European Federation of Pharmaceutical Industries and Associations

EFPIA members perspective on ENCePP
Use of real-life data and linkage with HTA related activities

Meeting ENCePP with Pharmaceutical Industry

22 may 2013

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Overview

- New Pharmacovigilance legislation with requirements for additional studies
- Industry faces increased number of requests from regulators and HTA bodies/payers for post-approval studies with different objectives (benefit/risk *vs.* effectiveness)
- Numerous similar requests triggering complex situation for industry
- EUnetHTA guidelines on health outcomes aspects already exist

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Industry perspective of ENCePP

- Methodological credibility
  - Promote and support high methodological standards in observational research
  - Code of conduct to manage intellectual property and relationships between investigators and funders
  - Secure access to medical individual data
- Helpful inventory of resources for observational research in the EU
  - Directory of research centres, networks and EU data sources
  - E-register of Studies (EU PASS Register)
- Regulatory credibility (EMA support)
  - Facilitate endorsement of submitted projects

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Industry perspective of ENCePP

- ENCePP study seal currently seen as a constraint
  - Seal not necessary to work with ENCePP centres with high study standards, independence and transparency
  - No seal = flexibility needed for observational studies during negotiations with regulators and/or HTA bodies
  - ENCePP centres sometimes prefer to perform studies outside this ENCePP study seal application

    → *No clear added value* for industry to apply for study seal

- No clear criteria for ENCePP membership
  - Pharma industry not allowed to apply
  - Not all members being academic
  - No quality assessment required to register

    → Industry experiences of collaboration show *mixed feedback*

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Learnings…

- ENCePP capabilities not well known and role not fully understood by industry
  - Possibility for consultation in placing an announcement in the ENCePP Partners' Forum not known
  - Notion of independency from the funder unclear
  - Positioning and role of ENCePP when PASS required by EMA or National Health Authorities, or for HTA studies unclear

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…and opportunities for improvements

- Possible ways for an improved collaboration between ENCePP and industry
  - Increase visibility on how ENCePP, as an organisation, could help and be of added value compared to the way we usually work
  - Leverage its consultative expert group for industry consultation on specific questions / topics
  - Continuously communicate and reinforce best practices for Pharmacoepidemiological studies and research
  - Develop high quality data collection throughout Europe and facilitate access to data (secondary data collection)
  - Maintain flexibility to address diversity of needs outside the regulatory framework

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Conclusion

- 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 regulators and academics
  - the definition of methods in order to secure application for comparative studies by HTA
- ENCePP can help
  - to collect data from real-life use of medicinal products
  - to enhance coordination of requests between regulators and HTA
  - to avoid duplication of studies
  - to save resources
- Industry performs real-life studies and would like to see more convergence between regulators and HTA