



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

23 May 2013
EMA/810501/2012
Patient Health Protection

Patients/Consumers Working Party (PCWP) and Healthcare Professionals Working Group (HCP WG) joint meeting Agenda

Chair: Isabelle Moulon - Head of Medical Information

27-28 February 2013 – Conference room: 4A

European Medicines Agency - 7, Westferry Circus, Canary Wharf, London E14 4HB

27 February 2013

13:00	Registration and reimbursement arrangements		
13:30	Welcome and introduction Health and safety issues Conflicts of interest / Adoption of the agenda Announcements		I. Moulon (EMA)
1. Legislation on falsified medicines			
13:35	1.1 Update on the implementation of the new legislation on falsified medicines	For information	S. Führung (European Commission)
2. Area of communication and information			
14:05	2.1 Communication on safety referrals 2.1.1 Communication following PRAC, CMD(h) & CHMP 2.1.2 Involvement of PCOS and HCPOs	For information and discussion	R. Harding (EMA) N. Bere (EMA)
14:35	2.2 Risk communication on medicines 2.2.1 Risk communication in a more transparent regulatory environment 2.2.2 Feedback from the 'Ditchley Group' 2.2.3 Global lessons learnt from the <i>Drug Safety</i> Risk Communication theme issue	For information and discussion	F. Boudier (Maastricht University) D. Haerry (EATG) P. Bahri (EMA)
16:00	<i>Coffee Break</i>		
16:15	2.3 Dissemination of new information on medicines – the example of Insulin degludec	For information	I. Silva (EMA)
16:25	2.4 EMA Online Roadmap	For information	S. Weatherley (EMA)



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3. Area of pharmacovigilance

17:00	3.1 EMA workshop on medication errors	For information	T. Goedecke (EMA)
17:30	3.2 Additional monitoring of medicinal products 3.2.1 Update of the implementation 3.2.2 Communication of additional monitoring	For information For information	A. Skarlatos (EMA) D. Glanville (EMA)
18:15	<i>End of first day</i>		

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4. Area of involvement in EMA activities

09:00	4.1 EMA policy on conflicts of interest – update	For information	J. Garcia Burgos (EMA)
09:30	4.2 Involvement of children and young people in the work of the paediatric committee	For information and discussion	E. H. Davies (EMA)
10:00	4.3 Urgent Union Procedure – stakeholders’ submission form	For information	H. Matos (EMA)
10:15	<i>Coffee Break</i>		
10:30	4.4 EMA Scientific Advice 4.4.1 Patient involvement in Scientific Advice 4.4.2 Patient involvement in protocol assistance	For information and discussion	J. Moseley (EMA) M. Mavris (EURORDIS)

5. Area of clinical trials

11:30	5.1 Release of data from clinical trials – feedback from EMA workshop	For information	F. Pignatti (EMA)
12:00	5.2 EU-CTR and EudraCT 5.2.1 General update 5.2.2 EudraCT V9 Results Simple form	For information and discussion	A. Rodriguez Sanchez Beato (EMA)

6. AOB

12:25	6.1 Revised PCWP mandate and rules of procedure	For adoption	N. Bere (EMA)
12:40	AOB		
12:45	<i>Close of meeting</i>		