15 September 2016
EMA/565316/2016
Inspections, Human Medicines Pharmacovigilance and Committees Division

Agenda – 9th industry stakeholder platform – operation of EU pharmacovigilance

21 September 2016, 14:00-18:00, Meeting room 3E

Item	Preliminary draft agenda	Time
1.	**Welcome and matters arising** – *Peter Arlett, Head of Pharmacovigilance and Epidemiology, EMA* – *June Raine, PRAC Chair, MHRA* ○ *Including* *- Medical Literature Monitoring workshop feedback* *- ISO IDMP workshop feedback* *- European Commission report on 3 years Pharmacovigilance legislation*	14:00-14:30
2.	**GVP VI ADR Reporting** • Initial perspective from industry – *Industry representatives* • Discussion – *Anja van Haren, MEB **TC*** – *Gilles Touraille, EMA*	14:30-15:00
3.	**GVP IX on signal management** • Initial perspective from industry – *Industry representatives*	15:00-15:30

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	• Discussion – *Sabine Straus, MEB* – *Julie Durand, EMA*	
4.	**GVP PII Biologics** • Reflections from industry – *Industry representatives* • Discussion – *Sabine Straus, MEB, Phil Bryan, MHRA* – *Xavier Kurz, EMA* – *All*	15:30-16:10
	Coffee break	16:10-16:40
5.	**Public hearings** • Presentation on public hearings dry-run and next steps – *June Raine, PRAC Chair* – *Nathalie Bere, EMA* • *Discussion* – *All*	16:40-17:10
6.	**Pharmacovigilance Impact** • Update and collaboration with industry – *Thomas Goedecke, EMA* • *Discussion* – *All*	17:10-17:40
9.	**Conclusion and next steps**	17:40-18:00
10.	**Close of meeting**	18:00

Participants List

Chair: Peter Arlett, Head of Pharmacovigilance & Epidemiology Department, EMA

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

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

- **EudraVigilance Expert Working Group**
  - Anja van Haren, MEB **TC**

- **European Commission**
  - Helen Lee

- **Medicines & Healthcare products Regulatory Agency**
  - Phil Bryan

- **European Medicines Agency**
  - Xavier Kurz, Head of Surveillance and Epidemiology, Pharmacovigilance & Epidemiology Department
  - Georgy Genov, Head of Signal and Incident Management, Pharmacovigilance & Epidemiology Department
  - Agnieszka Szmigiel, Signal and Incident Management, Pharmacovigilance & Epidemiology Department
  - Marie-Helene Pinheiro, Industry Stakeholders Liaison, Corporate Stakeholders Department
  - Jordi Llinares Garcia, Head of Scientific and Regulatory Management

- Maria Boulos, Human Medicines Research and Development Support Division, Regulatory Affairs
- Tom Paternoster-Howe, Data Standardisation and Analytics
- Sabine Brosch, Business Lead EudraVigilance and International Standardisation in Pharmacovigilance, Pharmacovigilance and Epidemiology Department
- Ioana Ratescu, Legal Administrator, Legal Department
- Gilles Touraille, Scientific Administrator, Signal and Incident Management, Pharmacovigilance & Epidemiology Department
- Julie Durand, Scientific Administrator, Signal and Incident Management, Pharmacovigilance & Epidemiology Department
- Nathalie Bere, Patients Liaison officer, Public Engagement Department
- Thomas Goedecke, Principal Scientific Administrator, Surveillance and Epidemiology, Pharmacovigilance & Epidemiology Department

Industry Stakeholder Organisations

- **AESGP**
  - Yasmine Boulkroun, Head of Corporate Vigilances Division, Pierre Fabre
  - Elmar Kroth, Director, German Medicines Manufacturers Association (BAH)
  - Miranda Moussa, Manager for Safety Issues and Medical Devices, AESGP
  - Lucy Pavesi, EU QPPV, Procter & Gamble
  - Maria Spyt, EU QPPV, Johnson & Johnson

- **EBE**
  - Zoe Conway, Deputy QPPV, Roche Products Limited
  - Katrina Skeer, Director EMEA Regulatory Compliance & Business Support, Janssen-Cilag
  - Catherine Akers, Regulatory Affairs Senior Manager, Amgen
  - Veronique Debaut, Regulatory Affairs Manager, EBE

- **EFPIA**
  - Vicki Edwards, Abbvie
  - Guy Demol, MSD
  - David Lewis, Novartis
  - Sue Rees, Amgen

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- Yogen Logesvaran, Jansen/J&J
- Sarah Montagne, Bayer
- Pari Nasseri-Sina, GSK
- Jean Kilgour-Christie, Takeda

- **EUCOPE**
  - Stefan Kaehler, Senior Director, Global Risk Management Standards & Special Advisor to the EEA QPPV, Global Drug Safety & Risk Management, Celgene Europe Ltd
  - Alexandra Thrower, Global Director, Legal, Regulatory and Quality, Atlantis Healthcare
  - John Poustie, Medical Director for Pharmacovigilance, Norgine
  - Boris Thurisch, Head of Pharmacovigilance, BPI
  - Philippe Bertrand, Head of Pharmacovigilance-Patient Safety & Drug Surveillance, EU QPPV, Onxeo
  - Maren von Fritschen, Regulatory Director, EUCOPE
  - Barbara Morollo, Senior Director, Pharmacovigilance, Bluebird Bio

- **EuropaBIO**
  - Christiane Abouzeid, Head of Regulatory Affairs, BioIndustry Association (BIA)
  - Margaret Walters, Deputy EU Qualified Person for Pharmacovigilance, MSD
  - Esteban Herrero-Martinez, Director, Regulatory Policy & Intelligence, Abbvie
  - Merete Schmiegelow, Senior Director, Regulatory Policy, Novo Nordisk
  - Johan Hellmér, Global Drug Safety, Head EMEA, Shire

- **Europharm SMC**
  - Margarida Estudiante, Tecnifar
  - Telma Costa, Tecnifar

- **Medicines for Europe**
  - John Barber, BGMA
  - Michael Forstner, Acino Pharma
  - Tanja Peters, Boehringer Ingelheim
  - Uwe Gudat, Merck
  - Katarina Nedog, Medicines for Europe

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- **Vaccines Europe**
  - Françoise Dumas Sillan, QPPV Coordination Worldwide Safety and Regulatory, Pfizer
  - Marc Ceuppens, Therapeutic Area Safety Head, Infectious Diseases and Vaccines, Janssen
  - Alison Bond, Director Global Regulatory Policy & Intelligence, Global Regulatory Affairs, Janssen
  - Anne Czwarno, Senior Manager, Vaccines Europe **TC**

Organisational and time recording:

NN.NN 17.07

Next meeting: 5 December 2016