7 March 2016
EMA/179833/2016

Agenda – 7th industry stakeholder platform - operation of EU pharmacovigilance legislation

4 April 2016, 10:00-13:30, Meeting room 2A

Item	Preliminary draft agenda	Time
1.	**Welcome and matters arising** – *Peter Arlett, Head of Pharmacovigilance, EMA* – *June Raine, PRAC Chair, MHRA* ○ Including – PRAC Strategy on measuring the impact of pharmacovigilance activities (workshop) – EU Network Governance	10:00-10:15
2.	**PSUR roadmap** • 1) Update on the PSUR and PSUSA roadmap – *Margarida Guimarães (INFARMED), Jolanta Gulbinovic (SMCA), Peter Bachman, (BfArM), Menno Van der Elst (MEB)* – *Ana Zanoletty (EMA)* • Discussion with industry – *All* • 2) PSUR Repository – *Ana Zanoletty (EMA)* – *Margarida Guimarães (INFARMED)*	10:15-11:00
3.	**Recording and reporting of Off-label use** • Orientations from Regulators – *Gilles Touraille, EMA* – *Anja van Haren, MEB* • Discussion with industry – *All*	11:00-11:30
	Coffee break	11:30-11:50
4.	**Update on GVP** • 1) Overview for 2016 – *Priya Bahri, EMA* • 2) RMP and RMP summaries	11:50-12:40

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	– Presentation from industry on their initial comments *Lucy Pavesi, AESGP* – *Emil Cochino, Juan Garcia, EMA* – *Kora Doorduyn-van der Stoep (MEB)* • 3) Biologics – key feedback received and next steps – *Xavier Kurz, EMA* – *Sabine Straus (MEB)*	
5.	**PRAC interaction with SAWP** • PASS pilot, and other consultations – *Anna Tavridou, EMA*	12:40-12:55
6.	**Update on preparation for signal management** • Update – *Georgy Genov, Julie Durand, EMA* – *Sabine Straus (MEB)* • Discussion with industry – *All*	12:55-13:20
7.	**Conclusion and next steps.**	13:20-13:30
8.	**Close of meeting**	13:30

Participants List

Chair: Peter Arlett, Head of Pharmacovigilance Department, EMA

- **PRAC**
  - June Raine, PRAC **Chair** and MHRA
  - Menno van der Elst, MEB
  - Margarida Guimarães, INFARMED
  - Sabine Straus, MEB
  - Jolanta Gulbinovic, SMCA

- **CMDh**
  - Peter Bachmann, CMDh Chair, BfArM
  - Kora Doorduyn - van der Stoep, MEB
  - Virginie Bacquet, ANSM

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  - Anja van Haren, MEB

- **Pharmacovigilance Inspectors Working Group**
  - Kiernan Trevett, MHRA

- **EMA**
  - Ana Zanoletty, Procedure Manager, Evaluation procedures E, Procedure Management Department
  - Gilles Touraille, Scientific administrator, Signal Management Service, Pharmacovigilance Department
  - Priya Bahri, Principal Scientific Administrator, Monitoring & Incident Management Service, Pharmacovigilance Department
  - Emil Cochino, Scientific Officer, Anti-infectives and Vaccines, Scientific and Regulatory Management Department
  - Juan Garcia Burgos, Head of Medical and Health Information, Communication Department
  - Xavier Kurz, Head of Monitoring & Incident Management, Pharmacovigilance Department
  - Georgy Genov, Head of Signal Management, Pharmacovigilance Department
  - Julie Durand, Scientific administrator, Signal Management Service, Pharmacovigilance Department
  - Jane Moseley, Scientific Advice, Product Development Scientific Support Department
  - Anna Tavridou, Scientific Advice, Product Development Scientific Support Department
  - Viola Macolic Sarinic, Scientific Advice, Product Development Scientific Support Department
  - 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

Industry Stakeholder Organisations

- **AESGP**
  - Tracy Crook, QPPV, RB
  - Omer de Mol, Global Safety Officer, Sanofi Genzyme
  - Mara Ernst, Manager Pharmacovigilance, BAH
  - Sophie Fairweather, Regulatory Executive, PAGB
  - Agnieszka Majcher-Dann, QPPV, Johnson & Johnson
  - Lucy Pavesi, GSSA Physician & European QP for Pharmacovigilance, Procter & Gamble
  - Miranda Moussa, Manager for Safety Issues, AESGP
- **EBE**
  - Zoe Conway, Roche, Deputy QPPV
  - Ute Hoeffner, Biogen, Senior Medical Director, Safety and Benefit-Risk Management, EU-QPPV Deputy
- **EFPIA**
  - Vicki Edwards, Abbvie
  - Dave Lewis, Novartis
  - Sarah Montagne, Bayer
  - Val Simmons, EliLilly
  - Michael Richardson, BMS
  - Logesvaran Yogendran, Jansen
  - Sini Eskola, Director, EFPIA
- **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
  - Barbara Morollo, Bluebird Bio

- **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,
  - Rebecca Stone, Amgen
  - Riccardo Mezzasalma, EuropaBio

- **Europharm SMC**
  - Margarida Estudiante, Tecnifar

- **Medicines for Europe**
  - Inge Boegh Jansen, Allergan
  - Nicole Lang, TEVA
  - Julia Appelskog, SE association, BlueFishPharma
  - Rakesh Barmy, Accord
  - Balwant Heer, Mylan
  - Uwe Gudat, Merck
  - Katarina Nedog, Safety and Regulatory Manager, EGA

- **Vaccines Europe**
  - Maria Grazia Zurlo, Head Safety Strategy, Policy and Standards, EUQPPV, Pfizer
  - Kathy Williams, Lead Pharmacovigilance and Regulatory Excellence, AstraZeneca