



14 September 2017  
EMA/303132/2017  
Inspections and Human Medicines Pharmacovigilance Division

## Agenda – Eleventh Stakeholder forum on the Pharmacovigilance legislation

21 September 2017, 10:00-16:00, Room 2/A, European Medicines Agency (EMA) - 30 Churchill Place, Canary Wharf, London, E14 5EU, UK

Time	Agenda item	Speakers
<i>09:30 – 10:00 Registration and reimbursement arrangements</i>		
<b>Session 1 – Building on five years of operation</b>		
10:00 – 10:10	Welcome and Introduction	Fergus Sweeney (EMA)
Session 1 - Co-Chairs: Almath Spooner (HPRA) and Fergus Sweeney (EMA)		
10.10-10.40	<ul style="list-style-type: none"><li>PRAC – 5 years of operation</li></ul>	June Raine (PRAC chair, MHRA)
10.40-10.55	Open discussion	
10.55-11.20	<ul style="list-style-type: none"><li>Activities report from SCOPE (The Strengthening Collaboration for Operating Pharmacovigilance in Europe) Joint Action</li></ul>	Louise Loughlin (MHRA)
11.20-11.45	<ul style="list-style-type: none"><li>How patient and healthcare professionals can be involved in public hearings</li></ul>	Juan Garcia Burgos (EMA)
11.45-12.00	Open discussion	
<i>12.00- 13.00 Lunch break</i>		



Time	Agenda item	Speakers
<b>Session 2 - Improvements for public health</b>		
Session 2 - Co-Chairs: Rafal Swierzewski (ECPC) and Xavier Kurz (EMA)		
13.00-13.15	<ul style="list-style-type: none"> <li>Eudravigilance – new functionalities and EudraVigilance access policy (patient access)</li> </ul>	Sabine Brosch (EMA)
13.15-13.30	<ul style="list-style-type: none"> <li>Signal management process</li> </ul>	Georgy Genov (EMA)
13.30-13.45	<ul style="list-style-type: none"> <li>Registries Initiative: lessons learned from the recent workshops</li> </ul>	Xavier Kurz (EMA)
13.45-14.10	<ul style="list-style-type: none"> <li>Disease registries: patients' perspective</li> </ul>	Jana Hlavacova (EMSP) Christoph Thalheim (EMSP)
14.10-14.30	Open discussion	
<i>14.30 – 15.00 Coffee break</i>		
<b>Session 3 - Looking to the future</b>		
Session 3 - Co-Chairs: June Raine (MHRA) and Georgy Genov (EMA)		
15.00-15.30	<ul style="list-style-type: none"> <li>Future opportunities for Pharmacovigilance</li> </ul>	Almath Spooner (HPRA)
15.30-15.45	Open discussion	
<b>15:45 – 16:00</b>	<b>Conclusions</b>	J.Raine (MHRA)/G.Genov (EMA)
<i>16:00 Close of meeting</i>		