# First Annual Symposium on Pharmacovigilance

# <u>Post-Symposium Training Workshop on Pharmacovigilance</u> <u>For Health Care Professionals</u>

Date: 19 March 2010 (Friday)

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

Supported by: Department of Health, The Government of the Hong Kong SAR

Hospital Authority of Hong Kong

International Society of Pharmacovigilance

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

Course Professor Thomas Y.K. Chan, JP

Directors: 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 Professor Vincent H.L. Lee

Speakers: Director, School of Pharmacy

The Chinese University of Hong Kong

**Professor Brian Tomlinson** 

Professor of Medicine and Therapeutics, and Head of Division of Clinical Pharmacology Department of Medicine and Therapeutics The Chinese University of Hong Kong

Secretary of

Dr. Raymond S.M. Wong

OC: 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:

Health care professionals involved in public and private clinical practice and in public and private community and hospital pharmacy, including those with involvements in public health, risk management, quality assurance, drug safety research and clinical trials, drugs and therapeutics committee members, drug selection committee members and academics involved in medical, dental, pharmacy and allied health education

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 the basic concepts in pharmacovigilance, including the important and essential contributions they as practitioners and educators can make to the successful monitoring of the safety of medicines.

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

Participants will also learn about important specific areas of current interests in the safe use of medicines – bioavailability and bioequivalence, monitoring the safety of medicines in children and pregnant women and legal aspects of pharmacovigilance.

Language: English

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

Certificate: All participants will receive a Certificate of Attendance.

Secretariat: Miss Elaine Li

c/o Department of Medicine and Therapeutics

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# Programme 19 March 2010

#### 8:30 – 9:00 REGISTRATION

### 9:00 – 11:15 Basic Concepts in Pharmacovigilance

#### **Chair Persons:**

Professor Thomas Y.K. Chan

**Professor Nicholas Moore** 

#### 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 Types of Post-Marketing 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 Setting Up and Running a Pharmacovigilance Programme

#### **Chair Persons:**

**Professor Brian Tomlinson** 

Dr. Brian Edwards

#### 11:30 – 12:00 Basic Steps in Setting up a National Programme

Professor Kenneth Hartigan-Go

#### 12:00 – 12:30 Strategies to Stimulate Voluntary Reporting

Dr. John McEwen

### 12:30 – 13:00 Education and Training of Pharmacovigilance Staff

**Professor Nicholas Moore** 

#### 13:00 – 14:00 LUNCH

# 14:00 – 15:30 Risk Management in Practice

#### **Chair Persons:**

**Professor Nicholas Moore** 

Professor Vincent H.L. Lee

## 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 Risk Communications Concerning Drug Safety Issues

Professor Vincent H.L. Lee

15:30 – 15:45 TEA BREAK

## 15:45 – 17:30 Current Topics in Drug Safety and Pharmacovigilance

#### **Chair Persons:**

Professor Vincent H.L. Lee

Dr. John McEwen

## 15:45 – 16:15 Interpretation of Bioavailability and Bioequivalence Studies

Professor Brian Tomlinson

#### 16:15 – 16:45 Pharmacovigilance in Children and Pregnant Women

**Professor Nicholas Moore** 

# 16:45 – 17:15 Legal Aspects of Pharmacovigilance

Professor Kenneth Hartigan-Go

## 17:15 – 17:30 Closing Remarks and the Way Forward

Dr. Brian Edwards