Pharmacovigilance Workshop – Risk Management; Electronic reporting; XEVMPD updates

Zagreb, 10 – 11 February 2015

Held at Double Tree by Hilton Zagreb

Ulica grada Vukovara 269A, 10000, Zagreb, Croatia

**Faculty**

John J. Borg, PhD, Medicines Authority, Malta

Calin LUNGU, MD, DDCS S.A., Luxemburg

**Agenda**

**Day one**

8:30 – 9:00 Welcome and registration

9:00 – 9:15 Introduction and overview of the agenda (C. Lungu)

9:15 – 10:00 What’s new in ICSRs and the importance of capturing the best information for causality assessment (John J. Borg)

10:00 – 10:40 Coffee break

10:40 – 11:10 Signal detection in EudraVigilance (C. Lungu)

11:10 – 11:40 Update on the XEVMPD requirements and ongoing activities of data maintenance (C. Lungu) – Part I

11:40 – 12:15 Data quality of ICSRs (C. Lungu)

12:15 – 12:30 Questions and answers

12:30 – 13:30 Lunch break

13:30 – 15:00 Explaining the Risk Management Plan and building the safety specification for abridged applications (John J. Borg)

15:00 – 15:30 Coffee break

15:30 – 16:15 Conditions of marketing authorizations and implementing additional risk minimization methods what do regulators want when stakeholders interact with them? (John J. Borg)

16:15 – 17:00 Electronic reporting in the EEA member states (C. Lungu)

17:00 End of Day 1

**Day two**

9:00 – 10:00 Update on the XEVMPD requirements and ongoing activities of data maintenance (C. Lungu) – Part II

10:00 – 10:30 What the regulator looks at during authorizations of the summary of pharmacovigilance system (John J. Borg)

10:30 – 11:10 Coffee break

11:10 – 11:40 Preparing audits and inspections using EudraVigilance (C. Lungu)

11:40 – 12:15 Preparing for pharmacovigilance audits (a regulators’ preparedness) (John J. Borg)

The Regulator’s Audit report to the Commission as per Directive 2010/84/EC (John J. Borg)

12:15 – 12:30 Questions and answers

12:30 – 13:30 Lunch break

13:30 – 14:15 GVP Module I – Quality Systems (C. Lungu)

14:15 – 15:00 Pharmacovigilance systems for MAHs, WHDs, Parallel Importers and 126a Authorization Holders (John J. Borg)

15:00 – 15:30 Coffee break

15:30 – 16:15 GVP Module III – IV – PV audits and inspections (C. Lungu)

16:15 – 17:00 Conditions of marketing authorizations and implementing risk minimization methods risk based inspections carried out by the regulators (John J. Borg)

17:00 End of Day 2