10 November 2014
EMA/632556/2014
Stakeholders and Communication Division

Agenda - Training session for patients and consumers involved in EMA activities

Chairperson: Isabelle Moulon (EMA)

Tuesday, 25 November 2014 - 09:00hrs – 16:30hrs, room 2F

European Medicines Agency (EMA) – 30 Churchill Place, Canary Wharf, London E14 5EU

Time	Agenda item	Speaker
09:00	Welcome and registration / Health and safety information	I. Moulon (EMA)
1. Overview of the EMA and the centralised procedure		
09:15	1.1 How are medicines evaluated at the EMA	N. Bere (EMA)
2. Scientific Advice (SA) procedures		
10:15	2.1 What is scientific advice (SA) / How are patients involved in SA 2.2 Patient experience	F. Cerreta (EMA) H. Sundseth (EIWH)
11:00	***Coffee break***	
3. Scientific Advisory Group (SAG) meetings		
11:15	3.1 What is a scientific advisory group (SAG) / How are patients involved in SAGs 3.2 Patient experience 3.3 Overview SA/SAG for 2014	F. Pignatti (EMA) C. Dehn (EHN) N. Bere (EMA)
12:00	***Lunch***	
4. Information to patients		
13:00	4.1 What is a package leaflet / how to review it	C. Espinasse (EMA)

30 Churchill Place ● Canary Wharf ● London E14 5EU ● United Kingdom
Telephone +44 (0)20 3660 6000 **Facsimile** +44 (0)20 3660 5555
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	4.2 What is an EPAR summary / how to review it 4.3 What are safety communications / how to review them 4.4 Overview of all documents	P. Blake (EMA) F. Castellani (EMA) N. Bere (EMA)
14:45	4.5 How to find information on the EMA website	C. Gadd (EMA)
15:00	***Coffee break***	
5. Pharmacovigilance		
15:15	5.1 What is Pharmacovigilance / Impact of Pharmacovigilance for patients	P. Bahri (EMA)
6. Practical aspects		
16:00	6.1 Eudralink 6.2 Declaration of Interest (DOI) submission	H. Hansen (EMA) Luc van Santvliet (EMA)
16:30	***Close of meeting***	