HQ

Dr Mary Couper
Medical Officer
Quality and Safety Medicines
Essential Medicines and Pharmaceutical Policies
Health Systems and Services
World Health Organization
20 Avenue Appia CH-1211
Geneva 27, Switzerland
Tel.: (41) 22 791 34 12
Fax: (41) 22 791 21 11
Email: couperm@who.int

WHO/WPRO

Ms Mitsuko Imai
Technical Officer, Quality and Safety: Medicines
Essential Medicines and Pharmaceutical Policies
Health Systems and Services
World Health Organization
20 Avenue Appia CH-1211
Geneva 27, Switzerland
Tel: (41) 22 791 34 12
Fax: (41) 22 791 21 11
Email: imaim@who.int

Dr Kwang Soo Park
Technical Officer in Pharmaceuticals
World Health Organization
Regional Office for the Western Pacific
United Nations Avenue, P.O. Box 2932
Manila, Philippines
Tel.: (632) 5289846
Fax: (632) 5211036
E-mail: parkk@wpro.who.int

Mr Yoshihiko Sano
Technical Officer in Pharmaceuticals
World Health Organization
Regional Office for the Western Pacific
United Nations Avenue, Manila, Philippines
Tel.: (632) 5289846
Fax: (632) 5211036
E-mail: sanoy@wpro.who.int

Dr Lee Soo Jin
Medical Officer in Traditional Medicines
World Health Organization
Regional Office for the Western Pacific
United Nations Avenue, P.O. Box 2932
Manila, Philippines
Tel.: (632) 528 9844
Fax: (632) 521 1036
Email: leeso@wpro.who.int



Cambodia Action Plan

Task 1

1) Reporting:

- Promoting reporting by health professionals and the public
- Who should report
- What should be reported
- How the report form (Vigiflow) to report to UMC and filling out

- 2) Establishing an adverse monitoring reaction monitoring system (the practicalities)
- 3) Information on traditional medicines and reporting ADR from TM & vaccines
- 4) Understanding how UMC evaluates the data (Vigibase)
- 5) Principles of causality assessment case studies and classification of ADR (possible, certain, etc)
- 6) Diagnosis and management of ADR and mechanisms of ADR
- 7) Good communications practice in Pharmacovigilance
- 8) Signal Detection
- 9) Pharmacovigilance and Rational Use of Drugs
- 10) Pharmacovigilance involving consumer reporting

Task 2

(1) Establishing an adverse monitoring reaction monitoring system (the practicalities)

- *This topic of learning was very important in order to understand the necessity of an ADR monitoring program and how it can be implemented to improve Public Health. Without the knowledge of how to establish the program it is not possible to implement.*

(2) Principles of causality assessment: Case studies and classification of ADR (possible, certain, etc)

- *Very difficult and interesting subject, we in Cambodia need more training. The cases studies in particular helped us understand the topic better. This topic will be one of the principle responsibilities of the PV center staff. They must classify the ADR and investigate (with assistance from the technical committee).*

(3) Pharmacovigilance in vaccines

- *It's also very important subject where there have been cases of ADR that have happened in our country (wrong manner in providing injections, error, storage issues)*

Future Plan

- Finalize, print and distribute the ADR report form by early 2009
- Awareness campaign to advocate ADR program & report form (bulletin, poster, leaflet, mass media-radio and TV-Apsara and Beyon, website, SMS sent out and received by PV center)
- Annual or semi-annual meeting (work shop) to remind health professionals of the PV center, activities, reporting, discuss ADR that were submitted. Share counterfeit and substandard medicine results from the on-going medicine quality monitoring program of Cambodia.
- The PV staff will be sent to a fully-functioning pharmacovigilance center for hands-on training.

Future Plan Con't

- Information and education on ADR, counterfeit medicines and on Rational Drug Use (RUD) will be made available to general health professionals and to the public
- Educate physicians, dentists, pharmacists, drug sellers, other health professionals, consumers on PV, how to report, who to report to, what is and ADR.
- Train students (physicians, dentists, pharmacists, nurses and other health professionals) and communities.

Five PV Projects



Thank You!



The 5 PV Projects

No	PV Projects	Strategy	Goal	Resources	Timeline			
					Q1	Q2	Q3	Q4
1	Finalize, print and distribute the ADR report form by early 2009	Hire graphic designer	High quality attractive ADR report form	USP_DQI	x			
2	PV staff training at a fully -functioning pharmacovigilance center	Send staff to PV Center in Bangkok, Thailand	Hands on training for PV staff to learn how to operate the center on a day to day basis and how to communicate effectively with the reporters.	USP-DQI	x			
3	Increase Public Awareness (IEC-Training)	Produce and distribute the material on the PV program: Pilot outreach training to selected target audience and place (one specific hospital or many people from different hospitals, or pharmacists, etc.)	Make target audience aware of the advantages of the PV program and how it can benefit their hospital/clinic/pharmacy,etc. Receiving ADR reports.	USP-DQI/WHO/GF	x	x		
4	Involve the PV center in the Cross border study and Public Health Programs	Discuss the idea with the study team and educate them why it is important for them to report ADR to PV center for monitoring.	Ensure the quality and efficacy of artemisinin-combination antimalarials; to protect patients from ADR	USP-DQI/WHO/GF	x	x	x	x

5	Meeting/Workshop to review progress made with PV after one year	Invite the target audience to meet at the national level or the PV staff could go down to the field-depends on resources	To maintain enthusiasm of reporting ADR, good communication with the PV center and reporting the accomplishments of the past year. Rewarding those who have reported by acknowledging their efforts. Discussing what can be improved	USP- DQI/WHO/GF					x
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Photos from the course



Course participants Ms. Mam Boravann and Mr. Huot Sengthong from the Cambodian Department of Drugs and Food



Ms. Krech introducing herself at the opening of the course. Dr. Mary Couper, a pharmacovigilance expert from WHO headquarters is on the left.



Some of the course participants and facilitators hard at work.



At the opening ceremonies of the pharmacovigilance course, from left Dr. Mary Couper and Ms. Mitsuko Imai from WHO headquarters, Dr. Soe Nyunt-U, WHO Representative in the Philippines and Professor Leticia Barbara B. Gutierrez, Director of the Bureau of Food and Drugs in the Philippines.



Mr. Bruce Hugman, consultant to the Uppsala Monitoring Center and Ms. Lovisa Sallstedt, course lecturer from the Uppsala Monitoring Center.



Group photo