EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

European Network of Centres for Pharmacoepidemiology and Pharmacovigilance

11 July 2013
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ENCePP Secretariat

Meeting Report - ENCePP Steering Group & Industry Associations

22 May 2013, 14.00 to 16.30, co-chaired by ENCePP & EFPIA

List of participants

See Annex.

Executive summary

The overarching objective of the meeting was to stimulate further collaboration between the European Network of Centres for Pharmacoepidemiology and Pharmacovigilance (ENCePP) and the pharmaceutical industry. In line with this, the key discussions at the meeting related to exploring the means of enhancing the utility of the network's outputs for industry to conduct methodologically robust post-authorisation studies in a transparent and scientifically independent manner.

While ENCePP and, in particular, the network's methodological guidance were generally well-received by industry, a clear need was identified for ENCePP to further engage with industry. Key issues highlighted related to:

- aspects of the provisions of the ENCePP Code of Conduct;
- the potential particular utility of the network to small and medium sized enterprises (SMEs) in the context of such organisations having fewer in-house pharmacoepidemiology resources;
- the potential for ENCePP to bridge requirements of stakeholders in 'real-life' effectiveness research; and,
- how the work undertaken by industry pharmacoepidemiologists in commissioned research might be acknowledged, including in publications and in the ENCePP Register of Studies.

It was concluded that the ENCePP Steering Group would reflect on potential lessons learned from the discussions for consideration by the ENCePP Steering Group in the context of increasing visibility of the network to industry, enhancing shared values and building trust. The outcomes of the Steering Group

7 Westferry Circus ● Canary Wharf ● London E14 4HB ● United Kingdom
Telephone +44 (0)20 7418 8400 **Facsimile** +44 (0)20 7418 8660
E-mail encepp_secretariat@ema.europa.eu **Website** www.encepp.eu

considerations would be shared with industry associations. A specific proposal to be further considered was for the formation of a joint ENCePP-industry working group.

Discussion

The co-Chairs welcomed the delegates and thanked them for their responses to the ENCePP survey of industry conducted in April 2013. The agenda was adopted without changes.

Presentation – ENCePP and the new pharmacovigilance legislation

A representative of the European Medicines Agency presented the interface between ENCePP and the new pharmacovigilance legislation focussing on regulatory requirements for post-authorisation safety and efficacy studies (PASS/PAES), PASS oversight and transparency measures. Relevant ENCePP resources were highlighted including those cited in the good pharmacovigilance practices (GVP) module VIII on post-authorisation studies and the ENCePP register of studies, which currently serves as the 'EU PAS Register'. The presentation was followed by a Q&A session on aspects of the information presented.

This introductory presentation was followed by a tour de table of all attendees.

Results of the ENCePP survey of industry associations

A member of the ENCePP Secretariat presented an overview of the responses received to the ENCePP survey. The survey had been undertaken in the first instance to facilitate discussion at this meeting. It also served to establish a baseline in how industry pharmacovigilance and pharmacoepidemiology colleagues perceive ENCePP as relevant to their work and whether they use its various outputs in practice. The presentation concluded with some key points to focus further discussions.

The ENCePP Seal: Examples of industry experience

Two industry representatives spoke informally on their experiences in having studies granted an ENCePP Study Seal, including in terms of how the idea came about and how industry and ENCePP researchers involved collaborated in practice. Both described important real life considerations in undertaking joint industry-ENCePP partner research. They highlighted the importance of clear definitions, and dialogue around potential misunderstandings around aspects of the Code of Conduct, in particular relating to access to data.

EFPIA members' perspective on ENCePP

A representative from the European Federation of Pharmaceutical Industry Associations (EFPIA) presented a summary of the association's view of ENCePP and opportunities for improvements. Points raised included the need for ENCePP to increase visibility on how it could add value to the work of industry, including by helping to collect data from real-life use of medicinal products, avoiding duplication of studies and saving resources. It was also raised that ENCePP should build on the acquired experience to foster its activities in areas such as the design and performance of real-life studies bringing together various stakeholders and the definition of methods for comparative studies for health technology assessment (HTA).

Conclusion

This first dedicated meeting of ENCePP with industry was acknowledged as having led to meaningful discussion. It was decided to prioritise consideration of the following aspects:

- How ENCePP might further engage with industry through increased dialogue and jointly exploring ways of improving its usefulness to industry e.g. through the establishment of a joint ENCePP-industry working group.
- The role of the ENCePP Steering Group observer from pharmaceutical industry (EFPIA) as an important link for dialogue.
- The need for a review of the Code of Conduct and application of the ENCePP Study Seal concept led by the existing ENCePP Working Group on Independence and Transparency.

It was noted that additional aspects for review might arise following ENCePP Steering Group discussion of the feedback received from industry colleagues.

