



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

8 November 2012
EMA/652724/2012
Patient Health Protection

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

8 November 2012, 9.00-17.00pm, room 3A, European Medicines Agency (EMA)

Co-chairs: **Morning:** June Raine/Noel Wathion; **Afternoon:** Almath Spooner/Noël Wathion

Time	Agenda item	Speakers
08:00 – 09:00	Registration and reimbursement arrangements	
09:00 – 09:15	Welcome and introduction	Noël Wathion (EMA)
09:15 – 09:45	Update on implementation: key achievements and GVP development	Franck Diafouka (EMA)
09:45 – 10:45	Session on Good pharmacoVigilance Practice - key themes from public consultations: • GVP module III - Inspections • GVP module X - Additional monitoring • GVP module IV - Pharmacovigilance audits • GVP module XV - Safety communication	Suvi Loikkanen (Finland) Mick Foy (United Kingdom) Edit Weidlich (EMA) Jane Ahlqvist-Rastad (Sweden) Juan Garcia (EMA)
10:45 – 11:00	Coffee break	
11:00 – 11:30	Update from European Commission	Helen Lee (European Commission)
11:30 – 13:00	Session on 'first experiences': • Functioning of PRAC • Publication of PRAC agendas and minutes, safety communication and notification of referrals • Publication of lists: EURD and signals • Black symbol and product information	Almath Spooner (PRAC, Vice-Chair) June Raine (PRAC, Chair) Kelly Brown (EMA) Alexios Skarlatos (EMA)
13:00 – 14:00	Lunch break	
14:00 – 15:00	Session on discussion and feedback on	



	experience to date: Perspective from patients, healthcare professionals and industry representatives: • Patients representative • Healthcare professionals representative • Industry representatives	David Haerry Jūratė Švarcaite Laurent Auclert/Val Simmons
15:00 – 15:30	Session on signals and emerging safety issues: • Signal management • Emerging safety issues	Sabine Straus (Netherlands) Georgy Genov (EMA)
15:30 – 16:00	Questions and Answers session: • EU PASS registry • Reporting of Adverse Drug Reactions • Questions & Answers	Xavier Kurz (EMA) Gilles Touraille (EMA) Christelle Bouygues (EMA)
16:00 – 16:15	<i>Coffee break</i>	
16:15 – 16:45	Session on 'looking forward'	Peter Arlett (EMA)
16:45 – 17:00	Conclusions	Co-chairs
17:00	<i>Close of meeting</i>	