EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

ENCePP Infoday
London – 26 November 2010

Presentation by Henry Fitt
ENCePP Steering Group Meeting, 07 May 2010

Meeting Format

(total: 360 mins presentations)

08:45 – 09:00	Welcome and Introduction	Chaired by: Noël Wathion, European Medicines Agency
09:00 – 10:30	Session (90 minutes)	
10:30 – 11:00	Coffee break (30 minutes)	
11:00 – 12:30	Session (90 minutes)	
12:30 – 13:30	Lunch break (60 minutes)	
13:30 – 15:00	Session (90 minutes)	Chaired by: Jytte Lyngvig, Danish Medicines Agency
15:00 – 15:30	Coffee break (30 minutes)	
15:30 – 17:00	Session (90 minutes)	
17:00	End of Information Day	

Session 1:
Introducing ENCePP

* Importance of post-authorisation studies

  - Valerie Simmons, European Federation of Pharmaceutical Industries and Associations (EFPIA)

* The EMA and Drug safety studies: Overview & History of ENCePP

  - Henry Fitt, European Medicines

* Research Centres, Networks & Data Sources

  - Camilla Smeraldi, European Medicines Agency

Session 2:
Pillars of ENCePP

* Common issues with pharmacoepidemiology studies (standards, transparency)

- Bert Leufkens, Medicines Evaluation Board (MEB), Holland

* Checklist of Methodological Standards for ENCePP Study Protocols

- Xavier Kurz, European Medicines Agency

* ENCePP Code of Conduct

-Stefanie Prilla, European Medicines Agency

Session 3:
Registration and ENCePP Studies

* The need to register studies before they start

-Ingemar Persson, Karolinska Institute, Sweden

* The ENCePP electronic registry of studies

-Rocio Fernandez, European Medicines Agency

* Concept of “ENCePP study” / How will ENCePP change the way we work?

-Peter Arlett, European Medicines Agency

Session 4:
Brave New World

*Post-authorisation studies: new legislation

- Els Geeraerts, Belgian Federal Agency for Medicines and Health Products

* ENCePP: Future developments

- June Raine, Chair of PhVWP, Medicines and Healthcare products Regulatory Agency, United Kingdom

* Other EMA activities in the field of pharmaco-epidemiology

- Henry Fitt, European Medicines Agency