



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

26 September 2012
EMA/43750/2012
Patient Health Protection

Patients/Consumers Working Party (PCWP) and Healthcare Professionals Working Group (HCP WG) Joint Meeting Agenda

Chair: Isabelle Moulon - Head of Medical Information

24-25 September 2012 – Conference room: 4A

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

24 September 2012

12:45	Registration and reimbursement arrangements		
13:00	Welcome and introduction Health and safety issues Conflicts of interest / Adoption of the agenda		Isabelle Moulon (EMA)
1. Area of pharmacovigilance			
13:05	1.1 Update on the implementation of the new legislation	For information	Franck Diafouka (EMA)
13:25	1.2 Call for patient and healthcare professional representatives to PRAC and CAT	For information	Florian Schmidt (European Commission)
14:00	1.3 Additional monitoring – proposals on the black symbol for SmPC/PL – PCWP/HCPWG position	For discussion and decision	Alexios Skarlatos (EMA)
15:00	<i>Coffee Break</i>		
15:15	1.4 Public Hearings		
	1.4.1 Patients' interest and proposals for public hearings on medicines in Europe	For information	François Houyez (EURORDIS)
	1.4.2 EMA preparatory work	For information and discussion	Monika Benstetter (EMA)
16:30	1.5 Reporting of adverse drug reactions -		
	1.5.1 update on direct reporting	For information	Sabine Brosch/ Victoria Newbould (EMA)
	1.5.2 UK e-yellow card reporting	For information	Phil Tregunno (MHRA)



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17:00	1.6 Understanding off-label use and the information needs of patients: a Eurordis survey in rare diseases	For information	Rob Camp (EURORDIS)
17:30	1.7 Good Vigilance Practice under consultation:	For information	Priya Bahri (EMA)
	1.7.1 Safety Communication	For information and discussion	Juan Garcia (EMA)
	1.7.2 Public Participation	For information and discussion	Isabelle Moulon (EMA)
18:30	<i>End of first day</i>		

25 September 2012			
2. Area of communication and information			
09:00	2.1 EMA current practice in disseminating information	For information	Monika Benstetter/ Sarah Weatherley/ Christopher Gadd (EMA)
09:45	2.2 Communicating and disseminating information received from EMA		
	2.2.1 Perspectives from healthcare professional organisations	For information	Jurate Svarcaite (PGEU)/ Michel Delvaux (UEG)
	2.2.2 Perspectives from patient organisations	For information	Susanna Palkonen (EPF)/ Christoph Thalheim (EMSP)
	2.2.3 General discussion		
10:30	Coffee Break		
10:40	2.3 Proposal to update the EPAR summary template	For information and discussion	Daniel Glanville (EMA)
3. Other EU activities			
11:30	3.1 The PROTECT project Benefit-risk integration and representation.	For information and discussion	Deborah Ashby (Imperial College London)
4. Area of involvement in EMA activities			
12:00	4.1 Handling of conflicts of interest of organisations	For discussion and agreement	Juan Garcia (EMA)
13:00	<i>Lunch</i>		
14:00	4.2 Pandemic communication strategy Outcome of the survey on communication practices during a pandemic influenza crisis and proposed lines for action	For information and discussion	Ivana Silva (EMA)
14:30	4.3 Update on the implementation of the HCPs framework	For information	Ivana Silva (EMA)
14:45	<i>Coffee Break</i>		

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15:00	4.4 PCOs Annual report 2011	For adoption	Nathalie Bere (EMA)
15:30	4.5 PCWP and HCPWP work programmes 2013	For adoption	Nathalie Bere/ Ivana Silva (EMA)
5. AOB			
16:15	AOB		
16:30	<i>Close of meeting</i>		