EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

25 May 2012
EMA/284201/2012

Agenda – fifth Stakeholders forum on the implementation of the new Pharmacovigilance legislation

25 May 2012, 9.00-17.00pm, room 3A

Co-chairs: June Raine (morning) / Peter Arlett (afternoon)

Time	Agenda item	Speakers
08:00 – 09:00	*Registration and reimbursement arrangements*	
09:00 – 09:15	**Welcome and introduction**	**Noel Wathion** *European Medicines Agency*
09:15 – 10:00	**Update on implementation: July 2012**	
	Pharmacovigilance: where we have come from	**June Raine** *Pharmacovigilance Working Party*
	Planning and processes	**Peter Arlett** *European Medicines Agency*
10:00 – 10.30	**Update on European Commission's implementing regulation**	**Florian Schmidt** *European Commission*
10:30 – 10:45	*Coffee break*	
10:45 – 11:30	**Session on Good Vigilance Practice**	
	Key themes from the consultation and next steps	**Priya Bahri** *European Medicines Agency*
11:30 – 12:30	**Session on identification and traceability of biological products**	
	Introductory remarks and international initiatives	**Sabine Brosch** *European Medicines Agency*
	Challenges and perspectives from a Regulatory viewpoint	**Sabine Straus** *Medicines Evaluation Board, Netherlands*

7 Westferry Circus • Canary Wharf • London E14 4HB • United Kingdom
Telephone +44 (0)20 7418 8400 **Facsimile** +44 (0)20 7418 8416
E-mail info@ema.europa.eu **Website** www.ema.europa.eu

	Views from the European Generic medicines Association	**Suzette Kox** *European Generic medicines Association*
	Views from the European Federation of Pharmaceutical Industries and Associations/European Biopharmaceutical Enterprises	**Peter De Veene** *European Federation of Pharmaceutical Industries and Associations/European Biopharmaceutical Enterprises*
12:30 – 13:30	*Lunch break*	
13:30 – 14:15	**Feedback on questions received**	
	Questions and Answers – focus on transitional arrangements	**Christelle Bouygues** *European Medicines Agency*
14:15 – 15:30	**General update session**	
	Risk Management Plans summaries	**Juan Garcia** *European Medicines Agency*
	Pharmacovigilance and Risk Assessment Committee	**Sheila Kennedy** *European Medicines Agency*
15:30 – 15:45	*Coffee break*	
15:45 – 16:45	**General update session**	
	'Article 57' implementation	**Ilaria Del Seppia** *European Medicines Agency*
	Additional monitoring and black symbol	**Mick Foy** *Medicines and Healthcare products Regulatory Agency, UK*
16:45 – 17:00	**Conclusions**	**Co-chairs**
17:00	*Close of meeting*	