EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

European Network of Centres
for Pharmacoepidemiology and Pharmacovigilance

Working Group 2: Progress Report & Mandate Revision

Presentation by Henry Fitt, EMA
to the ENCePP Plenary, 8 June 2010

Working Group 2

Scope: Independence and transparency

Chair: Helen Dolk

Subgroup 1: Code of Conduct (CoC)

Chair: Helen Dolk

Subgroup 2: Registry of post-authorisation studies

Chair: Joan Ramon Laporte

Subgroup 1: Code of conduct

Mandate (Jan 2009): To develop a Code of Conduct governing the responsibilities and interaction of stakeholders (Industry, Research centres, Regulators, etc) in the conduct of PhV studies in order to ensure scientific independence and transparency.

- ✓**Main point achieved: Code of Conduct adopted by Steering Group in May 2010**

- ✓**Some of subheadings in the mandate of the group might require further work**

Subgroup 2: Registry of PA studies

Mandate (Jan 2009): Register of non-interventional PhEpi Safety Studies: develop a draft paper addressing the appropriateness, feasibility, scope and framework. Start with ENCePP studies:

- elaborate approaches for establishment of a register of initiated and conducted studies through ENCePP
- define rules for the access of 3rd parties to research data in the register
- develop a proposal for standard forms for website publication and entries in the register.

✓ The mandate has been achieved: the EMA is developing the electronic register of studies on the basis of the specification provided by Subgroup 2

Existing mandate WG2 – Subgroup1

To develop a Code of Conduct governing the responsibilities and interaction of stakeholders (Industry, Research centres, Regulators, etc) in the conduct of PhV studies in order to ensure scientific independence and transparency, including:

- Data ownership: raw data, analysed data
- Centres' right/commitment to submit for publication
- Centres' and MAHs' obligation to follow transparency rules
- Authorships
- Funders or Sponsors' rights: observer/presence in steering groups, information and comments on reports and manuscripts, time limits for comments, etc.
- Regulatory requirements for reporting; interventional and non-interventional studies
- Rules for financial interactions
- Liability issues
- Mandatory elements for standard contracts and legal issues (e.g. legislation under which study is carried out, copyright).
- Introduce Annex with sample/template contract
- Protocol agreement, reporting of results etc
- Define milestones when information details of a PhEpi study in progress shall be made available, or public, to stakeholders
- Elaborate approaches/ways to ensure transparency, e.g. *web-publication* of the research protocol and/or the study results etc
- Ensure transparency translates into effective Public Communication (e.g. on future EMEA Safety Portal)
- Develop training programs

Possible revision of the mandate

Points from the existing mandate:

- Revision of the Code of Conduct in light of the experience gained
- Introduce Annex with sample/template contract
- Ensure transparency translates into effective Public Communication (e.g. on future EMEA Safety Portal) → New working group "Communication"?
- Develop training programs/workshops

Points raised by the Steering Group:

- Development of a Repository of Declarations of Interest
- Strategy – safety issues in Europe:
  - Funding of academic research/independent studies
  - Regulatory interface with ENCePP study requirements
- Audit/appeals/"policing" of ENCePP studies: compliance monitoring of implementation and enforcement of the Code of Conduct in the ENCePP Studies

→ New working group "Compliance monitoring"? Or Working Group 2?