EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

PCWP / HCPWP working methodology

Presented by Nathalie Bere / Ivana Silva on 4 March 2015
Stakeholders and Communication Division

Working methods

Work-plan 2014 – reflect on current practices / Feedback from surveys & co-chairs

- Currently majority of interaction occurs during plenary meetings;
  - Dense agendas
  - Not all members can participate systematically or provide input
  - Long periods without face-to-face meetings
  - Some topics need in-depth discussion whilst others require more immediate input

➢ Enhance collaboration outside of plenary meetings

➢ Best utilisation of time during meetings

Working methods; proposals for way forward

1. **Better utilisation of time between plenary meetings**:
   - Create topic groups on areas of common interest to be brainstormed in smaller groups between the plenary meetings

2. **Prepare lighter agendas with more time for discussion**:
   - Dedicated timeslot for feedback from Scientific Committees, other relevant groups and projects (e.g. Enpr-EMA, ENCePP)
   - Provide brief written updates (e.g. on a case-by-case; compiled in quarterly emails; as part of the meeting documentation, but not during meeting etc.)

3. **Maximise "learning from each other":**
   - Invite organisations to present their own activities/achievements where other organisations could benefit from their experience, directly or indirectly linked to EMA activities (slot at each plenary)

Better utilisation of time between plenary meetings

Creation of topic groups – identify topics of interest to both EMA and WP members to be brainstormed in smaller groups between the plenary meetings

- Nominate topic leader based on interest/experience who would present back to the WP
- Topic groups discuss (by email / conference call) and interact with different subgroups where topics converge
- Consider also participation of eligible organisations depending on topic

Proposed topic groups (PCWP)

Based on the Action Plan within the Revised Framework on interaction and the PCWP work-plan for 2015, we would like to propose 5 potential topic groups:

1. **Measure impact of patient involvement**
   - Explore how to measure the benefit/value of patient input on regulatory outcomes
   - Explore the impact that involvement in EMA activities has on empowerment of PCOs
2. **Acknowledge and promote visibility of patient input in the Agency's activities**
   - Explore how to raise awareness and visibility of the patients work at the EMA
3. **Training**
   - Explore synergies with existing training initiatives
   - Explore methods to further enhance support for patients involved in EMA activities

Proposed topic groups (PCWP)

4. Social media

- Explore how PCOs use social media to communicate with their members and the wider community
- Brainstorm on issues for discussion within a workshop on social media in 2006

5. Involvement of young people / children

- Identify existing youth groups within eligible organisations; look to create, within the umbrella of the PCWP, a "young persons network" with young participants
- Identify areas and methodologies for the involvement of young people in PDCO activities
- Explore how to raise awareness on the need for more participation in paediatric clinical trials (also for HCPWP)
- Brainstorm on possible 20th anniversary activity at the EMA with young people in October 2015

Proposed topic groups (HCPWP)

1. **Social media**
   - Brainstorm on issues for discussion within a workshop on social media in 2016
   - Discuss current digital practices and how data related with real use of medicines is being collected and used
2. **Acknowledge and promote visibility of stakeholders input in the Agency's activities**
   - Explore what can be done by the Agency and by the organisations
3. **Risk minimisation measures and assessment of their effectiveness**
   - Brainstorm on ensuring effectiveness of risk minimisation and integration of parallel discussions, e.g. post-authorisation Efficacy & Safety studies, registries, medication errors and safety communication.

Proposed topic groups (HCPWP)

4. **EMA/CHMP/PRAC projects on information on medicines**
   - Brainstorm on how to promote regulatory consistency between SmPC and therapeutic guidelines / prescribing recommendations, including possible collaboration with OWP
   - Discuss interaction with drug bulletins
5. **Academia, learned societies and healthcare professional organisations**
   - Brainstorm on synergies of approaches in relation to current interactions with EMA to support development of the EMA framework of collaboration with Academia
   - Share current practices/ initiatives intended to promote involvement in regulatory activities and raise awareness of that involvement amongst their members