



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

10 September 2014
EMA/449800/2014
Inspections and Human Medicines Pharmacovigilance Division

Agenda – Eighth Stakeholders forum on the implementation of the Pharmacovigilance legislation: Building on two years of operation

15 September 2014, 12.30-18.00, Room 2/A, European Medicines Agency (EMA) -
30 Churchill Place, Canary Wharf, London, E14 5EU, UK

Time	Agenda item		Speakers
12:00 – 12:30 <i>Registration and reimbursement arrangements</i>			
Session 1 – Building on two years of operation – looking to the future			
Session 1 - Co-Chairs: June Raine (PRAC Chair) and Fergus Sweeney (EMA)			
12:30 – 12:40	Welcome and Introduction		
12:40 – 14:00	• Building on two years of operation • Two years of operation of the Pharmacovigilance Risk Assessment Committee • Strengthening Collaboration for Operating Pharmacovigilance in Europe (SCOPE) Joint Action • Complementary initiatives for public health • Open discussion	Peter Arlett (EMA) June Raine (PRAC Chair) Paul Barrow (MHRA, UK) Franck Diafouka (EMA)	



Session 2 – Data collection		
Session 2 - Co-Chairs: Almath Spooner (PRAC Vice-Chair) and Peter Arlett (EMA)		
14:00 – 15:30	• Patient reporting update • Looking to the future: use of smart phones and beyond • Increasing access to ADR reports on the Web • Update on Post-Authorisation Safety Studies • Update on Post-Authorisation Efficacy Studies • Open discussion	François Houyez (EURORDIS) Mick Foy (MHRA, UK) Steven Le Meur (EMA) Almath Spooner (PRAC Vice-Chair) Kevin Blake (EMA) and Jane Moseley (EMA)
15:30 – 16:00 <i>Coffee break</i>		
Session 3 – Process improvement for public health and product lifecycle support		
Session 3 - Co-Chairs: Almath Spooner (PRAC Vice-Chair) and Peter Arlett (EMA)		
16:00 – 17:00	• Projects to deliver better IT systems and business change management • Translating regulatory science into better processes • EMA literature monitoring service • Open discussion	Peter Arlett (EMA) Xavier Kurz (EMA) Sabine Brosch (EMA)
Session 4 – Engaging with stakeholders		
Session 4 - Co-Chairs: June Raine (PRAC Chair) and Peter Arlett (EMA)		
17.00 – 17.45	• Strengthening interaction with stakeholders • Involving Patients and Health Care Professionals in benefit risk decision-making • Public hearings – consultation on PRAC procedures • Open discussion	Marie-Agnes Heine (EMA) Nathalie Bere (EMA) and Hildrun Sundseth (EIWH) Monika Benstetter (EMA) and June Raine (PRAC Chair)
17:45 – 18:00	Conclusion	
18:00	<i>Close of meeting</i>	