29 November 2016
EMA/636824/2016
Stakeholders and Communication Division

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

29 November 2016 – meeting room: 3E

08:30hrs registration, meeting start 09:00hrs to 17:15hrs

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. Morris-Jones V. Macolic Sarinic A. Tavridou J. Regnstroem T. Vetter	2B 3J 3H 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 M. Haas S. Sommer	2B 3J 3H 3E
12:20	*Lunch (1 hour)*		
4. Breakout session III			
13:20	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 A. Zanoletty V. Le Ber	2B 3J 3H 3E
14:50	*Coffee break (20 minutes)*		
5. Breakout session IV			
15:10	5.1 Document review – choice of EPAR summary or safety communication Learning outcomes: • Appreciate the aim and scope of the documents • Understand the structure of the documents • Feel confident about reviewing the documents	D. Mehta E. Scanlan M. Spanu I. Abed	2B 3J 3H 3E
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*		