

3 June 2014
EMA/136044/2014
Stakeholders and Communication Division

Agenda - EMA Human Scientific Committees' Working Parties with Patients' and Consumers' Organisations (PCWP) and Healthcare Professionals' Organisations (HCPWP) joint meeting

3 June 2014, 09:00hrs to 16:30hrs – meeting room: 4A

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

Co-Chairs: Isabelle Moulon (EMA) and David Haerry (PCWP)

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08:45	Registration and reimbursement arrangements		
08:55	Welcome and introduction Health and safety information Disclosure of interest Adoption of the agenda		I. Moulon (EMA)
1. Involvement in EMA activities			
09:00	1.1 Update on EMA's clinical-trial data policy - principles for redaction of clinical study reports to be published	For information	N. Wathion (EMA)
09:25	1.2 European Commission's study on off-label use	For information	B. Mentre (EC) (video-conference)
10:00	1.3 Update on the new clinical trials regulation	For information	F. D'Atri (EC) A. Marçal (EMA)
11:00	<i>Coffee break</i>		
11:30	1.4 RMP summaries – a new communication tool	For information and discussion	J. Garcia Burgos (EMA)
12:00	<i>Lunch</i>		

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2. Organisational matters

13:00	Agency on the move	For information	A. Brandt (EMA)
Tbc	Update on EMA's policy on handling of conflicts of interests (ColIs) – <i>discussion postponed until 16-17 September 2014 joint PCWP/HCPWP meeting</i>	For information	N. Wathion (EMA)

3. Sharing experiences of involving patients and healthcare professionals in regulatory decisions

13:30	France	For information	D. Nguyen-Bonnet (ANSM)
	Netherlands	For information	S. Kruger-Peters (CBG-MEB)
	UK	For information	J. Jolly (MHRA)
	Sweden	For information	J. Ahlqvist-Rastad (MPA)
14:30	<i>Coffee break</i>		
14:45	General discussion		All
16:15	A.O.B.		
16:30	End of meeting		