



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

26 September 2013
EMA/422496/2013
Patient Health Protection

Agenda – Seventh Stakeholders forum on the implementation of the new Pharmacovigilance legislation

27 September 2013, 08.20-16.00, Room 3/A, European Medicines Agency (EMA)

Co-chairs: Fergus Sweeney (EMA) and June Raine (PRAC Chair)

Time	Agenda item	Speakers
07:50 – 08:20	Registration and reimbursement arrangements	
Session 1		
08:20 – 08:30	Welcome and Introduction	Fergus Sweeney (EMA) June Raine (PRAC Chair)
08:30 – 09:45	Implementing the Pharmacovigilance legislation: what has been achieved? - General update on implementation	Peter Arlett (EMA)
09:45 – 10:30	PRAC’s perspective on implementation	June Raine (PRAC Chair)
10:30 – 10:50	Coffee break	
10:50 – 12:00	Member States’ perspective on implementation	Marina Dimov Di Giusti (Croatia) Sabine Straus (The Netherlands)
12:00 – 12:45	Lunch break	



Session 2		
12:45 – 13:30	Patients' perspective on implementation	Patient Representatives – Francois Houyez (Eurordis) - European Organisation for Rare Diseases Kaisa Immonen-Charalambous (EPF) - European Patients' Forum Rafal Swierzewski (ECPC) - European Cancer Patient Coalition
13:30 – 14:30	Industry's perspective on implementation	Industry Representatives – Ana Maria Tomé - EGA Hubertus Cranz – AESGP Laurent Auclert - EFPIA
14:30 – 14:45	<i>Coffee break</i>	
14:45 – 15:30	Healthcare professionals' perspective on implementation	Healthcare Professional Representatives – Jean-Pierre Baeyens (EUGMS) – European Union Geriatric Medicine Society Erzsebet Podmaniczky (CPME) – Standing Committee of European Doctors John Chave (PGEU) – Pharmaceutical Group of the European Union
15:30 – 15:45	Questions and Answers	
15:45 – 16:00	Conclusion	
16:00	<i>Close of meeting</i>	