21 November 2011
EMA/818489/2011
Patient Health Protection

Training session on the review of product information

Draft Agenda

Chair: Juan García Burgos (EMA)

Tuesday, 29 November 2011 - 09:00hrs – 16:30hrs, room 4B

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

Time	Agenda item	Speaker
09:00	Welcome and introduction	
1. Introduction to the EMA		
09:15	1.1 How medicines are authorised in the EU	V. Palmi (EMA)
2. Patients/consumers' experience		
09:45	2.1 Patients' perspective	L. Murphy (Eurordis)
10:15	2.2 Patient training for protocol assistance	M. Mavris (Eurordis)
10:45	***Coffee break***	
11:00	The European Medicines Agency and documents addressed to the public	N. Bere (EMA)
3. EPAR Summary		
11:15	3.1 Background information	I. Abed (EMA)
	3.2 Procedural aspects and analysis of experience during 2011	N. Bere (EMA)
	3.3 Patient feedback	F. Houyez (Eurordis)

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Time	Agenda item	Speaker
	3.4 Practical exercise	ALL
12:45	***Lunch***	
4. EudraLink		
13:45	4.1 Practical information	H. Hansen (EMA)
5. Package Leaflet		
14:15	5.1 Background information	A. Skarlatos (EMA)
	5.2 Procedural aspects and analysis of experience during 2011	N. Bere (EMA)
	5.3 Patient feedback	I. Passarani (BEUC)
15:00	***Coffee break***	
6. Safety communications		
15:15	6.1 Background information	D. Glanville (EMA)
	6.2 Procedural aspects and analysis of experience during 2011	N. Bere (EMA)
	6.3 Patient feedback	D. Haerry (EATG)
7. Training manual and CD-ROM		
16:00	Training material	N. Bere (EMA)
16:30	Close of meeting	