EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

12 June 2015
EMA/402820/2015

Agenda - Fourth industry stakeholder platform - operation of EU pharmacovigilance legislation

12 June 2015, 09:30-13:00, Meeting room 3A

Item	Preliminary draft agenda	Time
1.	**Welcome and matters arising** – *Peter Arlett, Head of Pharmacovigilance, EMA* – *June Raine, PRAC Chair, MHRA*	09:30-09:45
2.	**Update on the pharmacovigilance systems and services** – *Peter Arlett, EMA* ° Article 57 ° PSUR repository ° EudraVigilance ° Literature monitoring ° Fees • Industry feedback – *EGA, EUCOPE* • Discussion and next steps (All) – *Sabine Brosch, Irene Rager, Michael Lenihan, Nick Halsey, Paolo Alcini, EMA* – *Anne Ambrose, MHRA* – *Anja van Haren, MEB* **TC**	09:45-10:15
3.	**Impact of pharmacovigilance system** – *Almath Spooner, IMB* – *Anja van Haren, MEB* **TC** – *Peter Arlett, Jacoline Bouvy, Marie-Helene Pinheiro, Xavier Kurz, EMA* • Industry feedback on ongoing initiatives – *Industry Speaker, Telma Costa, on behalf of EuropharmSMC* • Discussion and next steps	10:15-10:45
4.	**Risk Management Plan (RMP) activities updates** • Good PharmacoVigilance Practices (GVP) Module V – *Corinne de Vries, EMA* – *Sabine Straus, MEB* • RMP template update	10:45-11:45

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	– *Caroline Voltz, EMA* • CMDh subgroup on RMP, for same active substances - CMDh RMP Webpage ➲Cover Note ➲List of safety concerns per approved Risk Management Plan (RMP) of active substances per product RMP Info Day programme – *Anne Ambrose, MHRA* – *Kora Doorduyn - van der Stoep, MEB* **TC** • Industry feedback – *Industry Speaker, Wendy Booth, on behalf of AESGP, EFPIA, EGA* – *Industry Speaker, Stefan Kaehler, on behalf of EGA, EUCOPE* • Discussion and next steps	
5.	**Patient Support Programmes: Industry observations** – *Industry Speaker, Sue Rees, EFPIA*	11:45-12:15
6.	**Good pharmacovigilance Practices (GVP) – Module P-II Biological medicinal products** – *Xavier Kurz, EMA* – *Sabine Straus, MEB* • Discussion and next steps	12:15-13:00
7.	**Close of meeting**	13:00