



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

2 March 2012
EMA/995452/2011
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

28 February 2012 – 09:00hrs -16:45hrs - Conference room: 4A

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

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08:30	Registration and reimbursement arrangements		
09:00	Welcome and introduction		I. Moulon (EMA)
	Tour de table		
	Interests disclosure		
	Adoption of the agenda		
1. Area of communication and information			
09:15	1.1 Professionalisation of civil-society representatives in a European Union agency: a challenge to effective communication	For information and discussion	C. Gadd (EMA)
10:00	1.2 Q&A on biosimilar medicines	For information and discussion	N. Mbaeliachi / R. Gonzalez-Quevedo (EMA)
10:30	1.3 Public webpage on the summary of product characteristics (SmPC)	For information and discussion	L. Brassart / O. Fasanya (EMA)
11:00	<i>Coffee Break</i>		



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11:15	1.4 Pandemic Lessons learned: main recommendations on communication	For information and discussion	M. Benstetter / R. Shivji (EMA)
2. Area of clinical trials			
12:15	2.1 EU Clinical Trials Register (EUCT) 2.2 WHO International Clinical Trials Registry Platform (ICTRP)	For information and discussion	A. Rodriguez Sanchez Beato / N. Manent (EMA)
12:45	<i>Lunch</i>		
3. Area of pharmacovigilance			
13:45	3.1 Patients/Consumers participation in the PhVWP: experience gained	For information	C. Cabrita (BEUC) / A. van der Zeijden (IAPO) / D. Haerry (EATG)
14:30	3.2 Outcome of consultation on additional monitoring of medicines and ADR reporting – impact on product information	For information and discussion	A. Sempere (EMA)
15:00	<i>Coffee Break</i>		
4. Area of involvement in EMA activities			
15:15	4.1 Involvement in benefit/risk activities: Scientific Advisory Groups (SAGs) 4.1.1 What are SAGs? 4.1.2 Participation of civil society	For information	F. Pignatti (EMA) I. Silva / N. Bere (EMA)
16:15	4.2 Framework for interaction with healthcare professionals and criteria to be fulfilled by healthcare professionals' organisations	For information	I. Silva (EMA)
5. AOB			
16:30	AOB		
16:45	<i>Close of meeting</i>		