



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

17 February 2011
EMA/45985/2011
Patient Health Protection

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

Draft agenda

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

Day 1: Tuesday, 22 February 2011 - 13:00hrs – 16:15hrs, room 4A

Day 2: Wednesday, 23 February 2011 - 09:15hrs – 15:45hrs, room 4A

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

Day 1 - 22 February			
Time	Agenda item	Action	Speaker
13:00	Welcome and introduction		I. Moulon (EMA) / L. Murphy (Eurordis)
	Conflicts of interest / Adoption of the agenda		
1. Brainstorming on training strategy for patients and consumers			
13:15	1.1 Design of EMA training strategy for patients 3 Topics: - Training material for the website - Increase visibility of patient involvement / dissemination of information - In-house training <i>Design of info pack for new patients</i>	For discussion	N. Bere (EMA)
13:45	Break-out sessions		



Day 1 - 22 February

<p>1.2 Training material for the website</p> <ul style="list-style-type: none"> • General info on Agency and procedures • Tutorials • Glossary • Info pack for PCOs 	<p>1.3 Increase visibility of patient involvement / dissemination of information</p> <ul style="list-style-type: none"> • Training activities by PCOs on regulatory activities • Info on EMA interaction with civil society • Methods of dissemination of EMA info • Info pack promotion 	<p>1.4 In-house training</p> <ul style="list-style-type: none"> • Identification of topics • Format/definition • Frequency • Invitees • Training material 	
<p>Topic leaders: I. Moulon (EMA) Sarah Weatherley (EMA) TBC (PCO)</p>	<p>Topic leaders: L. Murphy (Eurordis) Ivana Silva (EMA)</p>	<p>Topic leaders: N. Bere (EMA) TBC (PCO)</p>	
<p>Room 2C</p>	<p>Room 1H</p>	<p>Room 1G</p>	
<p>14:45</p>	<p><i>Coffee</i></p>		
<p>15:00</p>	<p>Feedback from groups:</p> <ul style="list-style-type: none"> - Training material for the website - Increase visibility of patient involvement / dissemination of information - On-site training 	<p>For information and discussion</p>	<p>Each group</p>
<p>15:45</p>	<p>General discussion</p> <ul style="list-style-type: none"> - Info-pack structure - Implementation and next steps - Priorities / timelines - Monitoring 	<p>For discussion and adoption</p>	<p>ALL</p>
<p>16:15</p>	<p><i>Close of meeting</i></p>		

Day 2 - 23 February

09:15	<p>Welcome back</p> <p>Update from previous meeting / general overview of PCO involvement</p> <ul style="list-style-type: none"> • Pharmacovigilance working party observer • Implementation of new pharmcovigilance legislation • PCWP draft meeting dates for 2012 		I. Moulon (EMA) / L. Murphy (Eurordis) / N. Bere (EMA)
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2. Product information

09:30	2.1 Package leaflet – update on the revision of the template	For information and discussion	A. Skarlatos (EMA)
10:00	2.2 Better packaging and labelling for better informed patients	For information and discussion	I. Passarani / Cristina Cabrita (BEUC)
10:45	<i>Coffee</i>		
11:00	2.3 Eligibility criteria	For information and discussion	N. Bere (EMA)
11.30	2.4 Feedback on PCO involvement in SAG meetings	For information	N. Bere (EMA) / Wim Wientjens (IDF)
12:00	2.5 Medicines subject to additional monitoring	For discussion	I. Abed (EMA)
12:30	<i>Lunch</i>		

3. Involvement of patients and consumers organisations in EMA activities

13:30	3.1 Performance indicators	For information and discussion	N. Bere (EMA)
14:15	3.2 Update on HCP WG and presentation of Joint meeting agenda	For Information	I. Silva (EMA)
14:45	3.3 Presentation to HMA; “EMA model of working with patients and consumers”	For information and discussion	L. Murphy (Eurordis)
15:15	3.4 Conflicts of interest form	For information and discussion	Sheila Kennedy (EMA)

Day 2 - 23 February

4. AOB

15:45	<i>Close of meeting</i>		