



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

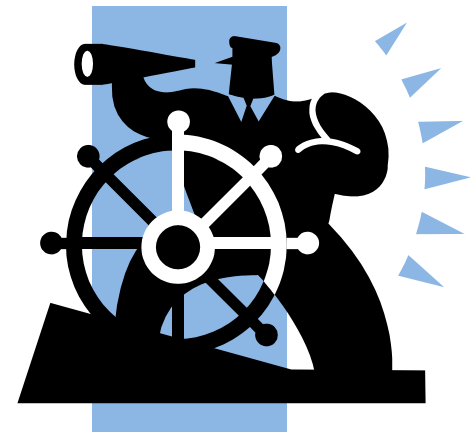


European Network of Centres
for Pharmacoepidemiology and Pharmacovigilance

Report from the Steering Group

ENCePP Plenary Meeting, 3 May 2012

Presented by: Nicola Magrini
Deputy Chair - ENCePP Steering Group



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Steering Group 2012/2013



No.	Representing	Name	Affiliation
1	ENCePP	Morten Andersen	Karolinska Institutet, Centre for Pharmacoepidemiology/Department of Medicine, Sweden
2	ENCePP	Alfonso Carvajal	Universidad de Valladolid, Spain
3	ENCePP	Corinne de Vries	Department of Pharmacy & Pharmacology, University of Bath, UK
4	ENCePP	Nicola Magrini (Deputy Chair)	CeVEAS Centre for the Evaluation of the Effectiveness of Health Care, Italy
5	ENCePP	Susana Perez-Gutthann	RTI Health Solutions, Spain
6	ENCePP	Miriam Sturkenboom	Erasmus Medical Centre, Netherlands
7	EMA	Peter Arlett (Chair)	European Medicines Agency
8	EMA	Stella Blackburn	European Medicines Agency
9	EMA	Henry Fitt	European Medicines Agency
10	HMA	Jytte Lyngvig	Sundhedsstyrelsen – National Board of Health, Denmark
11	CHMP	Hubert Leufkens	College ter Beoordeling van Geneesmiddelen, Netherlands
12	COMP	Ana Corrêa Nunes	INFARMED, Portugal
13	CHMP PhVWP	June Munro Raine	Medicines and Healthcare Products Regulatory Agency, UK
14	PCWP	David Haerry	European AIDS Treatment Group, Brussels, Belgium
15	ISPE	Yola Moride	Faculty of Pharmacy, Université de Montréal, Canada
16	ISoP	Nicholas Moore	Université Victor Segalen, Departement de Pharmacologie (INSERM), France
Observer	EFPIA	Laurent Auclert	Sanofi-aventis R&D, France



1st SG Meeting: 21 March 2012

Major issues arising for action:

1. Evidence integration/pooling of data

- Draft concept paper on the development of guidance on data integration (WG1)
- Review of ENCePP Guide relating to existing guidance on data integration (WG1 & WG3)
- Recommendations for structural measures to facilitate data integration (WG3)

2. Data Protection – new data privacy legislation

- Develop definitions for ‘aggregated’ and ‘non-identifiable’ data (WG3)
- Develop best practice for operational rules to protect personal data (WG3)
- Liaise with WG1 relating to impact of changes on data protection on methodologies currently in the Guide (WG3)

3. Establishment of ENCePP-HTA Task Force



1st SG Meeting: 21 March 2012

Key issues arising for further discussion by Steering Group:

- Further development of funding models to support observational research: **dedicated SG teleconference to take place**
- Approaches to optimising ENCePP with possible networks within the network: **for discussion later in to-day's Plenary to inform SG**
- Early draft European Medicines Regulatory Network Strategy to Optimise Informed Regulatory Decision-Making: **SG to input into a more mature document**



Ongoing work

Milestones & Deliverables (Work Plan 2011-2012)

- Continued review of the Code of Conduct in line with experience gained with ENCePP studies: **early days yet**
- 1st revision of ENCePP Guide on Methodological Standards ahead of implementation of Good Pharmacovigilance Practice (GVP) July 2012
- Continued development of approaches to facilitate the conduct of multi-source studies in terms of processes and data protection
- Further definition of the role of ENCePP and the interface with regulatory decision-making
- Continued impact analysis of ENCePP on research practices



Looking ahead: optimising ENCePP



- Elaboration and adoption of Work Plan 2013-2014
- Increased frequency of WG meetings to optimise output

⇒ 2006 – 2010 establishment
⇒ 2011 – 2012 consolidation
⇒ 2013 – 2014 **optimisation**



Looking ahead – Meeting dates

- Next meeting of SG: 6 July 2012 (Vitero)

++ UPDATE ++

New date for 2nd 2012 Plenary: **Thursday, 11 October 2012**