EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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European Network of Centres for Pharmacoepidemiology and Pharmacovigilance

Revision 3 of the ENCePP Code of Conduct

Summary of the main changes

1. Background

The ENCePP Code of Conduct was first released in 2010 setting out a framework for good practice, transparency and independence in the conduct of pharmacoepidemiology, pharmacovigilance and post-authorisation benefit-risk studies. While revision 1 focused on the requirements for access to study data, revision 2 provided further clarification on the practical implementation of the Code's requirements on access to study data, declaration of interests and sources of funding. Taking into account further feed-back from the ENCePP network and the practical experience from stakeholders including learned societies, regulatory authorities and pharmaceutical industry, the ENCePP Steering Group adopted on 21 February 2014 revision 3 as a result of the on-going work of the ENCePP Working Group on transparency and independence.

2. Summary of the main changes

The third editorial revision of the Code is aimed at improving the overall readability of the Code and to provide further clarifications on the key concept of scientific independence in a new chapter and on the conditions for the ENCePP Seal. The key concepts of the Code remain however unchanged.

2.1. Scientific independence

Whereas in previous versions reference to the concept of scientific independence was made in several chapters, a new chapter 6 summarising the Code's requirements of independent research has been introduced. This new chapter addresses specific aspects of the relation between researcher and funder in the context of declaration of interests, ownership of results and sharing of data, study conduct and reporting study results.

2.2. Conditions for the ENCePP Seal

For clarity the conditions for a study qualifying for the ENCePP Seal are now presented as a straight forward checklist (i.e. the primary lead investigator belongs to an ENCePP centre, provides documentation of commitment to adhere to the provisions of the ENCePP Code of Conduct and registers the study in the ENCEPP E-Register prior to study start). Furthermore, the ENCePP Seal

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documentation only needs to be provided in electronic format and references to the 'CoRe' requirements perceived as rather abstract were removed.

2.3. Role of the ENCePP E-Register

The Code clarifies that studies applying for the ENCePP Seal must be registered in the ENCePP E-Register of Studies (EU PAS Register) before the study commences, but also any other study in the fields of pharmacoepidemiology and pharmacovigilance not formally applying for the ENCePP Seal should be registered to ensure transparency. In addition, guidance has been provided with regard to who can register studies in the E-Register (i.e. the primary lead investigator or any individual on his behalf belonging to the coordinating study entity).