3 November 2015
EMA/727477/2015

Agenda – 6th industry stakeholder platform - operation of EU pharmacovigilance legislation

18 December 2015, 10:00-13:30, Meeting room 2F

Item	Preliminary draft agenda	Time
1.	**Welcome and matters arising** – *Peter Arlett, Head of Pharmacovigilance, EMA* – *June Raine, PRAC Chair, MHRA* – *Peter Bachmann, CMDh Chair, BfArM* ○ Including – Update on Pharmacovigilance systems and services – Scientific advice for PASS – Update on GVP – National Contraindications for NAPs	10:00-10:20
2.	**Roadmap to PSURs** • Follow-up from September meeting – *Irene Rager, EMA* – *Kora Doorduyn - van der Stoep, (MEB), Menno van der Elst, (MEB), Anne Ambrose (MHRA), Margarida Guimarães (INFARMED)* • Discussion – *All*	10:20-11:05
3.	**Medication errors** • EMA update: Highlights and discussion on implementation – *Thomas Goedecke*	11:05-11:25
4.	**GVP Module VIII – PASS** • Industry feedback – *Guy Demol, EFPIA (EGA, AESPG, EBE, EUCOPE, EuropaBIO, VE)* • Discussion – *Xavier Kurz, Giampiero Mazzaglia, Irene Rager, EMA* – *Almath Spooner (HPRA), Sabine Straus (MEB)*	11:25-12:10
	Coffee break	12:10-12:30

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5.	**EudraVigilance: preparing for business change** • Update on project delivery and planning industry training – *Francois Domergue* • Preparing for industry access to Eudravigilance – *Georgy Genov* • *Discussion with industry on needs* – *David Lewis, EFPIA (AESGP, EBE, EGA, EUCOPE, EuropaBIO, Europharm SMC, VE)*	12:30-13:15
6.	**Topics for next meeting** • Discussion – *All*	13:15-13:30
7.	**Close of meeting**	13:30

Participants List

Chair: Peter Arlett, Head of Pharmacovigilance Department, EMA

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

- **CMDh**
  - Peter Bachmann, CMDh Chair, BfArM
  - Kora Doorduyn - van der Stoep, MEB
  - Anne Ambrose, MHRA
  - Virginie Bacquet, ANSM

- **Pharmacovigilance Implementation Group**
  - Anja van Haren, MEB

- **EMA**
  - Irene Rager, Head of Evaluation Procedures E, Procedure Management & Business Support
  - Thomas Goedecke, Monitoring & Incident Management, Pharmacovigilance Department
  - Xavier Kurz, Head of Monitoring & Incident Management, Pharmacovigilance Department
  - Giampiero Mazzaglia, Scientific & Regulatory Management Department
  - Georgy Genov, Head of Signal Management, Pharmacovigilance Department
  - Francois Domergue, Data Standardisation and Analytics
  - Agnieszka Szmigiel, Signal Management, Pharmacovigilance Department
  - Marie-Helene Pinheiro, Industry Stakeholders Liaison, Corporate Stakeholders 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
  - Evdokia Korakianiti, Head of Procedure Management Department
  - Ioana Ratescu, Legal Department
  - Ilaria Del Seppia, Data Standardisation and Analytics Department
  - Jane Moseley, Scientific Advice, Product Development Scientific Support

- **MHRA**
  - Joanna Harper, Inspectorate Strategy & Innovation Unit, MHRA

Industry Stakeholder Organisations

- **AESGP**
  - Sarah Widdecombe, Head of Policy and PV Affairs, Johnson & Johnson
  - Mara Ernst, Manager Pharmacovigilance, BAH
  - Sophie Fairweather, Regulatory Executive, PAGB
  - Lucy Pavesi, GSSA Physician & European QP for Pharmacovigilance, Procter & Gamble
  - Julia Saemann, Deputy QPPV, Merz Pharmaceuticals
  - Miranda Moussa, AESGP
  - Yasmine Boulkroun, Head of Corporate Vigilances Division, Pierre Fabre

- **EBE**
  - Betina Østergaard Eriksen, Novo Nordisk
  - Zoe Conway, Roche
  - Katrina Skeer, J&J
  - Francoise Sillan, Sanofi
  - Sally Du Toit, Clovis Oncology
- **EFPIA**
  - Sini Eskola, Director, Regulatory Affairs
  - Sue Rees, Amgen,
  - Vicki Edwards, Abbvie
  - David Lewis, Novartis
  - Val Simmons, Lilly
  - Guy Demol, MSD
  - Liz Swain
- **EGA**
  - Katarina Nedog, Safety and Regulatory Manager, EGA **TC**
  - Inge Boegh Jansen, Allergan
  - John Barber, BGMA, Dr.Reddy's
  - Charlotte Barrett, TEVA
  - Julia Appelskog, SE association, BlueFishPharma
  - Katja Pecjak, Billev Pharma
- **EUCOPE**
  - Stefan Kaehler, Senior Director Global Risk Management Standards & Special Advisor to the EEA QPPV, Celgene Europe Ltd
  - Boris Thurisch, Head of Pharmacovigilance , German Association of Pharmaceutical Industry (BPI)
  - Aparna Desai, Sr. Manager UK Pharmacovigilance & Deputy DSO, Alexion
  - Geneviève Le Visage, Head EU Regulatory Intelligence & Policy, Alcon
- **EuropaBIO**

- Christiane Abouzeid, Head of Regulatory Affairs, BioIndustry Association (BIA)
- 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
- Pedro Franco, Director Europe for Global Regulatory & Scientific Policy, Merck KGaA,

- **Vaccines Europe**
  - Maria Grazia Zurlo, Head Safety Strategy, Policy and Standards, EUQPPV, Pfizer
  - 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
  - Corinne Jouquelet-Royer, VP, Head Global Pharmacovigilance, Sanofi Pasteur