



EUROPEAN MEDICINES AGENCY  
SCIENCE MEDICINES HEALTH

17 March 2015  
EMA/177559/2015

## Participants List - Industry Stakeholder platform - Operation of EU pharmacovigilance legislation

13 March 2015, 09:30-13:45, Meeting room 03-E

### Participants List

**Chair:** Peter Arlett, Head of Pharmacovigilance

- **PRAC**

- June Raine, PRAC **Chair** and MHRA
- Almath Spooner, PRAC **Vice Chair** and HPRA
- Menno van der Elst, MEB

- **CMDh**

- Peter Bachmann CMDh **Chair** and BfArM
- Virginie Bacquet, ANSM
- Kora Doorduyn - van der Stoep, MEB (**via TC**)

- **EMA**

- Michael Berntgen, Head of Scientific and Regulatory Management
- Sabine Brosch, Monitoring & Incident Management, Pharmacovigilance
- Nick Halsey, Procedure Management & Business Support, Data Collection & Management



- Michael Lenihan, Head of Finance and Budget Department
- Jane Moseley, Scientific Advice, Product Development Scientific Support
- Marie-Helene Pinheiro, Stakeholders & Communication Division, Corporate Stakeholders
- Irene Rager, Head of Evaluation Procedures E, Procedure Management & Business Support
- Tania Teixeira, Head of Evaluation Procedures F, Procedure Management & Business Support
- Constantinos Ziogas, SME Office Head

## **Industry Stakeholder Organisations**

- **AESGP**

- Miranda Moussa, AESGP
- Martin Terberger , AESGP
- Wendy Booth, Director, Global Regulatory Affairs, Classic and Established Products, GSK
- Emmanuelle Pines, Head of Corporate Vigilance Division, Pierre Fabre
- Mara Ernst, Manager Pharmacovigilance, BAH
- Birgit Rüdinger, Head of Regulatory Documentation, Schwabe

- **EBE**

- Mark Caldwell, J&J
- Sue Rees, Amgen
- Françoise Sillan , Sanofi Pharma, EUQPPV

- **EFPIA**

- Sini Eskola, Director, Regulatory Affairs, EFPIA
- Liz Swain, Chair of EFPIA PV committee, GSK
- Sarah Montagne, Referrals/Regulatory perspective, Bayer
- David Wilson, PSUR repository, J&J
- Judith Weigel, Referrals/National association and PV perspective, VFA

- **EGA**

- Katarina Nedog , Safety and Regulatory Manager, EGA
  - Wendy Huisman, EGA Pharmacovigilance WG chair, European QPPV, Teva
  - John Barber, QPPV, Dr Reddy's
  - Morana Simundic, Regional PhV Manager, Teva
  - Inge Boegh Jansen, Executive director, Global Pharmacovigilance, Actavis
- **EUCOPE**
    - Stefan Kaehler, QPPV, Celgene Europe Ltd
    - J David Hukin, Associate Director, Global Pharmacovigilance, Norgine
    - Boris Thurisch, Director Medicinal Products/Pharmacovigilance, BPI
- **EuropaBio**
    - Riccardo Mezzasalma, Officer, Healthcare Biotechnology, EuropaBio
    - Christiane Abouzeid, Head of Regulatory Affairs, BioIndustry Association (BIA)
    - Margaret Walters, Director and Deputy EU Qualified Person for Pharmacovigilance, MSD
    - Merete Schmiegelow, Senior Director EU Regulatory Advocacy Regulatory Policies & Intelligence, Novo Nordisk
- **Europharm SMC**
    - n/a
- **Vaccines Europe**
    - Aleksandra Opalska, Regulatory & Scientific Manager, Vaccines Europe
    - Maria Grazia Zurlo, EUQPPV, Pfizer
    - Katharina Hartmann, Global Head Vaccine Pharmacovigilance, Pharm D & Vaccine Business Unit, Takeda
    - Kathy Williams, Lead Pharmacovigilance and Regulatory Excellence, Astrazeneca