



14 September 2015  
EMA/501464/2015  
Stakeholders and Communication Division

## *Draft Work plan for the European Medicines Agency Human Scientific Committees' Working Party with Patients' and Consumers' Organisations (PCWP) 2016*

<b>Chairpersons:</b>	<b>Status</b>
Isabelle Moulon (EMA) and David Haerry (EATG)	Draft to be endorsed by PCWP 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 HCPWP
- 14 June - PCWP plenary meeting (including election of co-chair)
- 19 September - Joint PCWP/HCPWP workshop on 'Social Media'
- 20 September - Joint plenary meeting with HCPWP
- 29 November - Training session
- 30 November - Meeting with all eligible organisations

### **2. Introduction**

The PCWP supports and monitors patients, consumers and their organisations involvement throughout the Agency's activities. It identifies opportunities and challenges that may need special attention, particularly in the context of the revised framework of interaction.

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 Healthcare Professionals Working Party (HCPWP), two topics will receive particular attention: vaccines and social media.

Throughout 2016, the PCWP will continue to contribute to the Agency's discussions and initiatives to bring the real-life perspectives into the regulatory area, thus promoting a safer and more rational use of medicines.

In particular, the PCWP will work on the following main areas:

- Measure the impact of patient involvement in EMA activities
- Acknowledge and promote visibility of patient input in the Agency's activities
- Training
- Social Media
- Involvement of young people in EMA activities

This work will be supported by topic groups set up for each of these areas and the members (patient organisations) will be asked to reflect on and propose recommendations/ proposals for action.

### **3. Involvement in Agency Scientific Committees and working parties activities**

Continue to support participation of patients as members of committees, in addition:

#### **Actions:**

- Support enhanced involvement of patients within benefit/risk discussions, including evaluation of new methodologies for capturing patient input.
- Continue to monitor the involvement of patients within CHMP oral explanations and contribute to the analysis of the pilot project during 2016
- Respond to calls for ad-hoc consultations from committees
- Support the identification of patients for participation in SAG/Ad-hoc expert group meetings
- Support the identification of patients for participation in scientific advice / protocol assistance procedures

## **4. Information and communication**

### **4.1. Input on information on medicines and EMA communications targeted to patients**

#### **Actions:**

- Continue to support the identification of experts from PCOs to provide input on:
  - New and renewal package leaflets,
  - EPAR summaries for new medicines,
  - Safety communications addressed to the general public,
  - Summaries of Orphan designation,

- EMA communications & catalogue entries related to shortages.
- Look at potential involvement in the drafting of summaries of herbal monographs
- Look at potential involvement in the drafting of risk management plan summaries
- Participate in the EMA analysis on information needs of different stakeholders regarding the Agency's scientific output.

## **4.2. Dissemination of information**

### **Action:**

- Contribute to the dissemination of EMA key information to relevant patients/consumers.

## **4.3. EMA awareness**

### **Actions:**

- Raise awareness of the activities in which PCWP/PCOs 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 patients, etc.

# **5. Pharmacovigilance and Risk Management**

## **5.1. Risk minimisation measures and assessment of their effectiveness**

### **Actions:**

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

## **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. 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.

## **5.4. 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:**

- Follow up implementation of publication of clinical study reports.
- Contribute as appropriate to second stage stakeholder consultation on the concept of individual patient data.

## **7. EU-wide initiatives**

### **7.1. EMA Research networks**

#### **Actions:**

- European Paediatric Research Network (EnprEMA): contribute to the activities of EnprEMA through the involvement of a PCWP member in the coordinating group; and participation in the annual EnprEMA workshop
- European Network of Centres for Pharmacoepidemiology and Pharmacovigilance (ENCePP): contribute to the activities of ENCePP through the involvement of a PCWP member in the coordinating group.

### **7.2. EMA Research projects**

#### **Actions:**

- Follow up and disseminate as appropriate information on research projects where EMA is involved.
- Support direct participation of PCOs 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 EMA 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 healthcare professionals**

### **Actions:**

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

## **10. Organisational matters**

### ***10.1. Framework of interaction between the Agency and patient/consumer organisations***

#### **Action:**

- Continue to implement all actions defined within the revised framework of interaction; specifically those highlighted within the annexed [action plan](#).

### ***10.2. Mandate 2016-2019***

#### **Actions:**

- Organise renewal of mandate and elections of co-chair

### ***10.3. Training and awareness***

#### **Actions:**

- Provide training and support to patients and consumers in line with the adopted training strategy.
- Adapt the scope of the in-house training/awareness sessions depending on requirements.

### ***10.4. Monitoring and reporting***

#### **Actions:**

- Monitor the involvement of patients, consumers and their organisations in the Agency's activities.
- Collect patients, consumers and/or organisations' testimonies on how/where they see the added-value of the EMA interaction.
- Endorse, in conjunction with the HCPWP, an annual report on the progress of the interaction to be presented to the Management Board.