



EUROPEAN MEDICINES AGENCY  
SCIENCE MEDICINES HEALTH

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## Organisational matters

### CHMP meeting 20-23 October 2014

The main organisational topics addressed during the October meeting related to:

- Election of Jan Mueller-Berghaus as CHMP Co-opted member on the area of expertise “Quality and safety of biological medicinal products, including biotechnology derived medicines, cell therapy and gene therapy”.
- Election of Greg Markey as Vice Chair of Central Nervous System Working Party.
- The appointment of Peter Kiely from Ireland as alternate Scientific Advice Working Party Member.
- Discussion on Benefit-Risk methodology project: experience from pilot and next steps.
- Update on Risk Management Plan activities and review process.
- Information on the PROTECT symposium to be held 18-20 February 2015. The main topics will include methods to collect data directly from consumers, signal detection, methods to improve consistency between pharmacoepidemiological studies and benefit-risk integration and representation.
- Discussion on facilitation of registration of centrally authorised products in developing countries – pilot scheme. WHO proposed EMA to cooperate in a pilot scheme. As regulatory requirements are quickly developing in developing countries, whose competent authorities do not have the right resources to fully operate their key regulatory functions, therefore sharing regulatory outcomes and scientific grounds for regulatory decisions taken by Competent Authorities in more developed countries, can facilitate their regulatory decision making, thus enabling faster access to medicines by patients.

