



8 September 2016
EMA/348709/2016
Inspections and Human Medicines Pharmacovigilance Division

Draft Agenda – Tenth Stakeholder forum on the Pharmacovigilance legislation

21 September 2016, 09.00-13.00, Room 3/E, European Medicines Agency (EMA) - 30 Churchill Place, Canary Wharf, London, E14 5EU, UK

Time	Agenda item	Speakers
<i>08:30 – 09:00 Registration and reimbursement arrangements</i>		
Session 1 – Pharmacovigilance legislation - what has been achieved and future priorities		
09:00 – 09:15	Welcome and Introduction Guido Rasi (EMA)	
Session 1 - Co-Chairs: June Raine (PRAC Chair) and Fergus Sweeney (EMA)		
09:15 – 10:15	<ul style="list-style-type: none">3-year report on Pharmacovigilance activities	Helen Lee, European Commission
	<ul style="list-style-type: none">Scanning the horizon for 2016 – 2018	Peter Arlett, EMA
	<ul style="list-style-type: none">Activities report from SCOPE (The Strengthening Collaboration for Operating Pharmacovigilance in Europe) Joint Action	June Raine, MHRA, UK
	<ul style="list-style-type: none">Pharmacovigilance Impact – for better pharmacovigilance	Almath Spooner, HPRA, IE
10:15 – 10:30	Open panel discussion	Session speakers, co-chairs, PCWP representative, HCPWP representative, Representatives from Industry associations
<i>10:30 – 11:00 Coffee break</i>		



Time	Agenda item	Speakers
Session 2 - Regulatory science driving better Pharmacovigilance		
Session 2 - Co-Chairs: June Raine (PRAC Chair) and Peter Arlett (EMA)		
11:00 – 11:30	<ul style="list-style-type: none"> Turning regulatory science into better pharmacovigilance: experience from the PROTECT project 	Xavier Kurz, EMA
	<ul style="list-style-type: none"> Harnessing mobile apps and social media for product safety 	Philip Tregunno, MHRA, UK
11:30 – 11:45	Open panel discussion	Session speakers, co-chairs, PCWP representative, HCPWP representative, Representatives from Industry associations
Session 3 - Lifecycle Pharmacovigilance planning for public health		
Session 3 - Co-Chairs: Almath Spooner (HPRA) and Peter Arlett (EMA)		
11:45 – 12:30	<ul style="list-style-type: none"> Introduction: planning is key to product development and safe and effective use of products 	Almath Spooner, HPRA, IE and Peter Arlett, EMA
	<ul style="list-style-type: none"> Scientific Advice delivers planning during development 	Spiros Vamvakas, EMA
	<ul style="list-style-type: none"> Epidemiology as an enabler for health 	Alison Cave, EMA
	<ul style="list-style-type: none"> Actions from the Risk Minimisation Measures Workshop in 2015 	Jamie Wilkinson, PGEU
12:30 – 12:45	Open panel discussion	Session speakers, co-chairs, PCWP representative, HCPWP representative, Representatives from Industry associations
12:45 – 13:00 Conclusions		
13:00	<i>Close of meeting</i>	