First Annual Symposium on Pharmacovigilance

Post-Symposium Training Workshop on Pharmacovigilance For Pharmaceutical Associates

Date:	20 March 2010 (Saturday)
Time:	9:00 a.m. to 5:30 p.m.
Venue:	Lecture Hall, 3/F, Hong Kong Eye Hospital 147K Argyle Street, Kowloon Hong Kong
Organiser:	Centre for Food and Drug Safety Faculty of Medicine The Chinese University of Hong Kong
Co-organiser:	Department of Health, The Government of the Hong Kong SAR
Supported by:	Division of Clinical Pharmacology, Department of Medicine & Therapeutics The Chinese University of Hong Kong
	Department of Ophthalmology & Visual Sciences The Chinese University of Hong Kong
	School of Pharmacy, The Chinese University of Hong Kong
	International Society of Pharmacovigilance
	The Hong Kong Association of the Pharmaceutical Industry
	Hospital Authority of Hong Kong
Course Directors:	Professor Thomas Y.K. Chan, JP Director, Centre for Food and Drug Safety, Faculty of Medicine The Chinese University of Hong Kong
	Dr. Brian Edwards Director of Pharmacovigilance and Drug Safety NDA Regulatory Science Ltd., UK, and Director, International Society of Pharmacovigilance Ltd.

	Professor Kenneth Hartigan-Go Professor, Ateneo School of Medicine and Public Health, Philippines, and Former Vice-President and Chair of Education Training Program International Society of Pharmacovigilance
	Dr. John McEwen Adjunct Associate Professor Department of Pharmacy, University of Canberra, Australia
	Professor Nicholas Moore Professor of Clinical Pharmacology, and Head of Department of Pharmacology University of Bordeaux, France, and Former President of International Society of Pharmacovigilance
Guest Speakers:	Mr. Anthony W.K. Chan Chief Pharmacist Department of Health The Government of the Hong Kong SAR
	Professor Vincent H.L. Lee Director, School of Pharmacy The Chinese University of Hong Kong
Secretary of OC:	Dr. Raymond S.M. Wong Associate Consultant Prince of Wales Hospital Poison Treatment Centre, and Division of Clinical Pharmacology Department of Medicine and Therapeutics Prince of Wales Hospital, Hong Kong
Target Participants:	Executives, managers and regulatory associates of pharmaceutical firms operating in Hong Kong, including international companies, local agents and distributors and local companies
Course Objectives:	To promote awareness and emphasise the importance of pharmacovigilance in protecting the general public from ineffectiveness or harm of substandard medicines and from adverse reactions to medicines
	Participants will learn about basic concepts in pharmacovigilance, including the important and essential contributions pharmaceutical companies can make to the culture of awareness and the successful monitoring of the safety of medicines.

Participants will learn of the current post-marketing responsibilities that apply to pharmaceutical companies.

Participants will learn of new international developments for minimisation, communication and management of the risks of medicines and about the methodologies that are used to supplement spontaneous reporting.

Participants will also learn about important specific areas of importance to the pharmaceutical industry in ensuring safety products – building a safety culture, importance of quality management, training and teamwork and handling of product complaints.

Language: English

CPD Points: CME/CPE accreditation (pending for approval)

Certificate: All participants will receive a Certificate of Attendance.

Secretariat: Miss Elaine Li
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Programme 20 March 2010

8:30 – 9:00 REGISTRATION

9:00 – 11:15 Basic Concepts in Pharmacovigilance

Chair Persons:
Professor Thomas Y.K. Chan
Professor Vincent H.L. Lee

9:00 – 9:30 Classification, Risk Factors and Effects of Adverse Drug Reactions
Professor Kenneth Hartigan-Go

9:30 – 10:00 Roles and Aims of Pharmacovigilance
Dr. Brian Edwards

10:00 – 10:30 Sources and Proactive Methods for Collection of Drug Safety Data
Dr. John McEwen

10:30 – 11:00 Causality Assessment and Signal Detection in Pharmacovigilance
Professor Nicholas Moore

11:00 – 11:15 Open Forum for Questions and Answers

11:15 – 11:30 TEA BREAK

11:30 – 13:00 Regulatory Aspects of Pharmacovigilance

Chair Persons:
Dr. Brian Edwards
Professor Kenneth Hartigan-Go

11:30 – 11:45 Reporting and Monitoring Adverse Drug Reactions in Hong Kong
Mr. Anthony W.K. Chan

11:45 – 12:15 Regulatory Requirements for Monitoring of Safety of Medicines
Dr. John McEwen

12:15 – 12:45 Experience of the European Union Qualified Persons

Professor Nicholas Moore

12:45 – 13:00 Panel Discussion – Strategies to Enhance the Reporting and Monitoring of Adverse Drug Reactions

13:00 – 14:00 LUNCH

14:00 – 15:30 Risk Management in Practice

Chair Persons:

Professor Nicholas Moore

Professor Kenneth Hartigan-Go

14:00 – 14:30 Basic Risk Management Principles

Dr. Brian Edwards

14:30 – 15:00 Risk Management Programmes to Enhance Drug Safety

Dr. John McEwen

15:00 – 15:30 Communications Concerning Risks-Benefits Issues

Professor Vincent H.L. Lee

15:30 – 15:45 TEA BREAK

15:45 – 17:30 Practical Tips for Successful Pharmacovigilance Programmes

Chair Persons:

Professor Thomas Y.K. Chan

Dr. John McEwen

15:45 – 16:15 Building a Safety Culture

Professor Kenneth Hartigan-Go

16:15 – 16:45 Importance of Quality Management, Training and Teamwork

Professor Nicholas Moore

16:45 – 17:15 **Handling Product Complaints**
Dr. Brian Edwards

17:15 – 17:30 **Closing Remarks and the Way Forward**
Dr. John McEwen