EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

25 November 2015
EMA/654468/2015
Stakeholders and Communication Division

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

25 November 2015, 09:00hrs to 17:15hrs – meeting room: 3E

Chair: Isabelle Moulon

Time	Agenda item	Speaker	Room
08:30	Registration and reimbursement arrangements		
09:00	Welcome and introduction / Health and safety information	I. Moulon	3E
1. Overview of the EMA and centralised procedure			
09:15	1.1 Description of objectives of Training day	I. Moulon	3E
09:30	1.2 How are medicines evaluated at the EMA – part I Overview of the medicines evaluation process with particular emphasis on where patients are involved up to marketing authorisation	N. Bere	3E
2. Breakout session I			
9:50	2.1 Setting the scene for the breakout session activities and division of participants into groups	M. Mavris	3E
10:00	2.2 Scientific Advice procedure Learning outcome: gain an understanding of the relevant areas where patients can contribute, such as meaningful clinical trial endpoints, feasibility of trial design, etc.	S. Vamvakas S. Aarum J. Moseley E. Manolis	3G;3H,3J,3K
10:55	Debrief on breakout session	All participants	3E
11:00	*Coffee Break (20 mins)*		

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3. Breakout session II			
11:20	3.1 CHMP Scientific Advisory Group meeting Learning outcome: to understand the ways in which patients can contribute to an ongoing assessment e.g. consideration of trade-off of benefits and risks and unmet needs/needs of population	F. Pignatti F. Butlen (tbc) M. Haas N. Bere	3G;3H,3J,3K
12:15	Debrief on breakout session (Room 3E)	All participants	3E
12:30	*Lunch (1 hour)*		
4. Breakout session III			
13:30	4.1 How are medicines evaluated at the EMA – part II Overview of medicines evaluation process post-marketing authorisation	N. Bere	3E
13:50	4.2 PRAC written consultation (safety issue) Learning outcome: to understand post-authorisation procedures, the types of safety issues that may arise as well how patients can contribute to assessment of acceptable risk for population concerned and to risk management and communication	E. Vatzaki T. Teixeira N. Bere V. Le Ber	3G;3H,3J,3K
14:45	Debrief on breakout session (Room 3E)	All participants	3E
5. Breakout session IV			
14:50	5.1 Document review – choice of EPAR summary or safety communication Learning outcome: to ensure that the documents are written appropriately for the target audience and that the information is clear and understandable	J. Garcia R. Gonzalez-Quevedo F. Castellani P. Blake	3G;3H,3J,3K
15:45	Debrief on breakout session (Room 3E)	All participants	3E
15:50	*Coffee break (20 minutes)*		
6. Feedback and conclusions			
16:10	6.1 Feedback and quiz	N. Bere / M. Mavris	3E
17:00	6.2 Conclusions	I. Moulon	3E
7. AOB			
17:15	*End of meeting*		