Developing risk management capability: Maximising opportunities from global pharmacovigilance experience to ensure the safe and appropriate use of medicinal products

Training course – preliminary programme

25th-26th May, 2017, Bangkok, Thailand

Meeting venue: Mandarin Hotel – Managed by Centre Point

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www.isoponline.org or administration@isoponline.org

This two day-course leverages the Pharmacovigilance expertise of ISoP and has been designed to help interdisciplinary groups to learn and work together in contributing to patient safety when medicines are used.

At the end of the course, the participants are expected to understand current local and international legislative frameworks, and how they are expected to develop over the coming years. Participants will gain an understanding of considerations when developing strategies to increase volumes of ADRs, and how they might be handled through different signal management systems.

The second part of the course will focus in on risk management and minimization approaches. Participants will gain hand on experience of development of Risk Management Plans (RMPs) and the conduct of Benefit-Risk assessments.

Day one will take the form of lectures with opportunity for discussion through questions and answers and panel discussion, while day two will focus on hands-on interactive tasks.
Day 1: Thursday 25th May 2017

08:30 – 09:00 Registration

09:00 – 09:10 Introduction to the course
Ian Wong (ISoP EC member) and Puree Anantachoti (Faculty of Pharmaceutical Sciences, Chulalongkorn University) (TBC)

Session 1: Current landscape and regulatory frameworks
Moderators: Ian Wong (ISoP EC member) and Rungpetch Sakulbumrungsil (Dean of the Faculty of Pharmaceutical Sciences, Chulalongkorn University)

09:10 – 09:45 Globalisation of pharmacovigilance: current setting and predicted evolution
Speaker: Sten Olsson (ISoP President)

09:45 – 10:25 ASEAN progress and Thailand perspective
Speaker: Wanchai Sattayawuthipong (Secretary General, Thai FDA)

10:25 – 10:55 Coffee break

10:55 – 11:30 Advances in international legislation: what’s coming next?
Speaker: Ian Wong (ISoP EC member)

11:30 – 12:00 Panel discussion

12:00 – 13:00 Lunch break

Session 2: ADR Collection and signal detection
Moderators: Vittaya Kulsomboon (Faculty of Pharmaceutical Sciences, Chulalongkorn University) and Yaowares Oppamayun (Head of Health Product Vigilance Center, Thai FDA)

13:00 – 13:35 Signal detection and statistical approaches
Speaker: Phil Tregunno (ISoP Board member)

13:35 – 14:10 Data sources for pharmacovigilance
Speaker: Kenneth Hartigan-Go (Asian Institute of Management, Philippines)

14:10 – 14:45 Raising awareness levels: findings from the EU SCOPE Joint Action Project
Speaker: Phil Tregunno (ISoP Board member)

14:45 – 15:15 Panel discussion

15:15 – 15:45 Coffee break
Session 3: Risk Management and early access schemes
Moderators: Ian Wong (ISoP EC member) and Tarnkamol Chanprapaph (Chief of Pre-Marketing Control Division, Bureau of Drug Control, Thai FDA)

15:45 – 16:15 Risk management planning: the theory
Speaker: Kenneth Hartigan-Go (Asian Institute of Management, Philippines)

16:15 – 16:45 Early access to medicines schemes
Speaker: Sten Olsson (ISoP President)

16:45 – 17:15 Communicating Benefit and Risk: a patient centred approach
Speaker: Paula Alvarado (Head of Global Communications, Uppsala Monitoring Centre)

17:15 – 17:30 Panel discussion
Day 2 (Group 1): Friday 26th May 2017

Session 5: Risk Management Plan Preparation  
Moderators: Jean-Christophe Delumeau (ISoP EC member), Chen Wen Wen (Taiwan Drug Relief Foundation), Andreas Wortmann (Novartis Pharmaceuticals Australia)

09:00 – 9:45 Development of a Risk Management Plan (RMP)  
Speakers: Jean-Christophe Delumeau, Chen Wen Wen, Andreas Wortmann

09:45 – 10:30 Key considerations and common pitfalls  
Speakers: Jean-Christophe Delumeau, Chen Wen Wen, Andreas Wortmann

10:30 – 11:00 Coffee-break

11:00 – 12:00 Workshop: RMPs  
Facilitators: Jean-Christophe Delumeau, Chen Wen Wen, Andreas Wortmann

12:00 – 12:45 Lunch break

Session 6: Benefit-Risk Assessment  
Moderators: Mira Harrison-Woolrych (ISoP EC member) and Wimon Suwankesawong (Expert in Drug Standard, Thai FDA)

12:45 – 13:30 Key considerations in benefit-risk assessment  
Speaker: (TBC)

13:30 – 14:15 Workshop: Benefit risk assessment  
Facilitators: Jan Petracek (ISoP Board member) & TBC

14:15 – 14:45 Coffee break

14:45 – 15:45 Workshop: Benefit risk assessment continued  
Facilitators: Jan Petracek (ISoP Board member) & TBC

Session 7 (Groups 1 and 2): Panel discussion  
Moderators: Sten Olsson (ISoP President) and Puree Anantachoti (Faculty of Pharmaceutical Sciences, Chulalongkorn University)

15:45 – 16:15 Issues arising from workshop sessions

16:15 – 16:30 Closing remarks

16:30 Close
Day 2 (Group 2): Friday 26th May 2017

Session 5: Benefit-Risk Assessment
Moderators: Mira Harrison-Woolrych (ISoP EC member), and Wimon Suwankesawong (Expert in Drug Standard, Thai FDA)

09:00 – 09:45  Key considerations in benefit-risk assessment
   Speaker: TBC

09:45 – 10:30  Workshop: Benefit risk assessment
   Facilitators: Jan Petracek (ISoP Board member) & TBC

10:30 – 11:00  Coffee break

11:00 – 12:00  Workshop: Benefit risk assessment continued
   Facilitators: Jan Petracek (ISoP Board member) & TBC

12:00 – 12:45  Lunch break

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