20 January 2017
EMA/42931/2016
Inspections, Human Medicines Pharmacovigilance and Committees Division

Agenda – 10th industry stakeholder platform – operation of EU pharmacovigilance

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

Item	Preliminary draft agenda	Time
1.	**Welcome and matters arising** ○ *Including* – *June Raine, PRAC Chair, MHRA* *- PRAC Work Programme 2017* *- Impact workshop* – *Georgy Genov, Acting Head of Pharmacovigilance and Epidemiology, EMA* *- Medical Literature Monitoring audit and survey* *- Update on EudraVigilance Auditable Requirements*	10:00-10:40
2.	**Good pharmacovigilance practices for the EU** – *Priya Bahri, EMA*	10:40-10:55
3.	**PSUR** 1. Update on the RSUR Roadmap – *Irene Rager, EMA* 2. Consultation on the explanatory note • Feedback from industry – *Industry representative* • Summary of comments – *Menno Van der Elst, MEB*	10:55-12:05

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	• Discussion – *All*	
	Coffee break	12:05-12:20
4.	**EU PASS, PAES requirements for disclosure** – *Thomas Goedecke, EMA* • Discussion – *All*	12:20-12:40
5.	**Registries** • Presentation of position paper – *Industry Representative* • Recommendations from the registries workshop – *Xavier Kurz, EMA* • Discussion – *All*	12:40-13:10
6.	**MAH compliance with PRAC signal recommendations for PI update of CAPs** – *Aniello Santoro, EMA*	13:10-13:25
7.	**Conclusion and next steps**	13:25-13:30
8.	**Close of meeting**	13:30

Organisational and time recording:

NN.NN

Next meeting:

Participants List

Chair: Georgy Genov, Acting Head of Pharmacovigilance & Epidemiology Department, EMA

- **PRAC**
  - June Raine, PRAC **Chair**
  - Almath Spooner, PRAC vice-Chair

- Sabine Straus, MEB
- Menno Van Der Elst, MEB

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

- **European Medicines Agency**
  - Xavier Kurz, Head of Surveillance and Epidemiology, Pharmacovigilance & Epidemiology Department
  - Agnieszka Szmigiel, Signal and Incident Management, Pharmacovigilance & Epidemiology Department
  - Aniello Santoro, Signal and Incident Management, Pharmacovigilance & Epidemiology Department
  - Francois Domergue, Data Standardisation and Analytics
  - 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
  - Thomas Goedecke, Principal Scientific Administrator, Surveillance and Epidemiology, Pharmacovigilance & Epidemiology Department
  - Priya Bahri, Principal Scientific Administrator, Surveillance and Epidemiology, Pharmacovigilance & Epidemiology Department
  - Irene Rager, Head of Evaluation Procedures, Procedure Management Department

Industry Stakeholder Organisations

- **AESGP**
  - Yasmine Boulkroun, Head of Global Pharmacovigilance, Pierre Fabre
  - Elmar Kroth, Managing Director, German Medicines Manufacturers Association (BAH)
  - Maria Spyt, EU QPPV for Consumer Healthcare, Johnson & Johnson
  - Wendy Booth, VP and Head, Consumer Health Safety, Global Clinical Safety & Pharmacovigilance, GSK
  - Leonie Zimmermann, pharmacovigilance department, BAH
  - Christelle Anquez-Traxler, Regulatory and Scientific Affairs Manager, AESGP

- **EBE**
  - Zoe Conway, Deputy QPPV, Roche Products Limited
  - Suzy Verheyen, J&J
  - Montse Soriano-Gabarro, Bayer
  - Yogendran Logesvaran, Janssen

- **EFPIA**
  - Vicki Edwards, Abbvie
  - Guy Demol, MSD
  - David Lewis, Novartis
  - Sue Rees, Amgen
  - Sue Rees, Amgen
  - Valerie Simmons, EliLilly
  - Achint Kumar, Biogen
  - Emma, Du Four, Abbvie
  - Sini Eskola, EFPIA

- **EUCOPE**
  - Stefan Kaehler, Senior Director, Global Risk Management Standards & Special Advisor to the EEA QPPV, Global Drug Safety & Risk Management, Celgene Europe Ltd
  - John Poustie, Medical Director for Pharmacovigilance, Norgine
  - Boris Thurisch, Head of Pharmacovigilance, BPI

- Trine Moulvad, Zealand Pharma

- **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
  - Pedro Franco, Director Europe for Global Regulatory & Scientific Policy, Merck Group
  - David Marchi, Manager Healthcare Biotechnology, EuropaBio
  - Barbara De Bernardi, Deputy EU QPPV and European Safety Office Head, Pfizer

- **Medicines for Europe**
  - John Barber, BGMA, Dr.Reddy's
  - Michael Forstner, Acino Pharma
  - Uwe Gudat, Merck
  - Katarina Nedog, Medicines for Europe
  - Segun Akintayo, Apotex, Apobiologix
  - Julia Appelskog, SE association, Bluefish Pharnaceuticals
  - Balwant S. Heer, Mylan

- **Vaccines Europe**
  - Françoise Dumas Sillan, QPPV Coordination Worldwide Safety and Regulatory, Pfizer
  - Katharina Hartmann, Takeda
  - Anna Rozmyslowicz, Seqirus
  - Maria Maddalena Lino, Seqirus
  - Anne Czwarno, Senior Manager, Vaccines Europe **TC**