



EUROPEAN MEDICINES AGENCY  
SCIENCE MEDICINES HEALTH

5 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	<ul style="list-style-type: none"><li>• Building on two years of operation</li><li>• Two years of operation of the Pharmacovigilance Risk Assessment Committee</li><li>• Strengthening Collaboration for Operating Pharmacovigilance in Europe (SCOPE) Joint Action</li><li>• Complementary initiatives for public health</li><li>• Open discussion</li></ul>	<p>Peter Arlett (EMA)</p> <p>June Raine (PRAC Chair)</p> <p>Paul Barrow (MHRA, UK)</p> <p>Franck Diafouka (EMA)</p>	



Session 2 – Data collection		
Session 2 - Co-Chairs: Almath Spooner (PRAC Vice-Chair) and Peter Arlett (EMA)		
14:00 – 15:30	<ul style="list-style-type: none"> <li>• Patient reporting update</li> <li>• Looking to the future: use of smart phones and beyond</li> <li>• Increasing access to ADR reports on the Web</li> <li>• Update on Post-Authorisation Safety Studies</li> <li>• Update on Post-Authorisation Efficacy Studies</li> <li>• Open discussion</li> </ul>	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	<ul style="list-style-type: none"> <li>• Projects to deliver better IT systems and business change management</li> <li>• Translating regulatory science into better processes</li> <li>• EMA literature monitoring service</li> <li>• Open discussion</li> </ul>	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	<ul style="list-style-type: none"> <li>• Strengthening interaction with stakeholders</li> <li>• Involving Patients and Health Care Professionals in benefit risk decision-making</li> <li>• Public hearings – consultation on PRAC procedures</li> <li>• Open discussion</li> </ul>	Marie-Agnes Heine (EMA)  Nathalie Bere (EMA) and Hildrun Sundseth (EIWH)  Monika Benstetter (EMA) and June Raine (PRAC Chair)
17:45 – 18:00	<b>Conclusion</b>	
18:00	<i>Close of meeting</i>	