



Monday, 23 June 2014

Time	Topic	Speaker
9.00–9.10 (10')	Welcome address	Andreas Pott (EMA) Sasa Jacovic (ALIMS)
9.10-9.25 (15')	Welcome note	Zlatibor Loncar (Ministry of Health) Michael Devenport (EU Del.)
9.25-9.40 (15')	Introduction to ALIMS responsibilities on Pharmacovigilance, Clinical Trials and relations with PO/HCP	Pavle Zelic (ALIMS)
9.40-10.50	Session 1: Clinical Trials	Chair: Thania-Aileen Spathopoulou, EMA Co-chair: Zorica Vucinic, ALIMS
9.40–10.20 (40')	Oversight of Clinical Trials in Europe <ul style="list-style-type: none"> Member State perspective EMA perspective 	Gunnar Danielsson (MPA) Thania-Aileen Spathopoulou (EMA)
10.20–10.40 (20')	Norms and guidelines related to ethical Clinical Trials: a patient's perspective	Nikos Dedes (EATG)
10.40–10.50	Discussion	
10.50–11.10	Coffee break	
11.10-13.10	Session 2: Pharmacovigilance	Chair: June Raine, MHRA Co-chair: Marko Eric, ALIMS
11.10-12.10 (1h)	Pharmacovigilance in the EU	Andrej Segec (EMA)
12.10–12.30 (20')	<ul style="list-style-type: none"> The role of PRAC in Pharmacovigilance decisions Pharmacovigilance requirements for Member States Pre-accession challenges 	June Raine (PRAC)
12.30-13.00 (30')	Safety communication and its role in risk minimisation	Juan Garcia Burgos (EMA) June Raine (MHRA)
13.00-13.10	Discussion	
13.10–14.30	Lunch	

Time	Topic	Speaker
14.30-16.00	Session 3: Developing meaningful collaboration	Chair: Isabelle Moulon, EMA Co-chair: Vesela Radonjic, ALIMS
14.30-15.10 (40')	Cooperation between EMA and Patients Organizations & Healthcare Professionals Organizations	Isabelle Moulon (EMA) David H.U.Haerry (EATG) Gonzalo Calvo Rojas (EACPT)
15.10-15.30 (20')	Good example of cooperation of a Member State	Dany Nguyen-Bonnet (ANSM)
15.30-15.50 (20')	Shortages of medicines: common position	Francois Houyez (EURORDIS)
15.50-16.00	Discussion	
16.00-16.20	Coffee break	
16.20-17.30	Session 4: Information to the public by regulatory authorities	Chair: Juan Garcia Burgos, EMA Co-chair: Tatjana Stojadinovic, ALIMS
16.20-17.20 (1h)	Information to patients and healthcare professionals on: <ul style="list-style-type: none"> • EMA website • ALIMS website 	Juan Garcia Burgos (EMA) Igor Vanevski (ALIMS)
17.20-17.30	Discussion	
17.30-17.50	Conclusions	
18.00-19.30	Cocktail Reception	