9 February 2015
EMA/91293/2015

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

12 January 2015, 09:30-13:45, Meeting room 02-F

Participants List

Chair: Peter Arlett, Head of Pharmacovigilance

- **PRAC**
  - June Raine, PRAC **Chair** and MHRA
  - Almath Spooner, PRAC **Vice Chair** and HPRA
  - Inmaculada Corrales, AEMPS
  - Margarida Guimarães, INFARMED
  - Sabine Straus, MEB
  - Rafe Suvarna, MHRA
- **CHMP**
  - Tomas Salmonson, CHMP **Chair** and MPA
- **CMDh**
  - Peter Bachmann CMDh **Chair** and BfArM
  - Virginie Bacquet, ANSM
  - Kora Doorduyn - van der Stoep, MEB
  - Anne Ambrose, MHRA
- **EV-EWG**
  - Anja van Haren, MEB **by teleconference**
- **EMA**
  - Michael Berntgen, Scientific and Regulatory Management Head

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- Kevin Blake, Best Evidence Development, Human Medicines Research and Development Support
- Maria Boulos, Human Medicines Research and Development Support Division, Regulatory Affairs
- Christelle Bouygues, Human Medicines Research and Development Support Division, Regulatory Affairs
- Sabine Brosch, Monitoring & Incident Management, Pharmacovigilance
- Melanie Carr, Corporate Stakeholders Head
- Henry Fitt, Best Evidence Development Head
- Georgy Genov, Signal Management Service Head, Pharmacovigilance Department
- Nick Halsey, Procedure Management & Business Support, Data Collection & Management
- Xavier Kurz, Monitoring and Incident Management Head
- Michael Lenihan, Finance and Budget
- Jane Moseley, Scientific Advice, Product Development Scientific Support
- Marie-Helene Pinheiro, Stakeholders & Communication Division, Corporate Stakeholders
- Luis Prieto, Risk Management Review, Scientific & Regulatory Management
- Irene Rager, Evaluation Procedures E Head, Procedure Management & Business Support
- Paolo Alcini, Data Collection & Management Head, Business Data & Support
- Gilles Touraille, Inspections & Human Medicines Pharmacovigilance, Signal Management
- Spiros Vamvakas, Scientific Advice Head, Product Development Scientific Support
- Corinne De Vries, Risk Management Specialist, Scientific & Regulatory Management
- Constantinos Ziogas, SME Office Head

Industry Stakeholder Organisations

- **AESGP**
  - Christelle Anquez-Traxler , AESGP Regulatory & Scientific Affairs Manager
  - Wendy Booth, Director, GSK Global Regulatory Affairs, Classic and Established Products, on secondment from GCSP (Global Clinical Safety & Pharmacovigilance)
  - Stephen Heaton, Head of Centre of Excellence Risk Management Sciences, Bayer, Global Pharmacovigilance
  - Emmanuelle Pines, Head of Corporate Vigilance Division, Pierre Fabre
  - Mara Ernst, Manager Pharmacovigilance, BAH
  - Ioulia Alekxandrova, Head of Global Medical Safety, Novartis
  - Birgit Rüdinger , Head of Regulatory Documentation, Schwabe

- Lucy Pavesi, GSSA Physician & European QP for Pharmacovigilance, PG

- **EBE**
  - Guy Demol, Merck
  - Mark Caldwell, J&J
  - Françoise Sillan, EUQPPV, Sanofi Pharma
  - Catherine Akers, Amgen
- **EFPIA**
  - Sini Eskola, Coordinator of PV topics EFPIA
  - Emma Du Four, topic leader: PAES
  - Gro Laier, topic leader: PASS
  - Val Simmons, topic leader: Important Risks
  - Michael Richardson, in Liz Swain's absence covering: Off Label Q&A
  - David Lewis, Novartis, Global Head of Pharmacovigilance
  - Kathy Williams, Regulatory Affairs Procedural expert/PV lead
- **EGA**
  - Beata Stepniewska, EGA Regulatory Affairs
  - Katarina Nedog, EGA Pharmacovigilance working group
  - Julia Appelskog, FGL, PSUR work stream
  - John Barber, BGMA, RMP work stream
  - Laura Herrera, Hospira
  - Klaudija Marijanovic, Teva, EGA RMP work stream
  - Vito Strasberger, Billev Pharma
- **EUCOPE**
  - Stefan Kaehler, Celgene
  - Frederique Roesch, Pharmalex
  - Joerg Plessl, Norgine
  - Boris Thurisch, BPI
- **EuropaBio**
  - Louis-Nicolas Fortin, EuropaBio Senior Manager Health Biotechnology
  - Christiane Abouzeid, Head of Regulatory Affairs, BioIndustry Association (BIA)
  - Magaret Walters, Director and Deputy EU Qualified Person for Pharmacovigilance, MSD

- Merete Schmiegelow, Director, EU Regulatory Advoccy Regulatory Policies & Intelligence, Novo Nordisk
- Karen Belton, Director, Global Safety – Deputy QP, Amgen

- **Europharm SMC**
  - Alexandra Soeiro
- **Vaccines Europe**
  - Michael Hellwig, Associate Director, PV Benefit Risk, Takeda
  - Mariagrazia Zurlo, EUQPPV, Pfizer
  - Susanne Belle, Deputy Director, QPPV, Sanofi Pasteur
  - Stéphanie Collomb, Deputy Director, PVRM, SPMSD