



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH



European Network of Centres for
Pharmacoepidemiology and
Pharmacovigilance

29 March 2011
EMA/196493/2011

Mandate of ENCePP Working Group 3

Inventory of EU data sources and methodological approaches for multi-source studies

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EU Inventory of data sources

- Identify existing data sources useful for PE and PV research.
- Explore ways to stimulate and support initiatives to create new data sources in EU Member States.

Approaches & processes for interoperability and sharing of European epidemiology data sources

- Discuss operational approaches for organising, initiating and performing observational safety studies and large simple randomised clinical trials through ENCePP. Explore ways of performing multi-source studies (e.g. combining data, using common protocols).
- Develop training programmes.

Data Privacy restrictions for PE/PV research

- Develop approaches to overcome differences in national legislation on data privacy in order to facilitate multi-national studies, taking into account legal advice.
- Develop common rules to protect patients' and providers' rights with respect to data confidentiality.

Publication of best practice guidance for pharmacoepidemiology studies in light of data privacy legislation.
- In the light of the ongoing EC consultation to strengthen EU data protection rules, ensure the ENCePP position is adequately conveyed and provide adequate follow-up.

