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Stakeholders and Communication

Draft Work plan for the European Medicines Agency Human Scientific Committees' Working Party with Healthcare Professionals' Organisations (HCPWP) 2016

Chairpersons	**Status**
Isabelle Moulon (EMA) and Gonzalo Calvo (EACPT)	Draft to be endorsed by HCPWP on 17 September 2015

1. Meetings scheduled for 2016

- 8 March - Joint PCWP/HCPWP session on 'Preventing infectious diseases: focus on vaccines' (tbc)
- 9 March - Joint plenary meeting with PCWP
- 15 June – HCPWP plenary meeting (including election of co-chair)
- 19 September – Joint PCWP/HCPWP workshop on 'Social Media'
- 20 September – Joint plenary meeting with PCWP

2. Introduction

During 2016 the working party will continue to engage in consultations where healthcare professionals' input can bring added value to benefit-risk assessment and decision-making; contribute to EMA activities related with information on medicines and communication with healthcare professionals; and support the continuous improvement of the operation of the pharmacovigilance system. As in previous years, the working party will continue to serve as a platform to promote a better understanding of the Agency's activities and involvement in EU-wide initiatives.

In the context of joint discussions with the Patients' and Consumers' Working Party (PCWP), two topics will receive particular attention: vaccines and social media. Throughout 2016, the HCPWP, in collaboration with the PCWP, will continue to contribute to the Agency's discussions and initiatives to

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bring the real-life perspectives into the regulatory area, thus promoting a safer and more rational use of medicines.

In addition, the HCPWP will continue the work initiated in 2015 covering the areas of information on medicines, risk minimisation measures, and EMA collaboration with academia, learned societies and healthcare professional organisations with a view to identify and reflect on aspects that may require future action from the EMA (including the review of its framework of interaction with healthcare professionals) and/or from healthcare professional organisations. This work will be supported by topic groups set up for each of these areas.

In order to stimulate further the active role of HCPWP members in the planning and running of working party meetings, and building upon experience gained throughout 2015, the working party will be asked to identify possible topics that could be closely followed and reported directly by HCPWP members.

3. Involvement in Agency Scientific Committees (SC) and Working Parties (WP) activities

Actions:

- Continue to support the identification of experts from HCPOs to provide input within benefit-risk discussions, including, for example:
  - Participation in scientific advisory groups and ad-hoc expert group meetings;
  - Responses to calls for ad-hoc consultations from committees and their working parties.
- Facilitate as appropriate healthcare professionals' input into the development of new/revised EMA guidelines.
- Gather, in close collaboration with the scientific committee members of the HCPWP and the EMA secretariat, topics and learnings where involvement of healthcare professionals in SC/WP activities has occurred to support re-assessment of this involvement.

4. Information and communication

4.1. Input on information on medicines and EMA communications targeted to healthcare professionals

Actions:

- Continue to support the identification of experts from HCPOs to provide input on:
  - Specific sections of Summary of Product Characteristics (SmPC) and labelling, particularly is the context of risk minimisation measures and medication errors;
  - Safety communications addressed to the general public, which include specific recommendations for healthcare professionals;
  - Direct healthcare professional communications (DHPCs);
  - EMA communications and catalogue entries related to shortages.
- Follow reflection to develop recommendations to EMA and to healthcare professional organisations on:

- How to use available resources to maintain high quality of product information throughout the lifecycle of the medicine whilst ensuring it reflects as much as possible clinical practice reality;
- How to use or improve current EMA information outputs to support clinical practice;
- How to bridge regulatory outputs with therapeutic guidelines/prescribing recommendations.

- Look at potential involvement in the drafting of risk management plan summaries.

4.2. Dissemination of information

Action:

- Contribute to the dissemination of EMA key information to relevant healthcare professionals.

