



22 June 2011
EMA/177671/2011
ENCePP Secretariat

Draft agenda - 7th ENCePP Plenary Meeting

30 June 2011, 09.30 to 16.30, room 2A

Chairperson: Peter Arlett

Time	Item	Name
09.30	1. General Matters 1.1 Welcome and introductory remarks 1.2 Adoption of agenda	Chair
09.45	2. Report from the Steering Group 2.1 Feedback from Task Force "Access to data" 2.2 Feedback from Journalist Editor Workshop 2.3 Results of the ENCePP Partners Survey	H. Dolk M. Sturkenboom D. Haerry
10.10	3. Open discussion 3.1 Barriers to entering data sources into the database 3.2 Specialist networks and ENCePP 3.3 Plenary Survey: List of suggestions for funding topics – next steps	all K. Blake J. Raine H. Fitt
~ 11.00	COFFEE BREAK (20 minutes)	
11.20	4. Definition of non-interventional clinical trials 4.1 Presentation of ENCePP Position paper 4.2 Update on EC Consultation on revision of Clinical Trials Directive	G. Schnetzler K. Blake
11.40	5. Synergies between ENCePP and Health Technology Assessment (HTA) 5.1 Effectiveness research based on common protocols/ methodologies 5.2 Views from HTA 5.3 Discussion	U. Bergman A. Solesse
~ 12.30	LUNCH (60 minutes)	
13.30	6. International initiatives on post authorisation safety monitoring of drugs 6.1 An update from the FDA 6.2 An update from Health Canada 6.3 Q & A	G. Zornberg R. Liteplo



Time	Item	Name
14.10	7. The Rosiglitazone Story 7.1 Motivation for an ENCePP study & Impact of regulatory action 7.2 ENCePP Study	X. Kurz V. Ehrenstein
~14.40	COFFEE BREAK (20 minutes)	
15:00	8. Session on Methodology 8.1 Meta-analysis and pooling of data 8.2 Discussion	M. Sturkenboom & N. Qizilbash
16.00	Summary of discussions & next steps	Chair
16.10	A.O.B - Pre-announcement of SG Elections (November Plenary)	Chair
16.30	Close of meeting	