

16 September 2014 EMA/323287/2014 Stakeholders and Communication Division

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

16 September 2014, 09:00hrs to 17:15hrs – meeting room: CP-03-E European Medicines Agency - 30 Churchill Place, Canary Wharf, London E14 5EU

Chair: Isabelle Moulon (Head of Patients and Healthcare Professionals)

16 September 2014					
08:45	Registration and reimbursement arrangements				
09:00	Welcome and introduction		I. Moulon (EMA)		
	Induction to the new building: health and safety information				
	Disclosure of interest				
	Adoption of the agenda				
1. Involvement in EMA activities					
09:25	1.1 EMA adaptive licensing pilot project	For information	S. Vamvakas (EMA)		
10:10	Coffee break				
10:25	1.2 Update on ongoing HTA-EMA interaction	For information			
	a. HTA Network/ EUnetHTA		F. Giorgio (EC)		
	b. Pre and post-authorisation collaboration		S. Vamvakas/ J. Moseley/K. Blake (EMA)		
11:45	1.3 Use of patient reported outcome measures in oncology studies - EMA public consultation	For information	Daniel O'Connor (COMP/MHRA/EMA Oncology WP)		





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12:15	Lunch				
13:15	<ul> <li>1.4 Supporting regulatory decision-making and looking at its effects; focus on pharmacovigilance</li> <li>a. Introduction and impact of regulation</li> <li>b. Effectiveness of risk minimisation</li> <li>c. Best evidence</li> </ul>	For information and discussion	P. Arlett/ C. de Vries/H. Fitt (EMA)		
14:15	1.5 EU Collaborative Framework for Patient Registries – pilot phase	For information and discussion	X Kurz (EMA)		
14:45	Coffee break				
15:00	1.6 EMA communication on medication errors	For information and discussion	J. Garcia Burgos/ I. Abed (EMA)		
15:25	1.7 Risk Management Plan summaries	For information and discussion	J. Garcia Burgos (EMA)		
2. Planning and reporting					
15:45	2.1 Update on work in the area of pandemic preparedness	For information	R. Shivji/ M. Benstetter/I. Silva (EMA)		
16:00	2.2 PCWP/HCPWP work plans 2015	For discussion	N. Bere/I. Silva (EMA)		
16:25	2.3 Feedback from Scientific Committees	For information			
16:55	2.4 Feedback from 6th annual workshop of Enpr-EMA	For information	A. Hadjipanayis (HCPWP)		
17:10	A.O.B.				
17:15	End of meeting				
17:30	New building Celebration: cocktail with the Executive Director				
	Promenade lounge				