4.3. EMA awareness

Actions:

- Raise awareness of the activities in which HCPWP/HCPOs are involved within the Agency by sharing practices between organisations.
- Support EMA communication activities to increase EMA awareness, as necessary.
- Promote the use and dissemination of new materials to raise awareness, e.g. EMA basics videos, presentations on EMA interactions with healthcare professionals, etc.

5. Pharmacovigilance and Risk Management

5.1. Risk minimisation measures and assessment of their effectiveness

Action:

- Follow reflection on the outcome of the PCWP/HCPWP workshop on risk minimisation measures organised in September 2015.

5.2. Reporting and monitoring of adverse drug reactions

Actions:

- Continue to provide input to EMA initiatives aimed at analysing the utility of social media, including the IMI-WebRADR project.

5.3. Prevention of medication errors

Actions:

- Provide input as needed on aspects related with the implementation of the EU regulatory network's good practice guide on medication errors.
- Continue to support the identification of experts from HCPOs to provide input on product information and additional risk minimisation measures aimed at preventing medication errors.

5.4. Other pharmacovigilance activities

Actions:

- Advise the Agency on approaches to measuring the impact of pharmacovigilance.
- Contribute to the update of the Guideline on Good Pharmacovigilance practices (GVP) modules, as requested.
- Continue to provide input and support to the EMA in the implementation of the pharmacovigilance legislation through the participation in dedicated stakeholder meetings.

5.5. Public hearings

Action:

- Support the Agency in the implementation of public hearings, as appropriate.

6. Clinical trials

6.1. Clinical trials regulation

Actions:

- Provide input and support to the EMA in the implementation of the clinical trial regulation through the participation in dedicated stakeholder meetings.
- Continue to contribute to the EU CT Information System Expert Group on aspects related with the operation of the EudraCT database and the EU Clinical Trials Register.

6.2. EMA policy on the pro-active publication of clinical-trial data

Actions:

- Follow up implementation of publication of clinical study reports.
- Contribute to user testing of the planned website for clinical data publication.

7. EU-wide initiatives

7.1. EMA research networks

Actions:

- European Paediatric Research Network (EnprEMA): contribute to the activities of EnprEMA through the continued involvement of a HCPWP observer in the plenary meetings.
- European Network of Centres for Pharmacoepidemiology and Pharmacovigilance (ENCePP): contribute to the activities of ENCePP through the continued involvement of a HCPWP observer in the plenary meetings.

7.2. Research projects

Actions:

- Follow up and disseminate as appropriate information on research projects where EMA is involved.
- Support direct participation of HCPOs where relevant.

7.3. Other initiatives

- Follow up and support participation as requested within identified initiatives (e.g. EUNetHTA).
- Follow up on outcome related to the EC study on off-label use of medicines, when available.

8. Participation in workshops and conferences

Action:

- Support the identification of the most appropriate candidates to participate, including when appropriate, speakers who can address identified topics.

9. Interaction with patients and consumers

Actions:

- Organise two joint HCPWP-PCWP meetings in 2016.
- In the context of the joint meetings, organise:
  - Dedicated session on 'Preventing infectious diseases: focus on vaccines' (tbc);
  - Workshop on 'Social Media'.
- HCPWP representative will regularly attend as observer at PCWP meetings and vice-versa.

10. Organisational matters

10.1. Framework for the interaction between the Agency and healthcare professionals' organisations

Action

- Reflect on the need to revise the framework of interaction.

10.2. Mandate 2016-2019

Action:

- Organise renewal of mandate and elections of co-chair.

10.3. Identification of topics to be addressed by members

Action:

- Identify possible topics that could be closely followed and reported directly by HCPWP members during its plenary meetings.

10.4. Monitoring and reporting

Actions:

- Monitor the involvement of healthcare professionals and their organisations in the Agency's activities.

- Collect organisations' testimonies on how/where they see the added-value of the EMA interaction.
- Endorse, in conjunction with the PCWP, an annual report on the progress of the interaction to be presented to the Management Board.