



INTERNATIONAL SOCIETY OF PHARMACOVIGILANCE

Basic Concepts in Pharmacovigilance **Training Course, 27th - 28th May 2010, Belgrade, Serbia**

(Faculty of Pharmacy, University of Belgrade - 450, Vojvode Stepe Street - 11221 Belgrade)

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This is a comprehensive two-day learning program and will consist of a mix of training in fundamental principles, processes and policies, complemented by presentations from PV experts from the South East Europe region. The program aims to introduce important basic concepts of pharmacovigilance and drug safety to interested healthcare professionals, academia and industry representatives.

The programme will be held in the historic city of Belgrade, one of the oldest in Europe.

<p>Day 1: Thursday 27 May 2010 The Building Blocks – Principles of Pharmacovigilance</p>
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Chairpersons: Viola Macolić-Šarinić & Deirdre McCarthy

8.30 to 9.00 am Registration

9.00 – 9.10 am
Introduction- Course objectives
Deirdre McCarthy, ISoP

9.10 – 9.50 am
Principles and Mechanisms of adverse drug reactions
Important lessons
Igor Francetić, Division of Clinical pharmacology, University Hospital Rebro, Zagreb, Croatia

9.50 – 10.20 am
Individual case safety reports: building blocks of the system
Brian Edwards, ISoP

10.20 to 11 am
Spontaneous reporting: biases, benefits and limits
Part I : Eugène van Puijenbroek, ISoP

11.00 – 11.30 am

Coffee-break

11.30 – 12 pm

Spontaneous reporting: biases, benefits and limits

Part II : Eugène van Puijenbroek, ISoP

12 to 1.00 pm

Causality assessment – working with individual and aggregate cases

Ugo Moretti, ISoP

Lunch : 1.00 – 2.00 pm

Chairperson: Deirdre McCarthy

2.00 – 2.45 pm

Counterfeit medicines

Luis Alesso, ISoP

2.45 – 3.30 pm

Signal detection

Marie Lindquist, ISoP

3.30 – 4.00 pm

Coffee-break

4.00 – 4.45 pm

Principles of Risk Management

Yola Moride, ISoP

4.45 – 5.30 pm

Training and education in Pharmacovigilance – short presentations and panel discussion

Igor Francetić, Division of Clinical pharmacology, University Hospital Rebro, Zagreb, Croatia

Milos P. Stojiljković, Pfizer H,C.P Corporation, Belgrade, Serbia
some ISoP Exec Comm Members: Hervé Le Louet

Close of Day 1

Day 2: Friday 28 May 2010
Policies and processes – Regulatory pillars of pharmacovigilance

Chairpersons: Natália Kocánková and Deirdre McCarthy

Welcome to Day 2

9.00 – 9.45 am

MAH's Pharmacovigilance System: regulatory expectations

Marija Petronijević, Medicines and Medical Devices Agency of Serbia (ALIMS)

Viola Macolić-Šarinić, Croatian Agency for Medicinal Products and Medical Devices

Reponses

Natália Kocánková, PharmaSwiss, Prague, Czech Republic

9.45 – 10.30 am

International Guidances relevant to Pharmacovigilance – ICH, CIOMS

Deirdre McCarthy, ISoP

10.30 to 11.00

Directives and Regulations that underpin PV in the EU

Elliot Brown, ISoP

11.00 – 11.30 am

Coffee-break

11.30 – 12.15 pm

Medication errors

Milos P. Stojiljković, Pfizer H.C.P Corporation, Belgrade, Serbia

12.15 – 1 pm

Safety Considerations for the Generics industry

Lucie Švédová, Zentiva Group, a.s, Prague, Czech Republic

1 to 2 pm

Lunch

2.00 – 2.45 pm

PSURs – current requirements and future directions

Natália Kocánková, PharmaSwiss, Prague, Czech Republic

2.45 – 3.30

Vaccino-vigilance

Alexander Dodoo, ISoP

3.30 to 4.00

Coffee-break

4.00 to 4.45

Introduction to Pharmacoepidemiology

Elliot Brown, ISoP

4.45 – 5.30 pm

Local topic – e.g. challenges with preparing for EU membership

Ivan Kovačević, Medicines and Medical Devices Agency of Serbia (ALIMS)

Viola Macolić-Šarinić, Croatian Agency for Medicinal Products and Medical Devices

Closing remarks

The International Society of Pharmacovigilance gratefully acknowledges assistance from ALIMS (Medicines and Medical Devices Agency of Serbia) and the Faculty of Pharmacy in Belgrade as partners co-organizers