



11 November 2010
EMA/564815/2010 Rev. 1
Patient Health Protection

Training session on the review of product information

Agenda

Chair: Juan García Burgos (EMA)

Monday, 29 November 2010 - 09:00hrs – 16:30hrs, room 4A

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

Time	Agenda item	Speaker
09:00	Registration and reimbursement arrangements	
09:15	Welcome and introduction	
1. Introduction to the EMA		
09:30	The European Medicines Agency and documents addressed to the public	N. Bere (EMA)
2. Reviewers' experience		
10:00	Patients' perspective	L. Murphy (Eurordis)
3. EPAR Summary		
10:30	3.1 Background information	N. Mbaeliachi (EMA)
	3.2 Analysis of experience gained during 2010	N. Bere (EMA)
	Coffee break	
	3.3 Patient feedback	F. Houyez (Eurordis)
	3.4 Practical exercises and examples	ALL



Time	Agenda item	Speaker
4. EudraLink		
12:00	Practical information	H. Hansen (EMA)
12:30	Lunch	
5. Package Leaflet		
13:30	5.1 The new PL template	M. Buch (EMA)
	5.2 Analysis of experience gained during 2010	N. Bere (EMA)
	5.3 Patient feedback	I. Passarani (BEUC)
	<i>Coffee break</i>	
6. Safety communications		
15:00	6.1 Background information	F. Castellani (EMA)
	6.2 Patient feedback	D. Haerry (EATG)
	6.3 Practical exercises and examples	ALL
7. Training manual and CD-ROM		
16:00	Training material	N. Bere (EMA)
16:30	Close of meeting	