EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

11 August 2016
EMA/375852/2016

Agenda – 8th industry stakeholder platform - operation of EU pharmacovigilance legislation

1 July 2016, 10:00-13:30, Meeting room 3A

Item	Preliminary draft agenda	Time
1.	**Welcome and matters arising** – *Peter Arlett, Head of Pharmacovigilance, EMA* – *June Raine, PRAC Chair, MHRA* ○ Including – Update on GVPs	10:00-10:15
2.	**Risk Management Plan guidance and templates** • Feedback from the public consultation – *Emil Cochino, Kristyna Schneiderova, EMA* • Feedback on procedural aspects – *Rocio Gonzalo Ruiz, EMA* – *Kora Doorduyn-van der Stoep , MEB* • Discussion with industry – *All*	10:15-10:45
3.	**Eudravigilance system** • Update on planning including industry testing, training and website – *Francois Domergue, EMA* – *Anja van Haren, MEB*	10:45-11:15
4.	**Medical Literature Monitoring update** • Presentation of the results of the joint survey from EFPIA,	11:15-11:55

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	Medicines for Europe and AESGP – *John Barber, Dave Lewis (AESPG, EBE, EFPIA, Medicines for Europe)* • Highlights of the EMA survey – *Tom Paternoster-Howe, EMA* • Discussion – All	
	Coffee break	11:55-12:05
5.	**Pharmacovigilance System Master File** • Discussion of the need to revision of the GVP guidance – *Miranda Moussa (AESGP, EFPIA, Medicines for Europe, EBE, EUCOPE)* – *Sophia Mylona, EMA*	12:05-12:20
6.	**AOB: RSI** • Discussion – *Sini Eskola, EFPIA* – *All*	12:20-12:30
7.	**ISO IDMP – pharmacovigilance interface** • Industry proposals – *Sini Eskola, Neil Newman (AESGP, EBE, EFPIA, EUCOPE, Medicines for Europe)* • Discussion – All	12:30-13:00
8.	**Counterfeit legislation** • Industry observations on opportunities for pharmacovigilance – *Paul Mills, EFPIA* • Discussion – *All*	13:00-13:20
9.	**Conclusion and next steps**	13:20-13:30
10.	**Close of meeting**	13:30

Participants List

Chair: Peter Arlett, Head of Pharmacovigilance Department, EMA

- **PRAC**
  - June Raine, PRAC **Chair** and MHRA
  - Margarida Guimarães, INFARMED
  - Ulla Wändel Liminga, MPA **TC**

- **CMDh**
  - Kora Doorduyn - van der Stoep, MEB **TC**
  - Virginie Bacquet, ANSM

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  - Anja van Haren, MEB

- **EMA**
  - Emil Cochino, Scientific Officer, Anti-infectives and Vaccines, Scientific and Regulatory Management Department
  - Kristyna Schneiderova, Scientific and Regulatory Management Department
  - Xavier Kurz, Head of Monitoring & Incident Management, Pharmacovigilance Department
  - Georgy Genov, Head of Signal Management, Pharmacovigilance 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
  - Iordanis Gravanis, Head of Evaluation Procedures, Procedures Management Department
  - Francois Domergue, Data Standardisation and Analytics
  - Tom Paternoster-Howe, Data Standardisation and Analytics

- Sophia Mylona, Clinical and Non-Clinical Compliance
- Rocio Gonzalo Ruiz, Procedure Manager, Evaluation Procedures, Procedures Management Department
- Paolo Alcini, Head of Data Standardisation and Analytics Department
- Nick Halsey, Business Data and Analytics Department

Industry Stakeholder Organisations

- **AESGP**
  - Wendy Booth, VP and Head, Consumer Health Safety, GSK
  - Mara Ernst, Manager Pharmacovigilance, German Medicines Manufacturers (BAH)
  - Elmar Kroth, Director, German Medicines Manufacturers Association (BAH)
  - Lucy Pavesi, EU QPPV, Procter & Gamble
  - Miranda Moussa, Manager for Safety Issues, AESGP

- **EBE**
  - Zoe Conway, Deputy QPPV, Roche
  - Katrina Skeer, Director EMEA Regulatory Compliance & Business Support, Janssen-Cilag
  - Veronique Debaut, Regulatory Affairs Manager, EBE
  - Amel Benkritly, QPPV, Sanofi
  - Paul Nasserini Sina, Deputy QPPV, GSK

- **EFPIA**
  - Vicki Edwards, Abbvie
  - Michael Richardsson, BMS
  - Sue Rees, Amgen
  - David Lewis, Novartis
  - Guy Demol, MSD
  - Val Simmons, EliLilly
  - Sini Eskola, EFPIA

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- John Kiser, Abbvie
- Neil Newmann, EliLilly
- Paul Mills, MelierSolutions

- **EUCOPE**
  - Stefan Kaehler, Senior Director, Global Risk Management Standards & Special Advisor to the EEA QPPV, Global Drug Safety & Risk Management, Celgene Europe Ltd
  - Jacqueline Bore, Director, Senior Regulatory Lawyer, Celgene Europe Ltd
  - Rainer Schmeidl, Vice President, Corporate Drug Safety, EEA Qualified Person for Pharmacovigilance, Biotest
  - Aparna Desai, Senior Manager & Local Safety Officer, UK PV
  - John Poustie, Medical Director, Global Pharmacovigilance, Norgine
  - Manav Patel, Scientific Advisor, Merz

- **EuropaBIO**
  - Merete Schmiegelow, Senior Director EU Regulatory Advocacy, Novo Nordisk
  - Esteban Herrero-Martinez, AbbVie
  - Johan Hellmér, Shire
  - Rebecca Stone, Amgen
  - Christina Guiton, Merck Group

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

- **Medicines for Europe**
  - Nick Rist, Mylan
  - Wendy Huisman, Teva
  - John Barber, BGMA/Dr.Reddy's
  - Augusto Eugénio Filipe, Tecnimede
  - Katarina Nedog, Safety and Regulatory Manager, Medicines for Europe

- **Vaccines Europe**
  - Maria Grazia Zurlo, Head Safety Strategy, Policy and Standards, EUQPPV, Pfizer

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- Magnus Ysander, QPPV, AstraZeneca
- Alison Bond, Director Global Regulatory Policy & Intelligence, Global Regulatory Affairs, Janssen
- Anne Czwarno, Senior Manager, Vaccines Europe **TC**

Organisational and time recording:

NN.NN 17.07

Next meeting: 21 September 2016