INTERNATIONAL SOCIETY OF PHARMACOVIGILANCE

Proactive Pharmacovigilance, Risk Management and Pharmacovigilance in the Era of Personalised Medicine

Training course

3rd to 4th April 2014, Zagreb, Croatia

Hotel Dubrovnik Zagreb

Ljudevita Gaja 1, Zagreb 10 000 - www.hotel.dubrovnik.hr

(meeting room: Ban Jelačić)

Programme

Day 1: Thursday, 3rd April 2014

Chairpersons: *Hervé Le Louet, Viola Macolić Šarinić*

8.30 to 9.00 am Registration

9.00 – 9.15 Introduction - Course objectives
Hervé Le Louet (ISoP) and Viola Macolić Šarinić (HALMED)

9.15 – 10.30 am
Medical assessment of adverse drug reactions (ADRs) – Part 1
How to apply principles of risk minimisation and how does it impact the design of pharmacovigilance processes?

Medical assessment of drug induced hepatotoxicity
Hervé Le Louet (ISoP)

Medical assessment of drug induced rhabdomyolysis and metabolic disorders
Marco Tuccori (ISoP)

Medical assessment of ADRs with late onset
Suzana Mimica Matanović (Clinical Hospital Centre Osijek)

10.30 – 11.00 am
Coffee-break

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Proactive pharmacovigilance: evaluating and minimising risk and medication errors through RMPs, PASS and other activities in the post-authorisation phase

11.00 – 11.45 am
Risk minimisation measures in Risk Management Plans (RMP) – Basics around education and communication
Ian Boyd (ISoP), Katarina Gvozdanović (HALMED)

11.45 – 12.30 pm
Risk minimisation measures and CIOMS IX: selection of tools and effectiveness indicators
Yola Moride (ISoP)

12.30 – 1.00 pm
Open discussion on practical implications, Questions & Answers
Moderator: Deirdre McCarthy (Quintiles, Ireland)

Lunch
1.00 – 2.00 pm

2.00 – 2.45 pm
Post-authorisation safety studies (PASS): evaluation of PASS, or how to recommend the most appropriate PASS design for selected medicinal products
Yola Moride (ISoP)

2.45 – 3.30 pm
Sensible interpretation of literature for the new format of PSUR and DSUR for assessing balance of effectiveness and harm – best practice in literature assessment as part in everyday practice in pharmacovigilance
Brian Edwards (ISoP)

3.30 – 4.00 pm
Coffee-break

4.00 – 4.30 pm
Medication errors: definition, reporting and assessment
Ian Wong (ISoP), Ulrich Hagemann (ISoP)

4.30 – 5.30 pm
South East European Chapter – SEEC - meeting

- EMA requirements, difficulties and challenges in pharmacovigilance: experiences of SEE EU-member states and their relevance and importance for non-EU-member states, *Viola Macolić Šarinić (HALMED)*
- Registries and Databases in Clinical Research - available sources and opportunities for collaboration, *Katarina Ilic (School of Pharmacy, Belgrade, Serbia)*

Closing remarks on Day 1

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Proactive Pharmacovigilance, Risk Management and Pharmacovigilance in the Era of Personalised Medicine

Day 2: Friday, 4th April 2014

Chairpersons: *Katarina Ilic, Ulrich Hagemann*

Welcome to day 2

9.00 – 10.30 am
Medical assessment of adverse drug reactions (ADRs) – part 2
How to apply principles of risk minimisation and how does it impact the design of pharmacovigilance processes?
Moderators: Marco Tuccori (ISoP), Igor Francetić (University of Zagreb)

Medical assessment of drug induced serious skin reactions (SJS, TEN etc.)
Vera Vlahović Palčevski (University Hospital Rijeka)

Medical assessment of drug induced renal impairment
Igor Francetić (University of Zagreb)

Medical assessment of neuropsychiatric ADRs
Marco Tuccori (ISoP)

10.30 – 11.00 am
Coffee-break

11.00 – 12.00 am
The era of personalised medicine: the safety of the individual patient and how will pharmacovigilance respond to new drug developments
Moderator: *Hervé Le Louet (ISoP)*

Pharmacogenomics and safety of drugs – basics and how the data should be used in everyday practice
Staffan Hägg (Linköping University, Sweden)

Questions & Answers

12.00 – 1.00 pm
Establishing a benefit-risk balance in orphan drugs
Ian Boyd (ISoP)

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Lunch
1.00 – 2.00 pm

2.00 – 2.30 pm
The role of patient groups in pharmacovigilance and the new PV legislation
Ulrich Hagemann (ISoP)

2.30 – 3.00 pm
Forensic pharmacovigilance
Alex Dodoo (ISoP), Kenneth Hartigan-Go (ISoP)

3.00 – 3.30 pm
Impact of needs of individual patients in regulatory environment of safety of medicines
Adriana Andrić (HALMED)

3.30 – 4.00 pm
Coffee-break

4.00 – 4.30 pm
Open discussion on practical implications, Questions & Answers
Moderator: Deirdre McCarthy (Quintiles, Ireland)

4.30 – 5.00 pm
Closing remarks on Day 2

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