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

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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.

Recommended Citation

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

<table>
<thead>
<tr>
<th>ACRONYM</th>
<th>FULL FORM</th>
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<tbody>
<tr>
<td>ADR</td>
<td>Adverse Drug Reaction</td>
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<tr>
<td>BFAD</td>
<td>Bureau of Food and Drugs</td>
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<tr>
<td>CPC or “Center”</td>
<td>Cambodian Pharmacovigilance Center</td>
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<td>DDF</td>
<td>Department of Drugs and Food</td>
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<td>MOH</td>
<td>Ministry of Health</td>
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<td>PV</td>
<td>Pharmacovigilance</td>
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<td>UMC</td>
<td>Uppsala Monitoring Center</td>
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<td>USAID</td>
<td>United States Agency for International Development</td>
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<td>USP DQI</td>
<td>United States Pharmacopeia Drug Quality and Information</td>
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<td>WHO</td>
<td>World Health Organization</td>
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<td>WPRO</td>
<td>WHO Western Pacific Regional Office</td>
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</table>
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.
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
<table>
<thead>
<tr>
<th>Time</th>
<th>Event</th>
<th>Speaker/Institution</th>
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<tbody>
<tr>
<td>09.00 - 09.30</td>
<td>Opening ceremony</td>
<td>Prof. Leticia B. Gutierrez, MS</td>
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<td>Welcome remarks</td>
<td>Director, Bureau of Food and</td>
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<td>Drugs</td>
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<tr>
<td>09.30 - 10.15</td>
<td>Introduction of participants and faculty</td>
<td>Dr Soe Nyunt U WR Philippines</td>
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<td>10.15 - 10.30</td>
<td>Photo session</td>
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<tr>
<td>10.30 - 11.00</td>
<td>Coffee Break</td>
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<tr>
<td>11.00 - 11.15</td>
<td>Introduction of the course and objective</td>
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<tr>
<td>11.15 - 12.00</td>
<td>The need for Pharmacovigilance including key definitions</td>
<td>Dr Mary Couper WHO/HQ</td>
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<td>12.00 - 12.30</td>
<td>Discussion</td>
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<td>12.30 - 13.30</td>
<td>Lunch</td>
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<tr>
<td>13.30 - 13.45</td>
<td>Pharmacovigilance - regional perspective</td>
<td>Ms Nazarita T. Tacandong WPRO</td>
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<tr>
<td>13.45 - 14.15</td>
<td>Discussion</td>
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<td>14.15 - 15.00</td>
<td>Country presentation: Pharmacovigilance</td>
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<td>activities and experiences (Philippines, China)</td>
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<td>15.00 - 15.30</td>
<td>Coffee break</td>
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<tr>
<td>15.30 - 17.00</td>
<td>Country presentation: Pharmacovigilance</td>
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<td>activities and experiences (Fiji, Republic of Korea, Viet Nam, Mongolia)</td>
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<td>Welcome Dinner</td>
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**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
<table>
<thead>
<tr>
<th>Time</th>
<th>Session</th>
<th>Presenter</th>
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<tbody>
<tr>
<td>09.00 - 09.15</td>
<td>Feedback from the previous day</td>
<td>WHO/HQ</td>
</tr>
<tr>
<td>09.15 - 09.45</td>
<td>WHO Adverse Drug Reaction Monitoring Programme</td>
<td>Dr Mary Couper</td>
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<tr>
<td>09.45 – 10.00</td>
<td>Questions and discussion</td>
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<tr>
<td>10.00 - 10.45</td>
<td>Constructing an ADR reporting form-design issues</td>
<td>Mr Bruce Hugman</td>
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<tr>
<td>10.45 - 11.15</td>
<td>Coffee break</td>
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<td>11.15 - 12.30</td>
<td>Working groups (by country): Development of monitoring system and reporting forms: What needs to be done?</td>
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<td>12.30 - 13.30</td>
<td>Lunch</td>
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<tr>
<td>13.30 - 14.00</td>
<td>Terminologies for coding of adverse reactions and diseases</td>
<td>Ms Lovisa Sällstedt</td>
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<tr>
<td>14.00 - 15.00</td>
<td>Working groups (4 groups): Discussion on traditional medicines</td>
<td>Dr Cynthia Diza,</td>
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<td>15.00 - 15.30</td>
<td>Coffee break</td>
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<tr>
<td>15.30 - 16.00</td>
<td>Feedback from working groups</td>
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<tr>
<td>16.00 - 16.45</td>
<td>Literature sources for ADR information</td>
<td>Dr Klara Tisocki,</td>
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<td>17.00 -</td>
<td>Medico-legal aspects of pharmacovigilance (Optional)</td>
<td>Dr Kenneth Hartigan Go</td>
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<tr>
<td>Time</td>
<td>Activity</td>
<td>Speaker(s)</td>
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<tr>
<td>09.00 - 09.15</td>
<td>Feedback from the previous day</td>
<td>WHO/HQ</td>
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<tr>
<td>09.15 - 09.45</td>
<td>Principles of causality assessment</td>
<td>Dr Kenneth Hartigan Go</td>
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<tr>
<td>09.45 - 10.45</td>
<td>Working groups (4 groups): Case causality assessments</td>
<td>Dr Kenneth Hartigan Go</td>
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<tr>
<td>10.45 - 11.15</td>
<td>Coffee break</td>
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<tr>
<td>11.15 - 12.30</td>
<td>Case causality assessments: Discussion</td>
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<tr>
<td>12.30 - 13.30</td>
<td>Lunch</td>
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<tr>
<td>13.30 - 14.00</td>
<td>VigiFlow - Computer software for management of ADR case data</td>
<td>Ms Lovisa Sällstedt</td>
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<tr>
<td>14.00 - 15.00</td>
<td>Practical recording of case information - hands on practice</td>
<td>Ms Lovisa Sällstedt Dr Klara Tisocki</td>
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<tr>
<td>15.00 - 15.30</td>
<td>Coffee break</td>
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<tr>
<td>15.30 - 16.30</td>
<td>Practical recording of case information - hands on practice (cont.)</td>
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<tr>
<td>16.30 - 17.15</td>
<td>Diagnosis and management of ADR and mechanisms of ADR</td>
<td>Dr Kenneth Hartigan Go</td>
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<tr>
<td>17.15 - 17.30</td>
<td>Discussion</td>
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</tbody>
</table>
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

