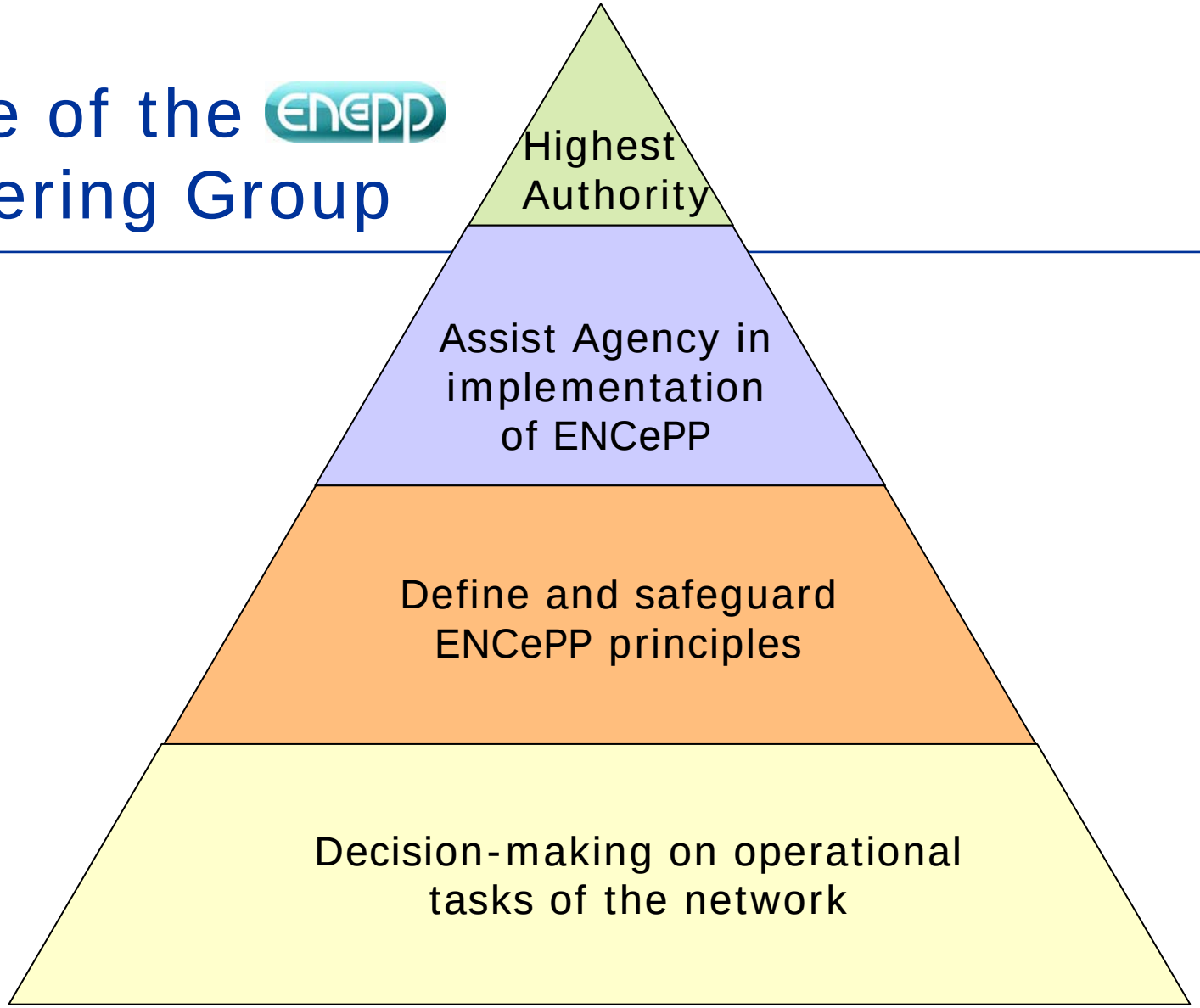
EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

European Network of Centres
for Pharmacoepidemiology and Pharmacovigilance

Report from the ENCePP Steering Group

Presentation by Ingemar Persson, Vice Chair of the ENCePP SG
to the ENCePP Plenary, 8 June 2010

Role of the Steering Group



Composition of ENCePP Steering Group 2010-2011

Elected from network

1. Corinne De Vries (University of Bath)
2. Joan-Ramon Laporte (FICF)
3. Ingemar Persson (Karolinska Institute)
4. Miriam Sturkenboom (EMC)
5. Giuseppe Traversa (Istituto Superiore di Sanita)

Appointed

6. Jytte Lyngvig (HMA)
7. Hubert Leufkens (CHMP)
8. June M. Raine (CHMP-PhVWP)
9. David Haerry (PCWP)
10. Yola Moride (ISPE)
11. Nicholas Moore (ISoP)

Observer:

Valerie Simmons (EFPIA)
International Regulatory Agency (to be appointed)

Composition of ENCePP Steering Group

European Medicines Agency Members

12. Peter Arlett (Chair)
13. Hans-Georg Eichler
14. Henry Fitt
15. Stella Blackburn

Principal Advisor: Xavier Kurz

Statistical Advisor: Jim Slattery

All members:

Terms of service: 2 years

Steering Group Meetings 2010

1. Inaugural Meeting: 19 February 2010 
2. Vitero meeting: 19 March 2010 
3. Face-to-face meeting: 7 May 2010 

- Minutes are available on the ENCePP website

4. Planned: 16 September 2010 (Vitero)
5. Planned: 2 December 2010 (Vitero)

Milestones to date

- Adoption of ENCePP Work Plan 2010

  (19 March 2010)
- Adoption of Checklist of Methodological Standards for ENCePP Study Protocols

  (19 March 2010)
- Adoption of ENCePP Code of Conduct

  (7 May 2010)

ENCePP Work Plan 2010: Main Goal and objectives

To have in place by the end of the year a high quality, self-sustainable network in the field of independent post-authorisation monitoring of medicinal products in the EU.

To promote ENCePP as a resource and increase its usage internationally.

ENCePP Work Plan 2010: Main Deliverables

- Code of Conduct
- Checklist of Methodological Standards for ENCePP Study Protocols
- Guide on the use of Methodological Standards and Guidelines
- ENCePP database of Research Resources
- Electronic ENCePP register of studies
- Consolidation of ENCePP Steering Group
- Development of ENCePP Forum on ENCePP web page
- Promotional events (Info Day, conferences, symposia…)

Looking ahead

Priority items identified for future direction of ENCePP:

- Strategy – safety issues in Europe
  - Funding of academic research / independent studies
  - Regulatory interface with ENCePP study requirements
- Repository of Declarations of Interest
- Dialogue with medical journals
- Data privacy & protection
- Evaluation of added value of the ENCePP study concept compared to the added bureaucratic burden (performance measures); measures of success of ENCePP; quality evaluation & assurance
- Audit/appeals/policing of ENCePP studies

Other achievements

- Identification of issues to be addressed during first review of Code of Conduct
- Review of Working Group mandates in light of priority issues identified
- Endorsement of interim solution pending release of ENCePP e-Register of studies