ENCePP Meeting with industry associations

List of Participants

22 May 2013, 14.00 to 16.30, meeting room 4A, EMA, London

N	Association	Last Name	First Name	Affiliation
1	EuropaBIO	Asiimwe	Alex	Lilly
2	EFPIA	Auclert	Laurent	Sanofi & ENCePP SG Observer
3	EuropaBIO	Baril	Laurence	GSK
4	EFPIA	Bate	Andrew John	Pfizer
5	VaccinesEurope	Bauchau	Vincent	GSK
6	EuropaBIO	Buffels	Regine	Genzyme
7	EuropaBIO	Busch-Sorensen	Michael	MSD
8	VaccinesEurope	Caspard	Herve	MedImmune
		Cassidy	*Daniel*	*Officer, Healthcare Biotech, EuropaBIO*
9	EFPIA	Clamou	Isabelle	EFPIA
10	EFPIA	Davis	Kourtney	GSK
11	VaccinesEurope	Demont	Clarisse	SP
12	EUCOPE	Dierks	Prof Christian	Dierks+Bohle
13	EFPIA	Dolin	Paul	Takeda
14	AESGP	Ernst	Dr Mara	BAH
15	EFPIA	Evans	David	BMS
16	VaccinesEurope	Fontaine	Sandrine	GSK
17	EBE	Francillard	Nathalie	Orphan Europe
18	EUCOPE	Fricke	Ulrich	Dr. Willmar Schwabe GmbH
19	EuropaBIO	Gargosi	Miriam	Healthcare Director, EuropaBIO
20	EFPIA	Gillen	David	?
21	EFPIA	Jimenez	Javier	AstraZeneca
22	VaccinesEurope	Jouquelet- Royer	Corinne	Sanofi Pasteur
23	EuropaBIO	Keisu	Marianne	Sobi
24	EUCOPE	Kooijmans	Mariska	Vice President for Drug Safety Risk Management, Biogen Idec, Inc.
25	EuropaBIO	McCarthy	Deirdre	Quintiles
26	EBE	Minjoulat-Rey	Marie-Christine	Sanofi
27	EFPIA	Mortimer	Orjan	Baxter
28	EUCOPE	Natz	Dr Alexander	Secretary General, EUCOPE
29	EFPIA	Niemcryk	Steve	AbbVie
30	EFPIA	Parker	Samantha	?
31	EUCOPE	Pattenden	Karen	Senior Director Drug Safety & Public Health/EU QPPV, Gilead Sciences International Limited
32	EFPIA	Pichler	Franz	Eli Lilly
33	EuropaBIO	Rindshoj	Christina Balslev	Novo Nordisk
34	EBE	Robinson	Jamie	Roche
35	EBE	Roddam	Andrew	AMGEN
36	EFPIA	Rosenberg	Daniel	Actelion
37	VaccinesEurope	Simondon	Francois	SPMSD
38	EFPIA	Soriano Gabarro	Maria Monserrat	Bayer
39	EFPIA	Swain	Liz	GSK
40	EFPIA	Techerny-Lessenot	Stephanie	Sanofi
41	EuropaBIO	Temple-Scotten	Sam	BTG International Limited
42	EUCOPE	Thurisch	Dr Boris	Geschäftsfeldleiter Arzneimittelsicherheit / Pharmakovigilanz, Bundesverband der Pharmazeutischen Industrie e.V. (BPI)
43	EFPIA	Van Agthoven	Michel	Janssen (Nefarma)
44	EFPIA	Van der Spuij	Willemijn	BMS
45	EFPIA	Verpillat	Patrice	Lundbeck
46	EFPIA	Zint	Kristina	Boehringer Ingelheim
	ENCePP SG	Carvajal	Alfonso	Universidad de Valladolid, Spain
	ENCePP SG	Nunes	Ana Corrêa	COMP - INFARMED, Portugal
	ENCePP SG	Sturkenboom	Miriam	Erasmus Medical Centre, Netherlands
	ENCePP SG	Andersen	Morten	Karolinska Institutet, Centre for Pharmacoepidemiology/Department of Medicine, Sweden
	ENCePP SG	Moore	Nicholas	ISoP - Université Victor Segalen, Departement de Pharmacologie (INSERM), France
	ENCePP SG	Perez-Gutthann	Susana	RTI Health Solutions, Spain
	ENCePP SG	Moride *	Yola	ISPE - Faculty of Pharmacy, Université de Montréal, Canada
	ENCePP SG	Arlett	Peter	European Medicines Agency
	ENCePP SG	Fitt	Henry	European Medicines Agency
	ENCePP SG	Blackburn	Stella	European Medicines Agency
	EMA	Kurz	Xavier	*Principal Advisor to ENCePP Steering Group*
	EMA	Slattery	Jim	*Statistical Advisor to ENCePP Steering Group*
	EMA	Blake	Kevin	ENCePP Secretariat
	EMA	Goedecke	Thomas	ENCePP Secretariat
	EMA	Vogl	Dagmar	ENCePP Secretariat
	EMA	Rossi	Eeva	ENCePP Secretariat