EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

26 January 2015
EMA/654663/2014

Agenda – Industry Stakeholder platform - Operation of EU pharmacovigilance legislation

12 January 2015, 09:30-13:45, Meeting room 02-F

Chair: Peter Arlett, Head of Pharmacovigilance

Item	Preliminary draft agenda	Time
1.	**Welcome and matters arising** – *Peter Arlett, Head of Pharmacovigilance, EMA* – *June M Raine, PRAC Chair*	09:30
2.	**Risk Management Planning follow up to September meeting** • RMPs (follow up from previous meeting) – *Luis Prieto, EMA* • RMPs for Nationally authorised products – *Kora Doorduyn - van der Stoep, CMDh* • Industry feedback • Discussion and next steps	09:40
3.	**Post-Authorisation Safety Studies (PASS), Update from the regulators** • Experience to date – *Almath Spooner, PRAC Vice Chair* • Encouraging joint studies – *Irene Rager, Head of Evaluation Procedures E, EMA* • Role of ENCePP – *Henry Fitt, Best Evidence Development Head, EMA* • Transparency	10:30
	Coffee Break	**11:15**
3.	**Post-Authorisation Safety Studies (PASS), Update from the regulators (2nd part)** • Scientific Advice – *Peter Arlett, Head of Pharmacovigilance, EMA* – *Jane Moseley, Scientific Advice, Product Development Scientific Support, EMA* – *Corinne De Vries, Risk Management Specialist, EMA*	11:30

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	• Registries initiative – *Xavier Kurz, Head of Monitoring and Incidence Management Service, Pharmacovigilance Department, EMA* • Industry feedback • Discussion and next steps	
4.	**Post-Authorisation Efficacy Studies (PAES)** • Update on the development of scientific and regulatory guidance – *Jane Moseley EMA* – *Tomas Salmonson, CHMP*	12:15
5.	**Q & A on Off-Label Use** • **Update on progress from EudraVigilance Expert Group** – *Anja van Haren, MBA and co-chair EV-EWG **TC*** – *Sabine Brosch, EMA and co-chair EV-EWG*	12:45
6.	**Update on development of pharmacovigilance information systems** • **PSUR repository, Article 57, EudraVigilance, Literature Monitoring, Fees: contact via the QPPV** – *Peter Arlett, Head of Pharmacovigilance, EMA* – *Irene Rager, Head of Evaluation Procedures E, EMA*	13:00
7.	**General Discussion and agreement on next steps** – *June M Raine, PRAC Chair* – *Peter Arlett, Head of Pharmacovigilance, EMA*	13:15
8.	**Close of meeting**	13:45