

6 October 2017
EMA/662990/2017
Stakeholders and Communication Division

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

21 November 2017 – meeting room: 3E

08:30hrs registration, meeting start 09:00hrs to 16:15hrs

Chair: Juan Garcia Burgos

Time	Agenda item	Speaker	Room
08:30	Registration and reimbursement arrangements		
09:00	Welcome and introduction / Health and safety information	J. Garcia Burgos	3E
1. Overview of the EMA and centralised procedure			
09:10	1.1 Description of objectives of Training day	J. Garcia Burgos	3E
09:20	1.2 How are medicines evaluated at the EMA – part I Overview of the medicines evaluation process with particular emphasis on where patients, consumers and healthcare professionals are involved up to marketing authorisation	M. Mavris N. Bere	3E
09:40	1.3 Setting the scene for the breakout session activities and division of participants into groups	M. Mavris	3E
2. Breakout session I			
09:50	2.1 Scientific Advice procedure Learning outcome: gain an understanding of the relevant areas where patients, consumers and healthcare professionals can contribute, such as meaningful clinical trial endpoints, feasibility of trial design, etc.	S. Vamvakas K. Cunningham J. Moseley I. Lucas J. Regnstrom S. Aarum M. Chapelin	2B 2C 2E 2H
11:05	Coffee Break (20 mins)		

Time	Agenda item		Speaker	Room
3. Breakout session II				
11:25	3.1	CHMP Scientific Advisory Group meeting Learning outcome: to understand the ways in which patients, consumers and healthcare professionals can contribute to an ongoing assessment e.g. consideration of trade-off of benefits and risks and unmet needs/needs of population	J. Llinares F. Pignatti L. Guizzaro F. Butlen	2B 2C 2E 2H
12:40	Lunch (1 hour)			
4. Breakout session III				
13:40	4.1	How are medicines evaluated at the EMA – part II Overview of medicines evaluation process post-marketing authorisation	N. Bere M. Mavris	3E
14:00	4.2	Document review – choice of EPAR summary or safety communication Learning outcomes: <ul style="list-style-type: none">• Appreciate the aim and scope of the documents• Understand the structure of the documents• Feel confident about reviewing the documents	F. Castellani P. Blake N. Mbaeliachi E. Scanlan M. Spanu S. Cohen	2B 2C 2E 2H
15:15	Coffee break (20 minutes)			
5. Feedback and conclusions				
15:35	5.1	Feedback and quiz	M. Mavris N. Bere	3E
15:55	5.2	Conclusions	J. García Burgos	3E
6. AOB				
16:15	End of meeting			