



INTERNATIONAL SOCIETY OF PHARMACOVIGILANCE

## **Reporting, Causality assessment, Risk factors & Mechanisms of ADRs**

**Training Course, 26<sup>th</sup> - 27<sup>th</sup> May 2011, Minsk, Belarus**

Belarusian Medical Academy of Post-Graduate Education  
3, Brovki str., build.3, 220013, Minsk, Republic of Belarus

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This basic two day-seminar will be dedicated to introduce HCP to the concepts of pharmacovigilance and drug safety, and to understand better the basics of pharmacovigilance, centred on the individual case reports (the patient), the identification of drug-related risks, and their management at the patient level.

<p><b>Day 1: Thursday 26<sup>th</sup> May 2011</b> <b>ADR evaluation and ADR reporting</b></p>
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*Chairpersons: Hervé Le Louet & Svetlana Setkina*

8.30 to 9.00 am      Registration

**9.00 – 9.15 am**  
**Introduction- Course objectives**  
Hervé Le Louet, ISoP

**9.15 – 9.55 am**  
**Epidemiology and identification of adverse drug reactions**  
Alexander Dodoo, ISoP

**9.55 – 10.40 am**  
**Adverse drug reactions: mechanism and classification**  
Raquel Herrera Comoglio, School of Medicine, Córdoba National University, Argentina

**10.40 – 11.00 am**  
**Adverse drug reactions terminology**  
Alexander Dodoo, ISoP

11.00 – 11.30 am  
Coffee-break

**11.30 – 12.15**  
**Causality assessment in individual case**  
Raquel Herrera Comoglio, School of Medicine, Córdoba National University, Argentina

**12.15 to 1.00 pm**

**Causality assessment in case series**

Richard Hill, Uppsala Monitoring Centre, Sweden

Lunch: 1.00 – 2.00 pm

**2.00 – 2.40 pm**

**Causality assessment in hepatotoxicity and dermatotoxicity**

Hervé Le Louet, ISoP

**2.40 – 3.00 pm**

**Causality assessment in gastrotoxicity**

Larisa Gavrilenko, Clinical Pharmacology, Belorussian State Medicinal University, Minsk, Belarus

**3.00 – 3.20 pm**

**Causality assessment in nephrotoxicity**

Marina Sachek, Republican Scientific and Practical Center for Medical Technologies, Informatization, Administration and Management of Health, Minsk, Belarus

**3.20 – 3.40 pm**

**Causality assessment in immunotoxicity**

Eduard Docenko, Medical Faculty for International Students of the Belorussian State Medicinal University, Minsk, Belarus

3.40 – 4.00 pm

Coffee-break

**4.00 – 4.35 pm**

**Reporting recommendations (international, EU and national)**

Ulrich Hagemann, ISoP

**4.35 – 5.00 pm**

**International Reporting – The WHO programme**

Marie Lindquist, ISoP

**5.00 – 5.20 pm**

**Averse drug reactions reporting form: essential information**

Alexander Doodoo, ISoP

**5.20 – 5.30 pm**

**Closing remarks**

**Day 2: Friday 27<sup>th</sup> May 2011**  
**ADR monitoring and risk minimization activity**

*Chairpersons: Hervé Le Louet & Svetlana Setkina*

**Welcome to Day 2**

**8.45 – 9.25 am**

**Drug therapy in various pharmacokinetics-modifying disorders**

Andryan Najaran, Republican Clinical Pharmacological Laboratory of the Centre for Examinations and Tests in Health Service, Minsk, Belarus

**9.25 – 9.55 am**

**Early signs of drug toxicity**

Eugène van Puijenbroek, ISoP

**9.55 - 10.25 am**

**Age factors in drug therapy**

Eugène van Puijenbroek, ISoP

**10.25 – 11.00 am**

**Clinically significant drug interactions**

Richard Hill, Uppsala Monitoring Centre, Sweden

11.00 – 11.30 am

Coffee-break

**11.30 – 12.00**

**Pharmacogenetic approach in understanding and preventing adverse drug reactions**

Raquel Herrera Comoglio, School of Medicine, Córdoba National University, Argentina

**12.00 – 12.40**

**Approaches to the individual benefit-risk assessment in high-risk groups**

Dzmitry Razdzestvensky, Republican Clinical Pharmacological Laboratory of the Center for Examinations and Tests in Health Service, Minsk, Belarus

**12.40 – 1.00 pm**

**Medication errors: definition and measures to avoid**

Ulrich Hagemann, ISoP

1.00 to 2.00 pm

Lunch

**2.00 – 2.30pm**

**Generics, similars and bioequivalence**

Luis Alesso, ISoP

**2.30 – 3.00**

**How to deal with lack of effectiveness' pharmacovigilance reports**

Luis Alesso, ISoP

3.00 to 3.30 pm

Coffee-break

**3.30 to 4.15**

**Challenges in establishing a local pharmacovigilance**

Svetlana Setkina, Center for Examinations and Testing in Health Service of the Republic of Belarus

**4.15 – 4.30 pm**

**Closing remarks**

*The International Society of Pharmacovigilance gratefully acknowledges assistance from the Center for Examinations and Testing in Health Service of the Republic of Belarus as partner co-organizer*