

15 September 2015
EMA/499552/2015
Inspections and Human Medicines Pharmacovigilance Division

Agenda – Ninth Stakeholder forum on the Pharmacovigilance legislation:

Observations on 3-years of operation and opportunities for the future

15 September 2015, 13.30-18.00, Room 2/A, European Medicines Agency (EMA) - 30 Churchill Place, Canary Wharf, London, E14 5EU, UK

Time	Agenda item	Speakers
13:00 – 13:30 <i>Registration and reimbursement arrangements</i>		
Session 1 – Building on three years of operation		
Session 1 - Co-Chairs: June Raine (PRAC Chair) and Fergus Sweeney (EMA)		
13:30 – 13:40	Welcome and Introduction	
13:40 – 14:00	Overview of 3-years of operation	Peter Arlett (EMA)
14:00 – 14:15	<ul style="list-style-type: none"> • Perspectives on: key achievements, areas of improvements and priorities for the future work <ul style="list-style-type: none"> – Members States – Industry 	Sabine Straus (CBG-MEB, NL)
14:15 – 14:30	<ul style="list-style-type: none"> – Patients 	Sini Eskola (on behalf of the Industry Associations, EFPIA)
14:30 – 14:45	<ul style="list-style-type: none"> – Health care professionals 	Albert van der Zeijden (Patients representative in PRAC)
14:45 – 15:00	<ul style="list-style-type: none"> – Academia 	Kirsten Myhr (HCPs representative in PRAC)
15:00 – 15:15		Marie Louise (Marieke) De Bruin (Utrecht Institute for Pharmaceutical Sciences, NL)

Time	Agenda item	Speakers
15:15 – 15:45	<ul style="list-style-type: none"> Open discussion – Panel 	Session speakers, co-chairs, PCWP chair, Representatives from Industry associations, PhV projects' representatives
15:45 – 16:15 <i>Coffee break</i>		
Session 2 –Further improvements and new opportunities		
Session 2 - Co-Chairs: Almath Spooner (HPRA) and Peter Arlett (EMA)		
16:15 – 16:30	<ul style="list-style-type: none"> Overview of key improvements 	June Raine (MHRA)
16:30 – 16:45	<ul style="list-style-type: none"> Public hearings – becoming a reality 	Isabelle Moulon (EMA)
16:45 – 17:00	<ul style="list-style-type: none"> Improving processes – referrals as a case study 	Ulla Wändel Liminga (MPA, SE)
17:00 – 17:15	<ul style="list-style-type: none"> Assessments for maximum utility: transparency supporting our work 	Juan Garcia (EMA)
17:15 - 17:45	<ul style="list-style-type: none"> Working together - Open panel discussion 	Session speakers, co-chairs, PCWP chair, HCPWP chair, Representatives from Industry associations
17:45 – 18:00 Conclusions and future communications		
18:00	<i>Close of meeting</i>	