EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

December 23, 2010

European Network of Centres for Pharmacoepidemiology and Pharmacovigilance

Submission of comments on the 'ENCePP Guide on Methodological Standards in Pharmacoepidemiology' (EMA/95098/2010)

Name of organisation or individual
International Society of Pharmacoepidemiology (ISPE)

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

When completed, this form should be sent to the ENCePP Secretariat (encepp_secretariat@ema.europa.eu) electronically, in Word format (not PDF).

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1. General comments

Stakeholder number *(To be completed by the Agency)*	General comment (if any):	Outcome (if applicable) *(To be completed by the Agency)*
	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 EMA, "ENCePP Guide on Methodological Standards in Pharmacoepidemiology". We find that the document represents highly qualified work and that it has the potential to become a very useful tool for the researchers within the field. It may also find some use in teaching. We have no general comments, but a few specific comments are listed below.	

2. Specific comments on text

Line number(s) of the relevant text *(e.g. Lines 20-23)*	Stakeholder number *(To be completed by the Agency)*	Comment and rationale; proposed changes *(If changes to the wording are suggested, they should be highlighted using 'track changes')*	Outcome *(To be completed by the Agency)*
Lines 1129-30		Comment: The Guide is a comprehensive overview of the methodological traditions within pharmacoepidemiology in 2010. It can quickly become dated and irrelevant, if it is not properly maintained. EMA has declared its intentions to do so on page 28 (line 1129-30), but the specifics about how and by whom are virtually absent. We suggest that the maintenance of the document, which is so essential for its usefulness, is described in more detail. Proposed change (if any):	
Lines 673-751		Comment: This document presumes to be comprehensive, covering a wide range of study designs appropriate to pharmacoepidemiology, but we could not find a single reference to case-control (CC) studies or, more specifically, case-control surveillance (CCS). We would have expected to see these covered in section 6 (Data Sources), either under 6.1 or 6.2. The latter refers to "prospective patient-based studies", and includes registries and surveys, but does not include mention of CC or CCS approaches. Indeed, a specific chapter on CCS appears in Strom's frequently-cited text (Rosenberg L: Case-control surveillance, Chapter 11 in the Part IIIa "Ad hoc data	

		sources available for Pharmacoepidemiology Studies". I would also cite for consideration: Kaufman DW, Rosenberg L, Mitchell AA: Signal generation and clarification: use of case-control data. Pharmacoepi Drug Safety 2001; 10:197-203. Proposed change (if any):	
		Comment: Proposed change (if any):	

Please add more rows if needed.