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.

### Day 1: Thursday 27 May 2010

**The Building Blocks – Principles of Pharmacovigilance**

*Chairpersons: Viola Macolić-Šarinić & Deirdre McCarthy*

<table>
<thead>
<tr>
<th>Time</th>
<th>Session</th>
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<tr>
<td>8.30 to 9.00 am</td>
<td>Registration</td>
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<tr>
<td>9.00 – 9.10 am</td>
<td><em>Introduction</em> - Course objectives</td>
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<td></td>
<td>Deirdre McCarthy, ISoP</td>
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<tr>
<td>9.10 – 9.50 am</td>
<td><em>Principles and Mechanisms of adverse drug reactions</em> Important lessons</td>
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<td>Igor Francetić, Division of Clinical pharmacology, University Hospital Rebro, Zagreb, Croatia</td>
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<td>9.50 – 10.20 am</td>
<td><em>Individual case safety reports: building blocks of the system</em></td>
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<td>Brian Edwards, ISoP</td>
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<td>10.20 to 11 am</td>
<td><em>Spontaneous reporting: biases, benefits and limits</em></td>
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<td>Part I : Eugène van Puijtenbroek, ISoP</td>
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<td>11.00 – 11.30 am</td>
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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 Pejović, 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