EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

PCWP and HCPWP work plans for 2014

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Stakeholders and Communication Division

Meetings scheduled for 2014

25/26 Feb	• PCWP/HCPWP joint meeting (including dedicated session on 'Regulatory and methodological standards to improve the benefit/risk evaluation')
18/19 Jun	• PCWP and HCPWP plenary meetings
16/17 Sep	• PCWP/HCPWP joint meeting (including dedicated workshop on 'Risk communication on medicines')
25 Nov	• PCOs training/awareness session
26 Nov	• Meeting with all eligible PCOs

Involvement in Agency Scientific Committees and Working Parties activities

- Respond to calls for ad-hoc consultations on medicines
- Support the identification of adequate independent experts for involvement in SAG/Ad-hoc expert group meetings and scientific advice procedures

PCWP

- Support the implementation of the proposal to further refine patients' involvement in benefit/risk discussions

HCPWP

- Contribute to EMA discussions on how to better recognise HCPs input provided in the context of the activities of scientific committees, working parties, scientific advisory groups and other expert groups

Communication and information

- Review of product information
  - Assess the current processes for the review of documents and discuss opportunities for efficiency gain and for facilitating participants (e.g. by widening the pool of experts)
- Review of risk management plan summaries
  - Support the implementation of the review and publication of RMP summaries
- Communication on shortages, medication errors and other activities
  - Support the review and dissemination of EMA communications on shortages
  - Support the implementation of a dedicated information tool for medication errors
  - Contribute as appropriate to the EMA work on communicating its activities (e.g. involvement in preparation and response to health threats)
- Risk communication
  - Organisation of a dedicated workshop
- Dissemination, EMA awareness and Agency's website

Communication and information

HCPWP

- Contribute to the establishment of an EMA (virtual) task force where interested HCPWP members, experts in communication, relevant EMA and NCAs' staff involved in the preparation of information on medicines (and other relevant experts such as drug bulletin editors) can:
  - analyse and reflect on how the Agency can better respond to current and future information needs of HCPs that could be addressed by the EMA and the EU regulatory network;
  - discuss available instruments and their effectiveness;
  - prepare proposals for action as appropriate.
- Explore the need to organise a dedicated workshop with drug bulletins.

Pharmacovigilance and Risk Management

- Pharmacovigilance legislation
  - Continue to participate in dedicated stakeholder meetings
- Reporting and monitoring of adverse drug reactions
  - Support EMA communication activities to increase awareness and clarity about additional monitoring of medicines
  - Participate as appropriate in the preparation of an EU reporting guideline
- Prevention of medication errors
  - Involve the WP in any relevant consultations to gather input on real life experience concerning proposed strategies to minimise risk of medication errors
- Public hearings
  - Support the Agency in future activities related to place public hearings, as appropriate
- GVP module on public participation
  - Contribute to the finalisation of the Guideline on Good Pharmacovigilance practices (GVP) module

Clinical trials and research

- Clinical trial legislation
  - Contribute to consultations on the on-going implementation of existing legislation, taking into account developments in light of the new clinical trial regulation
- Research projects
  - Gain a better understanding of the main research projects where EMA is involved (e.g. PROTECT) and support involvement of PCOs/ HCPOs as appropriate
- European Paediatric Research Network (EnprEMA)
- European Network of Centres for Pharmacoepidemiology and Pharmacovigilance (ENCePP)

Other emerging issues during medicines life-cycle

- Implementation of new legislation on falsified medicines
- Supply shortages of medicines due to manufacturing and quality problems
- EMA geriatric medicines strategy

Participation in workshops and conferences

- Support identification of most appropriate candidates to participate, including speakers who can address a specific topic
- Monitor participation of PCOs/ HCPOs representatives

Interaction between patients/consumers and healthcare professionals

- Organise two joint meetings
- Reflect on how to improve synergies between the two working parties

Organisational matters

- Frameworks of interaction
  - Implement all actions defined within the framework of interaction
  - Review procedures to identify and involve experts in EMA activities
  - Implement the proposal to improve the way the Agency evaluates organisations for eligibility
- Monitoring and reporting

PCWP

- Training and awareness
- Annual meeting with all eligible organisations

Looking forward to