



INTERNATIONAL SOCIETY OF PHARMACOVIGILANCE

## **Basic Concepts in Pharmacovigilance** **Training Course, 27<sup>th</sup> - 28<sup>th</sup> 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><b>Day 1: Thursday 27 May 2010</b> <b>The Building Blocks – Principles of Pharmacovigilance</b></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 in Spontaneous Reports**

Richard Hill, Uppsala Monitoring Centre, Sweden

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

**Vaccino-vigilance in practice**

Dragana Dimitrijevic, Institute of Public Health of Serbia

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***

Gordana Pejovic, 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*