



EUROPEAN MEDICINES AGENCY  
SCIENCE MEDICINES HEALTH

# PCWP and HCPWP work programmes for 2013

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An agency of the European Union





## Meetings scheduled for 2013

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27 Feb

- HCPWP Plenary meeting

28 Feb

- PCWP/HCPWP Joint meeting

5-6  
Jun

- PCWP Plenary meeting

11 Jun

- HCPWP Plenary meeting (tbc)

25/26  
Sep

- PCWP/HCPWP Joint meeting

10 Dec

- PCOs Training session

11 Dec

- Meeting with all eligible PCOs



# Communication and information

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- Regulatory information
  - Explore ways of promoting awareness and understanding of SmPC and EPAR
- Review of product information
  - Systematically review of all PLs and new EPAR summaries
  - Provide input on SmPC and labelling, as and when needed
- Review of safety communications
  - Review all safety related communications (Q&As)
    - Carry out a trial period of reviewing safety related communications (Q&As)
    - Pilot involvement in the preparation of DHPCs
- Review of information on herbal medicinal products
  - Involvement in the preparation of summaries of herbal monographs in lay language
- Public registry of EMA's interested parties
  - Promote the register among their stakeholders and partners



# Pharmacovigilance and Risk Management

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- New pharmacovigilance legislation
  - Participate in dedicated stakeholder meetings
- Reporting and monitoring of adverse drug reactions
  - Contribute to the further implementation of the Eudravigilance access policy
- Prevention of medication errors
  - Provide input and participate in the EMA workshop on medication errors; contribute to the outcomes as appropriate
  - Involvement on how the Agency communicates on medication errors
- Risk management plans (RMP)
  - Provide input on RMPs, especially the preparation of the RMP summary
- Public hearings
  - Provide input on modalities of participation and participate in public hearings as appropriate
- Contribution to PRAC activities



# Transparency and dissemination of information

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- Transparency
  - Promote visibility of HCPOS and PCOs input in the context of EMA activities e.g. in minutes, assessment reports, etc.
- Dissemination
  - Disseminate EMA documents containing key information
- EMA awareness
  - Support EMA communication activities to increase EMA awareness, as necessary
- Agency's website
- Access to clinical trial data
  - Provide support to the further development of the EudraCT database and the EU Clinical Trial Register



# Involvement in Agency Scientific Committees and Working Parties related activities

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- Additional source of independent expertise
- Input on current use of medicines in clinical practice
- Participation in SAG (& ad-hoc expert) group meetings
- Participation in scientific advice
  - Investigate ways to further increase PCOs involvement in the provision of scientific advice
- Establishing appropriate links with the new HCPWP



# Interaction between Patients/consumers and Healthcare professionals

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- Organise two joint meetings
- Ensure adequate co-ordination on issues of common interest
- Participation of each WP observers in the plenary meetings



# Organisational matters

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- Further implementation of the framework of interaction with HCPOs
  - Establishment and full operation of the HCPWP
- Revision of the framework of interaction with PCOs
- Eligibility criteria
  - SOP
  - Handling of potential conflicts of interest of organisations
- Training of PCOs and annual meeting with all eligible organisations
- Monitoring and reporting



## Other areas of participation

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- Involvement in medicines shortages
- Pandemic communication strategy
- EMA geriatric medicines strategy
- Pharmacogenomics and personalised medicine
- European Paediatric Research Network (EnprEMA)
- Implementation of new legislation on falsified medicines
- European Network of Centres for Pharmacoepidemiology and Pharmacovigilance (ENCePP)
- PROTECT – Pharmacoepidemiological research on outcomes of therapeutics by a European consortium
- Participation in EMA workshops and conferences



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Looking forward  
to a fruitful collaboration  
throughout 2013!