10 November 2017
EMA/496794/2018
Pharmacovigilance and Epidemiology Department

Agenda – 14th Industry Stakeholder Platform – Operation of EU Pharmacovigilance

28 September 2018, 10:00-17:00, Meeting room 3E

Co-Chairs: Sabine Straus and Peter Arlett

Item	Agenda	Time
1.	**Welcome and matters arising**	10:00-10:10
2.	**United Kingdom's withdrawal from the European Union: update on the implications** • General update – *Marie-Helene Pinheiro*, *EMA* • EMA business continuity planning – implications for pharmacovigilance – *Marie-Helene Pinheiro*, *Claudia Galeazzo, EMA*	10:10-10:30
3.	**Feedback on EudraVigilance new functionalities** • Update from EMA – *Anja van Haren, MEB* – *Sabine Brosch, Francois Domergue, Steven Le Meur, Oana Agheorghiesei, Christoph Buchhierl, EMA* • Industry experience – *David Lewis, Margaret Walters, EFPIA* • Discussion	10:30-11:20
	Coffee break	11:20-11:45
4.	**Industry experience with new RMP guidance and template** – *Magnus Ysander, EFPIA*	11:45-12:15

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	– *Wendy Booth, AESGP* • Discussion – *Emil Cochino, EMA*	
5.	**Update on the pilot of MAH Eudravigilance Signal detection** • Industry plans for metrics – *David Lewis, EFPIA* • Experience of Eudravigilance signal detection – *Alexandra Szabó, Medicines for Europe* – *David Lewis, EFPIA* • Next steps – *Sabine Straus, MEB* – *Georgy Genov, Julie Durand, EMA*	12:15-13:00
	Lunch break	13:00-14:00
6.	**Issues and update from CMDh** – *Kora Doorduyn van der Stoep, MEB* – *Maria Luisa Casini, AIFA* – *Laura Oliveira Santamaria, AEMPS* • Discussion – *All*	14:00-14:20
7.	**Industry perspectives on emerging scientific and technological approaches to collecting and managing pharmacovigilance data** • Industry views – *David Lewis, EFPIA* – *Peter Verdru, EFPIA* – *Sue Rees, EFPIA* • Discussion – *All*	14:20-16:15
8.	**Conclusion and next steps**	16:15-16:30
9.	**Close of meeting**	16:30

Participants List

Chairs: Sabine Straus, Chair of PRAC

Peter Arlett, Head of Pharmacovigilance & Epidemiology Department, EMA

- **CMDh**
  - Laura Oliveira Santamaria, Chair of CMDh ***TC***
  - Kora Doorduyn van der Stoep, MEB
  - Maria Luisa Casini, AIFA ***TC***

- **European Medicines Agency**
  - Georgy Genov, Head of Signal & Incident Management, Pharmacovigilance & Epidemiology Department
  - Agnieszka Szmigiel, Signal and Incident Management, Pharmacovigilance & Epidemiology Department
  - Marie-Helene Pinheiro, Industry Stakeholders Liaison, Corporate Stakeholders Department
  - Claudia Galeazzo, Head of Product and Application Business Support
  - Francois Domergue, Data Standardisation and Analytics
  - Sabine Brosch, Business Lead EudraVigilance and International Standardisation in Pharmacovigilance, Pharmacovigilance and Epidemiology Department
  - Paolo Alcini, Head of Data Standardisation and Analytics
  - Christoph Buchhierl, Head of IT Support
  - Steven Le Meur, Data Standardisation and Analytics
  - Oana Agheorghiesei, Data and Information Lifecycle Management
  - Emil Cochino, Anti-infectives and Vaccines, Scientific & Regulatory Management Department
  - Julie Durand, Signal and Incident Management, Pharmacovigilance & Epidemiology Department
  - Priya Bahri, Principal Scientific Administrator, Surveillance and Epidemiology, Pharmacovigilance & Epidemiology Department

Industry Stakeholder Organisations

- **AESGP**
  - Yasmine Boulkroun, Pierre Fabre
  - Wendy Booth, GSK

- Leonie Zimmermann, BAH
- Lucy Pavesi, Johnson and Johnson
- Barbara Di Bernardi, Pfeizer
- Ross Lewin, Ebeling Assoc
- Katarine Mason, PAGB ***TC***

- **EBE**
  - Suzy Verheyen, Senior Director for the Established Products Team, Janssen & Janssen
  - Leanne Angst-Wu, Roche Products Limited

- **EFPIA**
  - Sini Eskola, Director Regulatory, Drug Development and Manufacturing, EFPIA
  - David Lewis, Novartis
  - Margaret Walters, MSD
  - Magnus Ysander, Astrazeneca
  - Peter Verdru, UCB
  - Sue Rees, Amgen
  - Vicki Edwards, Abbvie
  - Guy Demol, Merck
  - Eric Teo, Sanofi
  - Valerie, Elizabeth Simmons, Lilly
  - Françoise Dumas-Sillan, Pfeizer
  - Giovanna Rizzetto, Senior Manager, Regulatory, Drug Development and Manufacturing, EFPIA

- **EUCOPE**
  - Stefan Kaehler, Celgene Europe Ltd
  - Liliana Hansen, Zealand Pharma
  - Boris Thurisch, BPI

- **EuropaBIO**
  - Julia Appelskog, Merck
  - Joanne Webbe, Gilead Sciences

- **Medicines for Europe**
  - Alexandra Szabo, Gedeon Richter
  - Jana Brajdih Cendak, Billev Pharma East
  - Eleni, Makrodouli, Pharos Group
  - Susana Almeida, Medicines for Europe

- **Vaccines Europe**
  - Subhash Mistry, Manager Application & Development Support, GCSP Case Management Support, GSK
  - Olaf Zent, Head of Global Vaccine Safety Evaluation, Vaccines Business Unit, Takeda