



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

20 January 2016
EMA/48691/2016

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

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

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