16 March 2015
EMA/56551/2015

Agenda – 3rd industry stakeholder platform - operation of EU pharmacovigilance legislation

13 March 2015, 09:30-13:45, Meeting room 03-E

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 pharmacovigilance programme** – *Peter Arlett, Head of Pharmacovigilance, EMA* • Article 57 • EudraVigilance • Literature monitoring – *Sabine Brosch, Monitoring & Incident Management, Pharmacovigilance, EMA* • Fees – *Michael Lenihan, Head of Finance and Budget, EMA* • Industry feedback & Discussion – Discussion and next steps *(all, with Nick Halsey, Data Collection & Management, Procedure Management & Business Support, EMA and Ilaria Del Seppia, Data Collection & Management, Procedure Management & Business Support, EMA)*	09:45-10:45
3.	**PSUR repository & EURD list update** • Industry feedback – PSUR and PSUSA – *David Wilson, on behalf of EFPIA, AESGP, EBE, EGA, EUCOPE, Vaccines Europe* • Update from Regulators – EURD list revision - *Menno van der Elst, PRAC & MEB* – Assessment feedback - *Margarida Guimarães, PRAC & INFARMED* – PSUR repository - *Irene Rager, Head of Evaluation Procedures E, EMA* • Discussion and next steps	10:45-11:45

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	Coffee Break	
4.	**Risk management planning** • Brief update on revision of guidance and on pilot of new template (note substantive discussion at next platform) – *Michael Berntgen, Head of Scientific and Regulatory Management, EMA* • Addendum to GVP XVI on educational materials – *Margarida Guimarães, PRAC & INFARMED*	12:00-12:15
5.	**Referrals** • Industry feedback – *Emmanuelle Pines, on behalf of AESGP, EFPIA, EGA, EUCOPE* – *Stefan Kaehler, on behalf of EUCOPE* • Update from Regulators – *Tania Teixeira, Head of Evaluation Procedures F, Procedure Management & Business Support, EMA* – *Almath Spooner, PRAC Vice Chair and HPRA* • Discussion and next steps	12:15-13:15
6.	**Scientific Advice for PASS** • Industry Feedback – *Sarah Montagne, on behalf of EFPIA, AESGP, EBE, EGA, EUCOPE, EuropaBio, Vaccines Europe* • Update from EMA – *Jane Moseley, Scientific Advice, EMA* • Discussion with industry on success factors for launching a scientific advice service for PASS	13:15-13:30
7.	**General discussion and agreement on next steps** – *June Raine, PRAC Chair, MHRA* – *Peter Arlett, Head of Pharmacovigilance, EMA*	13:30-13:45
8.	**Close of meeting**	13:45

Proposed dates for next meetings:

- Friday 12 June 2015 (09:30 – 13:30)
- Tuesday 15 September 2015 (09:00-12:30)