1 June 2017
EMA/286244/2017
Inspections, Human Medicines Pharmacovigilance and Committees Division

Agenda – 11th industry stakeholder platform – operation of EU pharmacovigilance

2 June 2017, 10:00-13:30, Meeting room 3E

Co-Chairs: June Raine and Georgy Genov

Item	Preliminary draft agenda	Time
1.	**Welcome and matters arising** Including • Update on EudraVigilance Auditable Requirements *- Georgy Genov, Acting Head of Pharmacovigilance and Epidemiology, EMA* • Update on PRAC Work Plan and Impact Strategy • SCOPE update – *June Raine, PRAC Chair, MHRA* • CMDh news *- Peter Bachmann, CMDh chair, BfArM* • United Kingdom's withdrawal from the European Union preparedness activities *- Marie-Helene Pinheiro, EMA*	10:00-10:30

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2.	**Good pharmacovigilance practices for the EU** • GVPs status and updates (GVP Module VI – ADR, pharmacovigilance guideline for paediatric medicines) – *Priya Bahri, EMA* – *Roberto De Lisa, EMA* • GVP V and RMP template Revision 2 – update on implementation *- Emil Cochin, EMA* *- Nuria Semis-Costa, EMA* • Assessment of RMPs for MPR/DCP procedures *- Michael Forstner (Medicines for Europe, EFPIA, AESPG)* *- Kora Doorduyn van der Stoep, MEB* • Discussion *- All*	10:30-11:15
	Coffee break	11:15-11:30
3.	**Signal Management process** • Presentation from Industry – *Sue Rees (EFPIA, AESGP, Medicines for Europe, EuropaBio, Vaccines Europe, EUCOPE, EBE)* – *Nicole Lang* • EV tools and opportunities – *Rodrigo Postigo, EMA* – *Sabine Straus, MEB* – *Julie Durand, EMA* • Discussion with Industry – All	11:30-13:15
4.	**Conclusion and next steps**	13:15-13:30
5.	**Close of meeting**	13:30

Participants List

- **PRAC**
  - June Raine, PRAC Chair
  - Almath Spooner, PRAC vice-Chair
  - Sabine Straus, MEB

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

- **European Commission**
  - Helen Lee **TC**
  - Aleksandra Opalska **TC**
  - Florian Schmidt **TC**

- **Pharmacovigilance Inspector**
  - Rory Littlebury

- **European Medicines Agency**
  - Georgy Genov, Acting Head of Pharmacovigilance & Epidemiology Department, EMA
  - Xavier Kurz, Head of Surveillance and Epidemiology, Pharmacovigilance & Epidemiology Department
  - Agnieszka Szmigiel, Signal and Incident Management, Pharmacovigilance & Epidemiology Department
  - Andrej Segec, Signal and Incident Management, Pharmacovigilance & Epidemiology Department
  - Marie-Helene Pinheiro, Industry Stakeholders Liaison, Corporate Stakeholders Department
  - Maria Boulos, Human Medicines Research and Development Support Division, Regulatory Affairs
  - Sabine Brosch, Business Lead EudraVigilance and International Standardisation in Pharmacovigilance, Pharmacovigilance and Epidemiology Department

- Ioana Ratescu, Legal Administrator, Legal Department
- Thomas Goedecke, Principal Scientific Administrator, Surveillance and Epidemiology, Pharmacovigilance & Epidemiology Department
- Priya Bahri, Principal Scientific Administrator, Surveillance and Epidemiology, Pharmacovigilance & Epidemiology Department
- Rodrigo Postigo, Signal and Incident Management, Pharmacovigilance & Epidemiology Department
- Julie Durand, Signal and Incident Management, Pharmacovigilance & Epidemiology Department
- Roberto De Lisa, Paediatric Medicines, Product Development Scientific Support department
- Emil Cochino, Anti-infectives and Vaccines, Scientific & Regulatory Management Department
- Nuria Semis-Costa, Rheumatology, Respiratory, Gastroenterology an Immunology

Industry Stakeholder Organisations

- **AESGP**
  - Wendy Booth, VP and Head, Consumer Health Safety, Global Clinical Safety & Pharmacovigilance, GSK
  - Lucy Pavesi – Director and Deputy QPPV, Consumer Health Division, Johnson & Johnson
  - Amel Benkritly – Head of QPPVT office, Global PV Policy, Sanofi
  - Yasmine Boulkroun, Head of Corporate Vigilances Division, Pierre Fabre
  - Christelle Anquez-Traxler, Regulatory and Scientific Affairs Manager, AESGP **TC**
  - James Bell, Vigilance Compliance Manager, RB
  - Léonie Zimmermann, Head of Pharmacovigilance, BAH

- **EBE**
  - Zoe Conway, Deputy QPPV, Roche
  - Suzy Verheyen, Senior Director, Head of Regulatory Affairs for Established Products, Janssen

- **EFPIA**
  - Dave Lewis, Global Head of Pharmacovigilance, Novartis
  - Sue Rees, EU QPPV, Executive Director, Global Patient Safety, Amgen
  - Vicki Edwards, Head of Affiliate Safety & Compliance Excellence, QPPV, Abbvie
  - Guy Demol, AVP, EU Qualified Person For Risk Management & Pharmacovigilance, MSD
  - Michael Richardson, VP International GPV&E and EU QPPV, BMS

- Sini Eskola, Director Regulatory Affairs, EFPIA

- **EUCOPE**
  - John Poustie, Medical Director for Pharmacovigilance, Norgine
  - Natascha Rippel, Head of Pharmacovigilance Department/Deputy to the QPPV, Medac
  - Maren von Fritschen, Regulator Director, EUCOPE

- **EuropaBIO**
  - Margaret Walters, Deputy EU Qualified Person for Pharmacovigilance, MSD
  - Esteban Herrero-Martinez, Director, Regulatory Policy & Intelligence, Abbvie
  - Pedro Franco, Director Europe for Global Regulatory & Scientific Policy, Merck Group
  - Johan Hellmér, Global Drug Safety, Head EMEA, Shire
  - Francoise Dumas-Silan, Qualified Person for Pharmacovigilance, Pfizer
  - Achint Kumar, Qualified Person for Pharmacovigilance, Biogen

- **Medicines for Europe**
  - Nicole Lange, TEVA
  - Michael Forstner, Samsung Bioepis
  - Arn Tellmann, Fresenius-Kabi
  - Doris Hacke, Fresenius-Kabi
  - Katarina Nedog, Medicines for Europe

- **Vaccines Europe**
  - Anna Rozmyslowicz, Deputy QPPV, R&D Pharmacovigilance, EU, Seqirus
  - Maria Wishart, Deputy QPVV, AstraZeneca
  - Kah-Lay Goh, Physician