17 June 2011
EMA/366836/2011
Patient Health Protection

Agenda - Second Stakeholders forum on the implementation of the new Pharmacovigilance legislation

Friday, 17 June 2011 - 09:00hrs – 16:00hrs, room 2A

European Medicines Agency (EMA) - 7 Westferry Circus, Canary Wharf, London E14 4HB

The objectives of this second meeting are to:

- Present an update on the implementation.
- Introduce topics of much relevance for stakeholders and for which specific feedback is sought.
- Discuss a range of topics particularly relevant to patients and healthcare professionals.

Co-chairpersons:

Morning session: **Noël Wathion/June Raine**

Afternoon session: **Isabelle Moulon/Dolores Montero**

Time	Agenda item	Speaker
08:30	Registration and reimbursement arrangements	
09:00	Welcome and introduction	**Andreas Pott** *EMA Acting Executive Director*
09:15	Implementation of the new Pharmacovigilance legislation: the challenges ahead	**Noël Wathion** *Head of Human Health Protection Unit (EMA)*
09:30	Update on Good Vigilance Practice and implementing measures: Project Planning and Consultation.	**Franck Diafouka** *Pharmacovigilance and Risk Management (EMA)* **Fergus Sweeney** *Head of Sector Compliance and Inspections (EMA)*

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Time	Agenda item	Speaker
10:15	Pharmacovigilance and Risk Assessment Committee (PRAC)	**Dolores Montero** *Head of pharmacoepidemiology and pharmacovigilance Division, Spanish Medicines Agency (AEMPS)* **Roberto De Lisa** *Pharmacovigilance and Risk Management (EMA)* **Sheila Kennedy** *Section Head Scientific Committees (EMA)*
	• Experience from patient observer in the PhVWP	**Albert van der Zeijden** *(International Alliance of Patients' Organizations - IAPO)*
10:45	*Coffee break*	
11:00	Public Hearings: when, who and why What is expected from public hearings: • The view of patients and consumers • The view of healthcare professionals • The view of industry	**Monika Benstetter** *External Communication Officer (EMA)* **Doris Stenver** *Chief Medical Officer Danish Medicines Agency* **Barbro Westerholm** *(AGE platform Europe)* **David Haerry** *(European AIDS Treatment Group - EATG)* **Tony West** *(European Association of Hospital Pharmacists - EAHP)* **Bettina Fiedler** *(European Federation of Pharmaceutical Industries and Associations - EFPIA)*

Time	Agenda item	Speaker
	Panel discussion (*with representatives from EMA, Danish Medicines Agency, AGE, EATG, EATH, EFPIA, AESGP and EuropaBio*)	**Christelle Anquez-Traxler** *(Association of the European Self Medication Industry - AESGP)* **Merete Schmiegelow** *(European Association for Bioindustries - EuropaBio)* *(In addition to previous speakers)*
12:00	*Lunch break*	
13:00	Direct patient reporting • Existing national experiences • Reporting experiences from patients and consumers • Reporting experiences from healthcare professionals Panel discussion *(with representatives from EMA, Danish Medicines Agency, Nottingham University Medical School, BEUC, EPF, PGEU, EFPIA and AESGP)*	**Peter Arlett** *Head of Sector Pharmacovigilance and Risk Management (EMA)* **Tony Avery** *Nottingham University Medical School* **Doris Stenver** *Chief Medical Officer Danish Medicines Agency* **Mick Foy** *(MHRA - Pharmacovigilance Signal Management Group Manager)* **Ilaria Passarani** *(European Consumers' Organisation - BEUC)* **Fred de Koning** *(Pharmaceutical Group of the European Union - PGEU)* **Kaisa Immonen-Charalambous** *(European Patients' Forum - EPF)* **Sabine Brosch** *Pharmacovigilance and Risk Management (EMA)* **Barry Arnold** *(European Federation of*

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		Pharmaceutical Industries and Associations - EFPIA) (in addition to previous speakers)
14:30	*Coffee break*	
14:45	Update on EudraVigilance: new developments and Eudravigilance access policy. What is expected from EudraVigilance: • The view of patients and consumers • The view of healthcare professionals • The view of industry • Panel discussion (*with representatives from EMA, MHRA, EURORDIS, PGEU, EFPIA and EGA*)	**Sabine Brosch** *Pharmacovigilance and Risk Management (EMA)* **Sarah Morgan** *Head of Pharmacovigilance Risk Management (MHRA)* **François Houÿez** *(European Organisation for Rare Diseases - EURORDIS)* **Jurate Svarcaite** *(Pharmaceutical Group of the European Union - PGEU)* **Wendy Huisman** *(European Generic Medicines Association - EGA)* **Subhash Mistry** *(European Federation of Pharmaceutical Industries and Associations - EFPIA)* (In addition to previous speakers)
15:45	Conclusions	**Isabelle Moulon** *Head of Sector Medical Information (EMA)* **Dolores Montero** *Head of pharmacoepidemiology and pharmacovigilance Division Spanish Medicines Agency (AEMPS)*
16:00	*Close of meeting*	