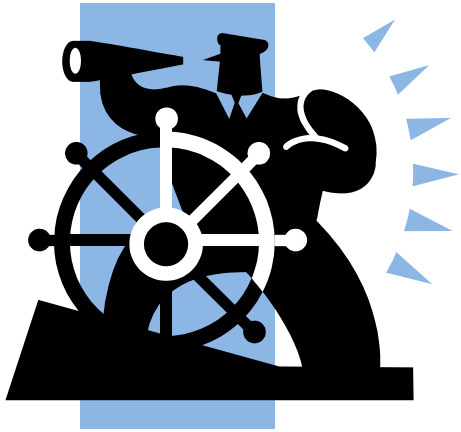
EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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

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