Pharmacovigilance Workshop
Bucharest, 9-10 September 2014
Novotel Hotel, Calea Victoriei 37B, sector 1

Risk Management; Electronic reporting; XEVMPD updates

Faculty
John J. Borg, PhD, Medicines Authority, Malta
Calin LUNGU, MD, DDCS S.A., Luxemburg

Agenda
Day one, September 9th

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 – 16:45	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, September 10th

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

REGISTRATION FORM
Pharmacovigilance Workshop - Risk Management, Electronic reporting, XEVMPD updates

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CANCELATION POLICY
Cancellations less than two weeks prior to the event lead to a 100 % penalty of the workshop fee.
Cancellations prior to 10th August 2014 will results in a 50% penalty of the workshop fee.

PLEASE REGISTER BEFORE AUGUST 10, 2014 TO ENSURE THE WORKSHOP IS NOT CANCELLED.