EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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ENCePP Secretariat

European Network of Centres for Pharmacoepidemiology and Pharmacovigilance

Draft agenda - 15th ENCePP Plenary Meeting

22 November 2016, 09.30 to 16.30, room 3A

Chairs: Xavier Kurz & Susana Perez-Gutthann

Time	Item	Name
09.30	**1. General Matters**	
	1.1 Welcome and adoption of agenda	Chairs (10')
09.40	**2. Report from the Steering Group**	
	2.1. Report from the ENCePP Steering Group ➢ *Key achievements 2016 & Looking ahead* ➢ *Personal reflections of the SG Chair on ENCePP impact to date, successes/failures, going forward* 2.2. Discussion / Q&A	Susana Perez-Gutthann (30')
	3. Report from Working Groups	
	3.1. Report from WG1 'Research Standards and Guidances'	Alejandro Arana (5')
	3.2. Report from SIG 'Drug Research in Pregnancy'	Laura Yates (5')
	3.3. Report from SIG 'Impact of PhV activities'	Agnes Kant (5')
	3.4. Q&A	Plenary (5')
10.30	**4. Election of ENCePP Partners to the Steering Group**	
	4.1. Explanation of election procedure	Thomas Goedecke (5')
	4.2. Secret Ballot	ENCePP Plenary (10')
10.45	***COFFEE BREAK** (30 minutes)*	
11.15	**5. The role of pharmacoepidemiology in medicines regulation** ➢ *This session aims at stimulating discussion in the context of the current general approach within regulatory bodies to increase use of pharmacoepidemiology ("real-world evidence") in benefit-risk evaluation and decision-making, i.e. to be less dependent of studies done by industry.*	
	5.1. 50 years of pharmacovigilance: unfinished job • *Q&A*	Joan-Ramon Laporte (30')
	5.2. Identifying opportunities for 'Big data' in medicines development and regulatory science ➢ *Outcomes from the EMA workshop on 'Big data' which took place on 14-15 November 2016.* • Q&A	Alison Cave (30')
	5.3. Meta-analysis of safety – thoughts from CIOMS X	Stephen Evans (30')

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Time	Item	Name
	• Q&A	
	5.4. Discussion	Plenary (30')
13.15	***LUNCH** (45 minutes)*	
14.00	**Announcement of election result**	Chair (10')
14.10	**6. Methods in Pharmacoepidemiology**	
	6.1. EURO-SALT - a study of drug exposed acute liver injury in European transplant centres • Q&A	Sinem Ezgi Gulmez (15')
	6.2. The *Salford Lung Study* • Q&A	Tjeerd van Staa (15')
	6.3. Discussion of methods and issues	Plenary (30')
15.10	***COFFEE BREAK** (15 minutes)*	
15.25	**7. Recent developments in EMA activities**	
	7.1. Framework of collaboration between EMA and Academia ➢ *Update on the EMA initiative to implement the strategic priority of establishing a greater collaboration with Academia.* • Q&A	Isabelle Moulon (15')
	7.2. Scientific guidance on post-authorisation efficacy studies • Q&A	Kevin Blake (15')
	7.3. Update on the new General Data Protection Regulation (GDPR) ➢ *The new data protection law reform has been adopted in May 2016; together with Regulation (EU) 679/2016 ('GDPR') it will have a big impact on processing of health data. This high-level overview will cover changes introduced by the GDPR in particular with regard to health data/research purposes.* • Q&A	Alessandro Spina (20')
	7.4. ENCePP Seal studies and imposed PASS: new compliance and disclosure measures • Q&A	Xavier Kurz (15')
16.30	**Summary of discussions & Close of meeting**	Chairs