



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

20 January 2016
EMA/47443/2016

Participants List – 5th industry stakeholder platform - operation of EU pharmacovigilance legislation

15 September 2015, 09:30-12:30, Meeting room 2A

Participants List

Chair: Peter Arlett, Head of Pharmacovigilance Department

- **PRAC**

- June Raine, PRAC **Chair** and MHRA
- Almath Spooner, PRAC Vice-chair and HPRA
- Sabine Straus, MEB
- Margarida Guimarães, INFARMED
- Menno van der Elst, MEB

- **CMDh**

- Kora Doorduyn - van der Stoep, MEB
- Virginie Bacquet, ANSM

- **EMA**

- Paolo Alcini, Head of Data Standardisation and Analytics 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

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- Emil Cochino, Scientific & Regulatory Management Department
- Georgy Genov, Head of Signal Management, Pharmacovigilance Department
- Evdokia Korakianiti, Head of Procedure Management Department
- Xavier Kurz, Head of Monitoring & Incident Management, Pharmacovigilance Department
- Marie-Helene Pinheiro, Industry Stakeholders Liaison, Corporate Stakeholders Department
- Irene Rager, Head of Evaluation Procedures E, Procedure Management & Business Support
- Juan Garcia, Head of Medical and Health Information, Communication Department
- Tom Paternoster, Data Standardisation and Analytics
- Agnieszka Szmigiel, Pharmacovigilance Department
- Paola Samassa, Head of Accounts, Finance and Budget Department
- Caroline Voltz, Scientific and Regulatory Management
- Ana Cochino, Data Standardisation and Analytics Department

Industry Stakeholder Organisations

- **AESGP**

- Mara Ernst, Manager Pharmacovigilance , BAH
- Lucy Pavesi, GSSA Physician & European QP for Pharmacovigilance, Procter & Gamble
- Emmanuelle Pinès, Manager Vigilance Division , Pierre Fabre
- Miranda Moussa, AESGP
- Martin Terberger, AESGP
- Sophie Fairweather, PAGB

- **EBE**

- Zoe Conway, Roche
- Sue Rees, Amgen
- Katrina Skeer, J&J
- Betina Østergaard Eriksen, Novo Nordisk
- Françoise Sillan, Sanofi

- **EFPIA**

- Sini Eskola, Director, Regulatory Affairs

- Liz Swain, GSK
 - Judith Weigel, VFA
 - Mark Caldwell, J&J
 - Val Simmons, Lilly
- **EGA**
 - Katarina Nedog, Safety and Regulatory Manager, EGA
 - Inge Boegh Jansen, Actavis
 - John Barber, UK association, Dr.Reddy's
 - Julia Appelskog, SE association, Bluefish Pharmaceuticals Group
- **EUCOPE**
 - Stefan Kaehler, QPPV, Celgene Europe Ltd
 - Boris Thurisch, BPI
 - Irfan Ahmad, Norgine
 - Alexander Natz, EUCOPE
 - Philip Weatherill, EMIG
- **EuropaBio**
 - 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
 - Riccardo Mezzasalma, Healthcare Biotechnology Manager, EuropaBio
 - Geneviève Le Visage, Head EU Regulatory Intelligence & Policy, Novartis
- **Europharm SMC**
 - Telma Costa, Head of WP RA, EuropharmSMC
- **Vaccines Europe**
 - Barbara De Bernardi, Deputy EUQPPV, Head of European Safety Office, Pfizer Worldwide Safety and Regulatory
 - 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