<table>
<thead>
<tr>
<th>Time</th>
<th>Event</th>
<th>Speaker(s)</th>
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<tr>
<td>09.00 - 09.15</td>
<td>Feedback from the previous day</td>
<td>WHO/HQ</td>
</tr>
<tr>
<td>09.15 - 10.00</td>
<td>Pharmacovigilance and rational use of drugs</td>
<td>Dr. Kenneth Hartigan Go</td>
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<tr>
<td>10.00 - 10.30</td>
<td>Discussion</td>
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<td>10.30 - 11.00</td>
<td>Coffee break</td>
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<tr>
<td>11.00 - 12.00</td>
<td>Role of Regulators in Pharmacovigilance including the translational process from signal identification to regulatory decision making</td>
<td>Dr. Cynthia Diza</td>
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<tr>
<td>12.00 - 12.30</td>
<td>Discussion</td>
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<tr>
<td>12.30 - 13.30</td>
<td>Lunch</td>
<td></td>
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<tr>
<td>13.30 - 14.00</td>
<td>Pharmacovigilance involving consumer reporting</td>
<td>Ms. Nazarita T. Tacandong</td>
</tr>
<tr>
<td>14.00 - 14.30</td>
<td>Discussion</td>
<td></td>
</tr>
<tr>
<td>14.30 - 15.00</td>
<td>Individual work: Development of country-specific action plan for Pharmacovigilance for the next year</td>
<td></td>
</tr>
<tr>
<td>15.00 - 15.30</td>
<td>Coffee break</td>
<td></td>
</tr>
<tr>
<td>15.30 - 16.30</td>
<td>Individual work: Development of country-specific action plan for Pharmacovigilance for the next year</td>
<td></td>
</tr>
<tr>
<td>16.30 – 17.00</td>
<td>Report back from some volunteers on their work</td>
<td></td>
</tr>
</tbody>
</table>
**Wednesday, September 10: Day 8**

