24 June 2015
EMA/402803/2015

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

12 June 2015, 09:30-13:00, Meeting room 3A

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

- **CHMP**
  - Tomas Salmonson, CHMP **Chair** and MPA - **Apologies**

- **CMDh**
  - Kora Doorduyn - van der Stoep, MEB - **TC**
  - Anne Ambrose, MHRA

- **Pharmacovigilance Implementation Group**
  - Anja van Haren, MEB - **TC**

30 Churchill Place ● Canary Wharf ● London E14 5EU ● United Kingdom
Telephone +44 (0)20 3660 6000 **Facsimile** +44 (0)20 3660 5555
Send a question via our website www.ema.europa.eu/contact

- **EMA**
  - Paolo Alcini, Head of Data Standardisation and Analytics Department
  - Priya Bahri, Pharmacovigilance Department
  - Michael Berntgen, Head of Scientific and Regulatory Management
  - Jacoline Bouvy, Pharmacovigilance Department
  - Christelle Bouygues, Human Medicines Research and Development Support Division, Regulatory Affairs
  - Sabine Brosch, Monitoring & Incident Management, Pharmacovigilance
  - Melanie Carr, Head of Corporate Stakeholders Department
  - Corinne de Vries, Scientific & Regulatory Management Department
  - Georgy Genov, Head of Signal Management, Pharmacovigilance Department
  - Xavier Kurz, Head of Monitoring & Incident Management, Pharmacovigilance Department
  - Michael Lenihan, Head of Finance and Budget Department
  - Marie-Helene Pinheiro, Industry Stakeholders Liaison, Corporate Stakeholders Department
  - Laura Pioppo, Compliance and Inspection Department
  - Irene Rager, Head of Evaluation Procedures E, Procedure Management & Business Support
  - Agnieszka Szmigiel, Pharmacovigilance Department
  - Sandra Vanlievendael, Head of Long Term and Special Projects Office, Legal Department
  - Caroline Voltz, Scientific & Regulatory Management Department

Industry Stakeholder Organisations

- **AESGP**
  - Miranda Moussa, AESGP
  - Martin Terberger , AESGP
  - Wendy Booth, Director, Global Regulatory Affairs, Classic and Established Products , JSK
  - Omer De Mol, Global Safety Officer, Sanofi/Genzyme
  - Stephen Heaton, Head of Centre of Excellence Risk Management Sciences, Global Pharmacovigilance, Bayer
  - Lucy Pavesi, GSSA Physician & European QP for Pharmacovigilance, Procter & Gamble
  - Mara Ernst, Manager Pharmacovigilance, BAH

- **EBE**
  - Françoise Sillan, Sanofi
  - Eszter Teleki, BMS
  - Zoe Conway, Roche
  - Christina Ström Möller, AstraZeneca
  - Johan Hellmer, Baxter
  - Michael Richardsson, BMS

- **EFPIA**
  - Sini Eskola, Director, Regulatory Affairs
  - Sue Rees, Amgen
  - Vicki Edwards, Abbvie
  - David Lewis, Novartis
  - Sarah Montagne, Bayer
  - Jukka Pesonen, Orion Pharma
  - Val Simmons, Lilly

- **EGA**
  - Suzette Kox, Senior Director, Scientific Affairs & Coordinator of the European Biosimilars Group, EGA
  - Katarina Nedog, Safety and Regulatory Manager, EGA
  - John Barber, QPPV and Director, Head of Pharmacovigilance, European Operations, Dr Reddy's
  - Klaudija Marijanovic, Director, Global Risk Management Group Leader, TEVA
  - Rakesh Barmy, EU QPPV, Accord Ltd
  - Julia Appelskog, SE generic association, EU QPPV, BlueFish Pharma
  - Katja Pecjak, Director of Regulatory Affairs, Billev Pharma
  - Inge Boegh Jansen, Executive Director, Global Pharmacovigilance, Actavis

- **EUCOPE**
  - Stefan Kaehler, QPPV, Celgene Europe Ltd
  - 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
  - Christina Balslev Rindshøj, Director Lira Obesity, GlucaGen and Early Projects, Novo Nordisk
  - Emma Du Four, Senior Director Regulatory Policy, Abbvie
  - Alan Morrison, Vice President International Regulatory Affairs & Safety, Amgen
  - Johan Hellmér, EU Qualified Person for Pharmacovigilance, Baxalta

- **Europharm SMC**
  - Telma Costa, Head of WP RA, EuropharmSMC

- **Vaccines Europe**
  - Maria Grazia Zurlo, EUQPPV, Pfizer
  - Kathy Williams, Lead Pharmacovigilance and Regulatory Excellence, Astrazeneca
  - Jacquelyn Awigena-Cook, Associate Director, Head of Pv Policy Group, Global Medical Safety, Crucell, J&J