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Revision 2 of the ENCePP Code of Conduct to facilitate conduct of ENCePP studies

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. Considering the wide scope of the Code, the need to closely monitor the practical implication of its provisions was recognised by the ENCePP Steering Group, who consequently requested a review of the Code one year after its launch. Questions arising from the Code's requirement to provide access to study data led to its 1st revision and the adoption of implementation guidance on access to data only a few months after the initial launch. Further feedback was received from ENCePP researchers and various stakeholders, including learned societies, regulatory authorities and pharmaceutical companies. This feedback formed the basis for a thorough review of the Code by the ENCePP Working Group for Transparency and Independence with input from an ad-hoc Task Force on Access to Data in 2011. As a result, the 2nd revision was adopted on 21 November 2011. The main changes introduced with the latest revision are summarised below.

2. Summary of the main changes

While various areas of the Code were amended, the focus of the review was on access to study data, declaration of interests and conditions applicable to different sources of funding.

2.1. Sharing of Study Data

Further clarification was provided on the conditions, purpose, suitable approaches as well as limitations for sharing of study data. To this end the Implementation Guidance for Sharing of Study Data was substantially revised and introduced as an Annex to the Code (Annex 4).

While keeping the principle of maximum openness and unrestricted access where possible, additional consideration has been given to the need for protection of data privacy, special cases such as secondary data as well as practicalities on how to respond to data access requests. The requirement to provide on request the *analytical data set* and a *detailed description of how raw data were transformed into the data set for analysis* has been sustained by better defining these terms and by clarifying that

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modifications to the data set for the purpose of removing personal identifiers are acceptable. The purposes for which, under the scope of the Code, access to data can be requested have been refined and now also include audits by competent authorities. Moreover, concrete ways of replying to access requests have been introduced including on-site access and post-hoc analyses by independent statisticians. It has been clarified that it is possible for ENCePP researchers to require data-sharing agreements as well as reasonable compensation for costs incurred in providing access to data. Finally, to be consistent with the principle of maximum transparency, any research conducted with shared ENCePP study data has to follow the same transparency requirements as for ENCePP studies, including registration of the study in a public register.

2.2. Declaration of Interests

The comments received from stakeholders revealed a need to clarify the obligation to declare interests (e.g. indirect versus direct interests and interests of a personal, commercial and financial nature) with a view to potential conflicts when conducting studies. To address this issue a Declaration of Interest form was created to be used by ENCePP researchers (Annex 5 to the Code).

2.3. Different Sources of Funding

Furthermore, to accommodate different sources of financing, relevant provisions were reviewed and distinct requirements were introduced, where necessary, for self-funded studies and studies financed from external sources - either using public funding schemes and/or private funds. In particular, the fact is now reflected that many public funding schemes such as the European Commission's Framework Programme use standard grant agreements whose content cannot be altered.

2.4. Other Changes

For clarity and consistency, amendments were made in relation to intellectual property rights and ownership of results. Any direct condition for ownership of data was omitted due to potential contractual conflicts and infringement of third party rights; however the right of the investigator to independently prepare publications of the study results irrespective of data ownership was maintained.

Finally, clarification was provided that certain feasibility studies - necessary to finalise the study protocol - are allowed provided their conduct is specified in the protocol.