EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

11 August 2015
EMA/549299/2015

Agenda – 5th industry stakeholder platform - operation of EU pharmacovigilance legislation

15 September 2015, 09:30-12:30, Meeting room 2A

Item	Preliminary draft agenda	Time
1.	**Welcome and matters arising** – *Peter Arlett, Head of Pharmacovigilance, EMA* – *June Raine, PRAC Chair, MHRA* ○ Including – GVP update – Medication errors – Q&A off label use – Revised procedures – new MAA, renewals – Scientific Advice for observational studies	09:30-09:45
2.	**Medical Literature Monitoring** • Industry feedback – *Mara Ernst, AESPG,* – *John Barber, EGA (EFPIA, EUCOPE)* • Update and current status – *Tom Paternoster-Howe, EMA* • Discussion and next steps – All	09:45-10:35
3.	**Pharmacovigilance systems and services** • Presentation of highlights – *Peter Arlett, EMA* • Questions and discussion (All) – *Paola Samassa, Ana Cochino, Paolo Alcini, EMA*	10:35-11:00
4.	**PSUR** • Industry feedback – *Julia Appelskog, EGA,* – *Liz Swain, EFPIA* • *Discussion* – *Irene Rager (EMA)* – *Margarida Guimarães (INFARMED), Menno van der Elst (MEB)*	11:00-11:50

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5.	**Risk Management summary publication** • Industry feedback – *Mark Caldwell (EFPIA)* • Review of experience – *Juan Garcia, Caroline Voltz (EMA)* – *Kora Doorduyn - van der Stoep (MEB)* • Discussion – *All*	11:50-12:30
6.	**Close of meeting**	12:30

Participants List

Chair: Peter Arlett, Head of Pharmacovigilance Department

- **PRAC**
  - June Raine, PRAC **Chair** and MHRA
  - Almath Spooner, PRAC Vice-chair and HPRA
  - Sabine Straus, MEB
  - Margarida Guimarães, INFARMED
  - Menno van der Elst, MEB

- **CMDh**
  - Kora Doorduyn - van der Stoep, MEB
  - Virginie Bacquet, ANSM

- **EMA**
  - Paolo Alcini, Head of Data Standardisation and Analytics Department
  - Michael Berntgen, Head of Scientific and Regulatory Management
  - Maria Boulos, Human Medicines Research and Development Support Division, Regulatory Affairs
  - Christelle Bouygues, Human Medicines Research and Development Support Division, Regulatory Affairs
  - Melanie Carr, Head of Corporate Stakeholders Department
  - Emil Cochino, Scientific & Regulatory Management Department
  - Georgy Genov, Head of Signal Management, Pharmacovigilance Department
  - Evdokia Korakianiti, Head of Procedure Management Department

- Xavier Kurz, Head of Monitoring & Incident Management, Pharmacovigilance Department
- Marie-Helene Pinheiro, Industry Stakeholders Liaison, Corporate Stakeholders Department
- Irene Rager, Head of Evaluation Procedures E, Procedure Management & Business Support
- Juan Garcia, Head of Medical and Health Information, Communication Department
- Tom Paternoster, Data Standardisation and Analytics
- Agnieszka Szmigiel, Pharmacovigilance Department
- Paola Samassa, Head of Accounts, Finance and Budget Department
- Caroline Voltz, Scientific and Regulatory Management
- Ana Cochino, Data Standardisation and Analytics Department

Industry Stakeholder Organisations

- **AESGP**
  - Mara Ernst, Manager Pharmacovigilance , BAH
  - Lucy Pavesi, GSSA Physician & European QP for Pharmacovigilance, Procter & Gamble
  - Emmanuelle Pinès, Manager Vigilance Division , Pierre Fabre
  - Miranda Moussa, AESGP
  - Martin Terberger, AESGP
  - Sophie Fairweather, PAGB

- **EBE**
  - Zoe Conway, Roche
  - Sue Rees, Amgen
  - Katrina Skeer, J&J
  - Betina Østergaard Eriksen, Novo Nordisk
  - Françoise Sillan, Sanofi

- **EFPIA**
  - Sini Eskola, Director, Regulatory Affairs
  - Liz Swain, GSK
  - Judith Weigel, VFA

- Mark Caldwell, J&J
- Val Simmons, Lilly

- **EGA**
  - Katarina Nedog, Safety and Regulatory Manager, EGA
  - Inge Boegh Jansen, Actavis
  - John Barber, UK association, Dr.Reddy's
  - Julia Appelskog, SE association, Bluefish Pharmaceuticals Group

- **EUCOPE**
  - Stefan Kaehler, QPPV, Celgene Europe Ltd
  - Boris Thurisch, BPI
  - Irfan Ahmad, Norgine
  - Alexander Natz, EUCOPE
  - Philip Weatherill, EMIG

- **EuropaBio**
  - Merete Schmiegelow, Senior Director EU Regulatory Advocacy, Novo Nordisk
  - Margaret Walters, Deputy EU Qualified Person for Pharmacovigilance, MSD
  - Emma Du Four, Senior Director Regulatory Policy, AbbVie
  - Riccardo Mezzasalma, Healthcare Biotechnology Manager, EuropaBio
  - Geneviève Le Visage, Head EU Regulatory Intelligence & Policy, Novartis

- **Europharm SMC**
  - Telma Costa, Head of WP RA, EuropharmSMC

- **Vaccines Europe**
  - Barbara De Bernardi, Deputy EUQPPV, Head of European Safety Office, Pfizer Worldwide Safety and Regulatory
  - Kathy Williams, Lead Pharmacovigilance and Regulatory Excellence, AstraZeneca

- Katharina Hartmann, PharmD Head Vaccine Pharmacovigilance, Takeda Vaccine Business Unit
- Jacquelyn Awigena-Cook, Associate Director, Head of Pv Policy Group Global Medical Safety, JnJ