

30 November 2011
EMA/545915/2011
Patient Health Protection

EMA Human Scientific Committees' Working Party with Patients' and Consumers' Organisations (PCWP) meeting with all eligible organisations

Agenda

Co-chairpersons: Isabelle Moulon (EMA) – Lise Murphy (EURORDIS)

30 November 2011 - 09:00hrs – 16:30hrs, room 4B

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

Time	Agenda item	Action	Speaker
09:00	Welcome and introduction - Tour de table Conflicts of interest / Adoption of the agenda		I. Moulon (EMA) / L. Murphy (Eurordis)
09:05	Introduction by Guido Rasi – EMA Executive Director		
1. General			
09:30	1.1 Implementation of the roadmap to 2015; implications for patients/consumers	<i>For information and discussion</i>	E. Cooke (EMA)
2. New pharmaceutical legislation			
10:15	2.1 Implementation of the anti-falsification legislation	<i>For information and discussion</i>	D. Cockburn (EMA)
10:45	2.2 General update on implementation of pharmacovigilance legislation	<i>For information and discussion</i>	P. Arlett (EMA)
11.15	Coffee break		
11:30	2.2.1 Additional monitoring of medicines & direct patient reporting - impact on the package leaflet	<i>For information and discussion</i>	A. Sempere (EMA)

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12:00	2.3 Proposal for legislation on information to patients.	<i>For information and discussion</i>	P. Brunko (EC)
12:45	Lunch		
3. Patient/consumer organisation activities			
13:45	3.1 Results of survey project on representativeness in Agency stakeholder groups <i>Postponed until next meeting</i>	<i>For information and discussion</i>	C. Gadd (EMA)
4. Involvement of patient/consumer organisations in EMA activities			
14:15	4.1 Outcome of SAG pilot phase <i>Postponed until next meeting</i>	<i>For information and discussion</i>	N. Bere (EMA)
15:00	Coffee		
15:15	4.2 Process for re-evaluation of PCO eligibility	<i>For discussion and adoption</i>	J. Garcia (EMA)
16:00	4.3 General update and PCWP Work plan for 2012	<i>For discussion and adoption</i>	N. Bere (EMA)
16:30	<i>Close of meeting</i>		