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

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Recent changes in the pharmacovigilance legislation in various regions in the world have introduced mandatory elements to pharmacovigilance practice, some of which are new, while other existing elements have been developed further. In this advanced course, two important elements will be elucidated, with a focus on proactive risk management and the role of rapidly evolving pharmacogenomics in pharmacovigilance. The training course will offer an opportunity for open discussion and thoughts on how to fill gaps in good pharmacovigilance practice.

This course is targeted at regulators, scientists and industry, with a strong focus on practical examples and real-life solutions.

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
Andrew Bate (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?

Moderator: Andrew Bate (ISoP)

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 Osilek)

10.30 – 11.00 am
Coffee-break

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 (Faculty of Pharmacy, Belgrade, Serbia)*

Closing remarks on Day 1

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 Francetic (University of Zagreb)

Medical assessment of drug induced serious skin reactions (SJS, TEN etc.)

Vera Vlahović Palčevski (Clinical Hospital Centre 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

The era of personalised medicine: the safety of the individual patient and how will pharmacovigilance respond to new drug developments

11.00 – 12.00 am
Pharmacogenomics and safety of drugs – basics and how should the data be used in everyday practice
Moderator: *Hervé Le Louet (ISoP)*

(e.g. pharmacogenomics in skin or metabolic ADRs, role of gene mutations: HLA, CYP450, transporter proteins)
Staffan Hägg (Linköping University, Sweden)

Q&A

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

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

3.30 – 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