



Public Consultation

ENCePP Code of Conduct
& Checklist of MRS

ENCePP Plenary, 11 December 2009
Stefanie Prilla



Public consultation - Key dates

- Launch: **16 November 2009**
- Deadline for comments:
5 January 2009

⇒ 6 weeks plus holidays

November 2009

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December 2009

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January 2010

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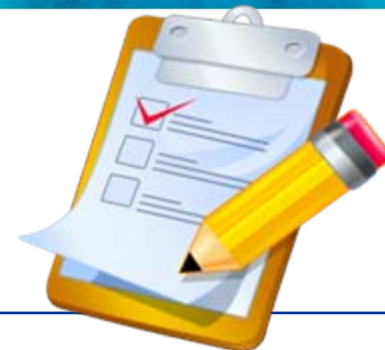


Document History

ENCePP Code of Conduct

- May 2009: First draft prepared by Working Group *Transparency & Independence* (chair: Helen Dolk)
- 18 Sept 2009: Core elements of the draft CoC presented to ENCePP Plenary
- Oct 2009: Consultation of ENCePP partnership; revised draft by WG implementing comments received
- End Oct 2009: Adoption by ENCIAG of draft for public consultation





Document History

Checklist of Methodological Research Standards

- July 2009: Key areas and methodological aspects to be considered when conducting PE & PhV research agreed by Working Group on *ENCePP research standards and guidances*
(Chair: Gonzalo Calvo Rojas, Subgroup chair: Bert Leufkens)
- August 2009: First draft Checklist of ORS (agreed scope, key points translated into sections & questions)
- Sept 2009: Consultation of ENCePP partnership; revised draft by WG implementing comments received; presentation at ENCePP Plenary on 18 Sept
- End Oct 2009: Adoption by ENCIAG of draft for public consultation

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Welcome to the ENCePP website!

ENCePP Code of Conduct for Independence and Transparency & Checklist of Methodological Research Standards

On 16 November 2009, a public consultation was launched on a draft **Code of Conduct for Independence and Transparency**, and a draft **Checklist of Methodological Research Standards** that lay down key elements and principles for the conduct of "European Network of Centres for Pharmacoepidemiology and Pharmacovigilance (ENCePP) Studies".

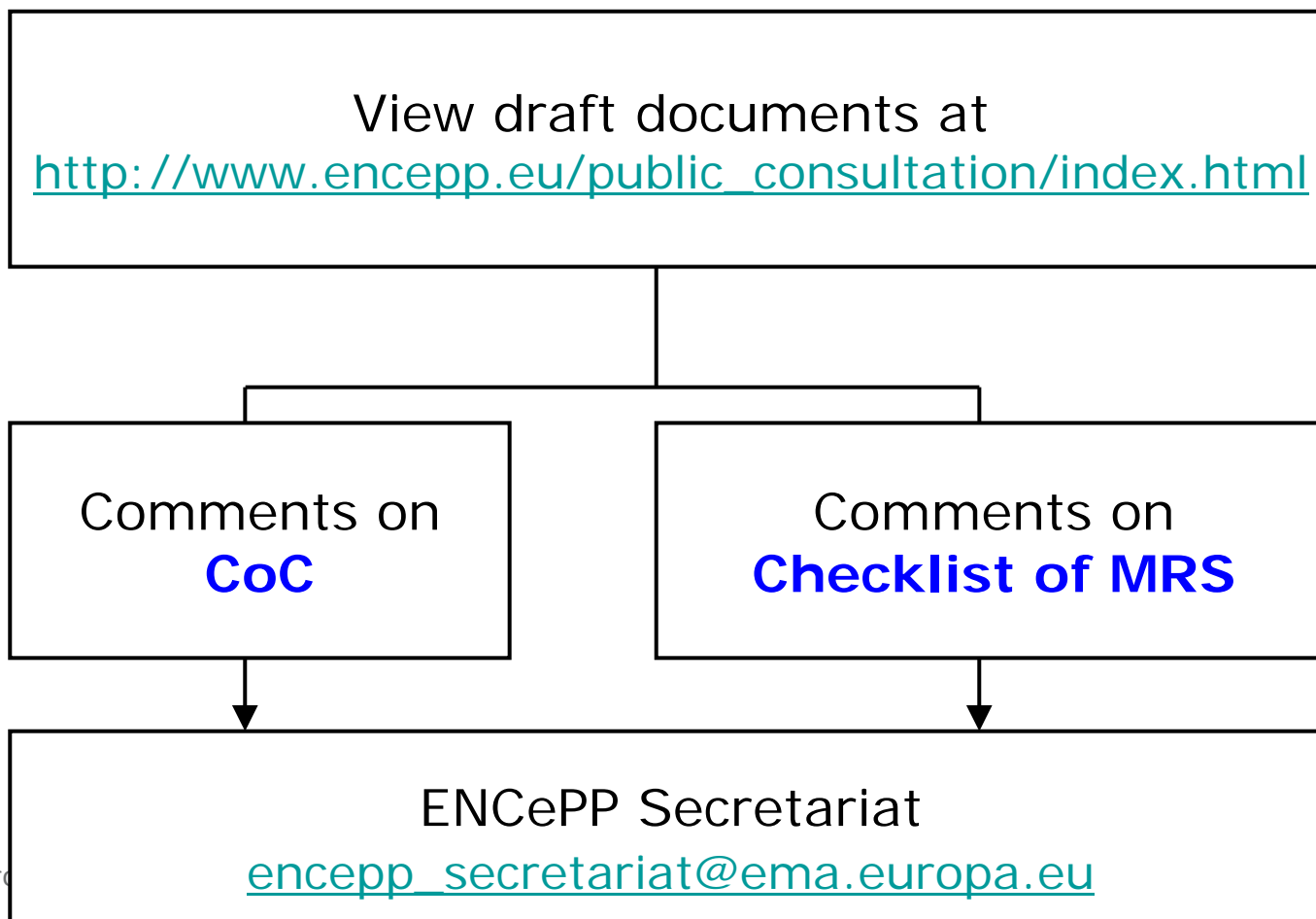
The consultation is open until 5 January 2010.

[More details here >>](#)

The European Network of Centres for [Pharmacoepidemiology](#) and [Pharmacovigilance](#) (ENCePP) is a project led by the [European Medicines Agency](#) (EMA) intended to further strengthen the postauthorisation monitoring of medicinal products in Europe by facilitating the conduct of multi-centre ~~independent post authorisation safety studies~~ and studies focusing on lack of efficacy. This will



How to provide comments





Stakeholders

- **Regulatory Authorities** (EU and non-EU)
 - **European Medicines Agency Committees**
- **Pharmaceutical Industry**
- **Learned societies**
- **Patients**
- **Health Care Professionals**
- **European Commission**
- **ENCePP** → interested individuals in- and outside own centre



Next steps

Separately for the CoC & the Checklist of MRS