<table>
<thead>
<tr>
<th>Time</th>
<th>Activity</th>
<th>Presenter</th>
</tr>
</thead>
<tbody>
<tr>
<td>09.00 - 09.15</td>
<td>Feedback from the previous day</td>
<td>WHO/HQ</td>
</tr>
<tr>
<td>09.15 - 10.15</td>
<td>Developing training material and in-country pool of speakers and trainers</td>
<td>Mr Bruce Hugman</td>
</tr>
<tr>
<td>10.15 - 11.00</td>
<td>Interacting with the media</td>
<td>Mr Bruce Hugman</td>
</tr>
<tr>
<td>11.00 - 11.30</td>
<td>Coffee break</td>
<td></td>
</tr>
<tr>
<td>11.30 - 12.15</td>
<td>Pharmacovigilance in Public Health Programmes</td>
<td>Dr Mary Couper</td>
</tr>
<tr>
<td>12.15 - 12.30</td>
<td>Discussion</td>
<td></td>
</tr>
<tr>
<td>12.30 - 13.30</td>
<td>Lunch</td>
<td></td>
</tr>
<tr>
<td>13.30 - 14.00</td>
<td>Patient safety - medication errors</td>
<td>Dr Kenneth Hartigan Go</td>
</tr>
<tr>
<td>14.00 - 14.20</td>
<td>Discussion</td>
<td></td>
</tr>
<tr>
<td>14.20 - 14.50</td>
<td>Quality assurance, WHO Prequalification Programme and safety problems related to drug counterfeiting</td>
<td>Dr Mary Couper</td>
</tr>
<tr>
<td>14.50 - 15.20</td>
<td>Coffee break</td>
<td></td>
</tr>
<tr>
<td>15.20 - 17.00</td>
<td>Individual work: Preparation for action plans</td>
<td></td>
</tr>
</tbody>
</table>
**Thursday, September 11: Day 9**

<table>
<thead>
<tr>
<th>Time</th>
<th>Activity</th>
</tr>
</thead>
<tbody>
<tr>
<td>09.00 - 09.15</td>
<td>Feedback from the previous day</td>
</tr>
<tr>
<td>09.15 - 12.30</td>
<td>Presentation of country action plans</td>
</tr>
<tr>
<td></td>
<td>(including Coffee break)</td>
</tr>
<tr>
<td>12.30 - 13.30</td>
<td>Lunch</td>
</tr>
<tr>
<td>13.30 - 14.00</td>
<td>Lessons and questions from the country action plans</td>
</tr>
<tr>
<td>14.00 - 14.30</td>
<td>Lessons and questions from the whole course</td>
</tr>
<tr>
<td>14.30 - 15.00</td>
<td>Networking, agreeing on a way forward and evaluation</td>
</tr>
<tr>
<td>15.00</td>
<td>Thanks and closure</td>
</tr>
</tbody>
</table>
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.
INTRODUCTORY TRAINING COURSE
ON PHARMACOVIGILANCE

Manila, Philippines
2-11 September 2008

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

ENGLISH ONLY

INFORMATION BULLETIN NO. 2
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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. The 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

<table>
<thead>
<tr>
<th>No</th>
<th>PV Projects</th>
<th>Strategy</th>
<th>Goal</th>
<th>Resources</th>
<th>Timeline</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Finalize, print and distribute the ADR report form by early 2009</td>
<td>Hire graphic designer</td>
<td>High quality attractive ADR report form</td>
<td>USP_DQI</td>
<td>Q1 x</td>
</tr>
<tr>
<td>2</td>
<td>PV staff training at a fully-functioning pharmacovigilance center</td>
<td>Send staff to PV Center in Bangkok, Thailand</td>
<td>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.</td>
<td>USP-DQI</td>
<td>Q2 x</td>
</tr>
<tr>
<td>3</td>
<td>Increase Public Awareness (IEC-Training)</td>
<td>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.)</td>
<td>Make target audience aware of the advantages of the PV program and how it can benefit their hospital/clinic/pharmacy, etc. Receiving ADR reports.</td>
<td>USP-DQI/WHO/GF</td>
<td>Q3 x</td>
</tr>
<tr>
<td>4</td>
<td>Involve the PV center in the Cross border study and Public Health Programs</td>
<td>Discuss the idea with the study team and educate them why it is important for them to report ADR to PV center for monitoring.</td>
<td>Ensure the quality and efficacy of artemisinin-combination antimalarials; to protect patients from ADR</td>
<td>USP-DQI/WHO/GF</td>
<td>Q4 x</td>
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<tr>
<td>5</td>
<td>Meeting/Workshop to review progress made with PV after one year</td>
<td>Invite the target audience to meet at the national level or the PV staff could go down to the field—depends on resources</td>
<td>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</td>
<td>USP-DQI/WHO/GF</td>
<td></td>
</tr>
</tbody>
</table>
Annex 5

Photos from the course

Course participants Ms. Mam Boravann and Mr. Huot Sengsthong 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.