European Medicines Agency

London, 16 November 2009
Doc. Ref. EMEA/692879/2009

SUBMISSION OF COMMENTS ON

The ENCePP Code of Conduct (Doc.Ref. EMEA/489873/2008)

Draft for Public Consultation

COMMENTS FROM:

Name of Organisation or individual
International Society for Pharmacoepidemiology (ISPE)

Please note that these comments and the identity of the sender will be published unless a specific justified objection is received.

Comments should be sent to the ENCePP Secretariat (mailto:encepp_secretariat@emea.europa.eu) electronically and in word-format (not pdf).

The International Society for Pharmacoepidemiology (ISPE) is very pleased to have the opportunity to offer our perspectives and suggestions, and submits for your consideration the following comments on the European Medicines Agency document.

ISPE is an international, nonprofit, professional membership organization dedicated to promoting the health of the public by advancing pharmacoepidemiology, the science that applies epidemiological approaches to studying the use, effectiveness, values and safety of pharmaceuticals. ISPE is firmly committed to providing an unbiased scientific forum to the views of all parties with interests in drug, biologics, and devices development, delivery, use, costs and value, adverse and beneficial effects, and therapeutic risk management.

Moreover, the Society provides an international forum for the open exchange of scientific information among academia, government, and industry and for the development of policy; a provider of education; and an advocate for the fields of pharmacoepidemiology and therapeutic risk management.

The Society's more than 1,000 members represent 45 countries. ISPE members work in academic institutions, the pharmaceutical industry, government agencies, and non-profit and for-profit private organizations. ISPE members are researchers with background and training in epidemiology, biostatistics, medicine, public health, nursing, pharmacology, pharmacy, law, and health economics.

Our comments are based on a careful review of the EMEA document by the Society's membership at-large as well as by ISPE Fellows, Past Presidents, members of the Board of Directors and Executive Committee and Public Policy Committee. Due to the development process of the draft documents in which many ISPE members from academia, research centers and regulatory bodies were involved, many of the responses have originated from members from the industry sector and some of these were directly sent to EMEA and have therefore not been included again in this document.

We thank EMEA for allowing us the opportunity to comment on this document. ISPE welcomes any future dialogue with EMEA.

Sincerely,

Public Policy Committee,

International Society for Pharmacoepidemiology (ISPE)

1. GENERAL COMMENTS

Stakeholder No. *<to be completed by EMEA>*	**General Comment (if any)**	**Outcome (if applicable)** *<to be completed by EMEA>*
	ISPE thanks the Agency for the opportunity to review this document. It is an important initiative for the strengthening of pharmacoepidemiology in Europe that impacts worldwide all those in practice in the field.	
	The respective practical roles of the lead investigator, study funder and operation group should be clarified. E.g., can the operation group be the study funder (as suggested in line 523) or does the operation group need to be external as suggested by lines 252-255?	

2. SPECIFIC COMMENTS ON TEXT

Chapter No and/or Line No of the first line(s) affected.<*e.g. Line 20-23*>	**Stakeholder No.** <*to be completed by EMEA*>	**Comment and Rationale; proposed changes** <*if changes to the wording are suggested, they should be highlighted using "track changes"*>	**Outcome** <*to be completed by EMEA*>
Line 72 -		In terms of scope, it states any kind of observational research - does it include all methods or tools - i.e. chart reviews, prospective data collection and even database analyses? Scope seems very broad, is that the intent?	
Line 101		"inventory of resources". Does this mean that the academic investigator (lead investigator?) needs to come from an established list? Does the same principle apply if one is working in very rare disease areas?	
Line 336		Should it be possible to have a protocol with a brief statistical section if the intent is to develop a more detailed SAP at a later stage?	
Lines 388 & 399		Does this exclude to have both academic authors and authors from the study funder?	