



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH



European Network of Centres
for Pharmacoepidemiology and Pharmacovigilance

WG2: Independence and transparency Progress report 12 Nov 2013





Key Developments since September Plenary

Factors contributing to the poor uptake of the ENCePP Study Seal and registration of studies on the ENCePP e-Register:

1. 3rd revision ENCePP Code of Conduct drafted
 - previous plenary discussions incorporated
 - dedicated chapter on Independence
 - issues / changes logged
2. Revised text for ENCePP website drafted

Consistency, simplification and clarification of ENCePP Study Seal and E-Register of Studies

Safety Signals:

3. NEW link on ENCePP website to [PRAC recommendations on safety signals](#)



Status of ongoing work and next steps

- **3rd revision of Code of Conduct** – for final comment by WG2 members prior to submission to the SG
- **ENCePP website text** - for final comment by WG2 members prior to submission to the SG
- **Verifying compliance throughout ENCePP Seal Studies**
 - for finalisation by WG2 members prior to submission to the SG
- **Survey on uptake of the ENCePP Study Seal and registration of studies on the ENCePP e-Register by ENCePP Centre**
 - draft in preparation, to be circulated to ENCePP members prior to the next plenary



Input required from plenary....

- **NEW Link on ENCePP website to the EMA's Pharmacovigilance Risk Assessment Committee (PRAC) recommendations on safety signals**

- ? Additional text required

- ? Are additional methods of alerting ENCePP centres about safety signals required

- **Please complete the Survey on uptake of the ENCePP Study Seal and registration of studies on the ENCePP e-Register by ENCePP Centre**

- to be circulated by WG2 prior to the next plenary to identify reasons contributing to poor uptake