EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

26 September 2013
EMA/437597/2013
Stakeholders and Communication

Patients/Consumers Working Party (PCWP) and Healthcare Professionals Working Party (HCPWP) joint meeting
Workshop on the patient's voice in the evaluation of medicines
Agenda

Chairs: June Raine (Chair of the Pharmacovigilance Risk Assessment Committee) and Isabelle Moulon (Head of Patients and Healthcare Professionals)

26 September 2013, 9:00hrs to 16:30hrs – meeting room: 4A

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

26 September 2013			
09:00		Registration and reimbursement arrangements	
09:10		Introduction and objectives	I. Moulon (EMA)
1. Patient input in medicine development and post-authorisation studies			
09:25	1.1	Working model of the European Community Advisory Board (ECAB); review report	D. Haerry (EATG)
09:45	1.2	a) Project results concerning measures of patients' benefit-risk preferences in the context of MS medicines b) PROTECT WP6 – EMA benefit/risk assessment project "visualisation and interpretation of results of b/r evaluations"	A. Beyer (EMA)
10:15	*Coffee*		
10:30	1.3	Patient involvement in benefit/risk during drug development - an industry perspective	R. Bergström / M. Rosenblatt (EFPIA)

7 Westferry Circus • Canary Wharf • London E14 4HB • United Kingdom
Telephone +44 (0)20 7418 8400 **Facsimile** +44 (0)20 7523 7129
E-mail info@ema.europa.eu **Website** www.ema.europa.eu

26 September 2013			
10:45	1.4	Scientific Advice / Protocol Assistance; experience and impact of patient involvement	K. Larsson (EMA) / M. Mavris (Eurordis)
11:15		General discussion	All
12:00	*Lunch*		
2. Patient input in evaluation of medicines			
13:00	2.1	Patient involvement in benefit/risk during drug licensing - an industry perspective	R. Bergström / T. Hoos (EFPIA)
13:15	2.2	Scientific Advisory Groups (SAG); experience and impact of patient involvement	F. Pignatti (EMA) / E. Briers (EUomo)
13:45		General discussion	All
14:30	*Coffee*		
3. Principles for involvement of patients in benefit/risk assessments at the EMA			
14:45	3.1	Patient involvement in the Pharmacovigilance Risk Assessment Committee (PRAC) & the Committee for Medicinal Products for Human Use (CHMP)	P. Salmon (CHMP) F. Houÿez (Eurordis) J. Ahlqvist Rastad (PRAC) A. van der Zeijden (IAPO)
15:15	3.2	Proposal document; involvement of patients in benefit/risk assessments at EMA	J. García Burgos (EMA) / C. Prieto (CHMP)
15:45		Discussion and conclusions	All
16:30	*End of meeting*		