17 March 2010
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Minutes of the ninth meeting of the EMA Human Scientific Committees' Working Party with Patients' and Consumers' Organisations (PCWP)

30 September 2009

Role	Name
Chairpersons:	Isabelle Moulon (EMA) and Nikos Dedes (EATG)
Present:	Representatives of: European AIDS Treatment Group (EATG), European Cancer Patient Coalition (ECPC), European Patients Forum (EPF), European Organisation for Rare Diseases (EURORDIS), European Public Health Alliance (EPHA), Health International Alliance of Patients' Organizations (IAPO), International Diabetes Federation (IDF), International Patient Organisation for Primary Immunodeficiencies (IPOPI) and The European Consumers Organisation (BEUC). Committee for Advanced Therapies (CAT), Committee on Herbal Medicinal Products (HMPC), Co-ordination Group for Mutual Recognition and Decentralised Procedures–Human (CMD(h)) and European Medicines Agency Management Board and Secretariat.

Introduction

The EMA Human Scientific Committees' Working Party with Patients' and Consumers' Organisations (PCWP) plenary meeting took place at the European Medicines Agency on 30 September 2009.

The co-chairs of the meeting welcomed the participants. The draft agenda was adopted with the addition of a topic under Any Other Business (see 5.6, MRI Product Index). Topic 1.2 has been postponed to the next PCWP meeting, which will take place on 08 December 2009.

7 Westferry Circus ● Canary Wharf ● London E14 4HB ● United Kingdom
Telephone +44 (0)20 7418 8400 **Facsimile** +44 (0)20 7523 7129
E-mail info@ema.europa.eu **Website** www.ema.europa.eu

1. Area of involvement of patients and consumers in EMA activities

1.1. Draft Reflection Paper on the further involvement of patients and consumers in EMA activities

The European Medicines Agency secretariat presented the "Draft Reflection Paper on the further involvement of patients and consumers in EMA activities" which will be presented to the EMA Management Board in December 2009. The main objective of this draft reflection paper is to propose specific actions to the EMA Management Board on how to further progress towards a more structured involvement of patients/consumers in various EMA activities. This would include considerations on the role that patients/consumers are to play in the different scientific committees, including to which extent they should be involved in benefit/risk considerations. Also, the provision of financial support to patients/consumers when participating in EMA activities has been proposed. The draft reflection paper analysed the experience gained so far, including patients'/consumers' involvement in the activities of the Agency, the benefits derived form the contribution of patients/consumers to such activities, as well as the difficulties encountered so far.

PCWP members acknowledged that this reflection paper represents a good step forward in recognising the extra effort that patients/consumers organisations' representatives make to participate in the activities of the EMA; this acknowledgment makes the patients' and consumer's representatives feel more valued.

PCWP members noted that participating in the meetings held at the Agency is a major commitment, especially considering that the majority of patients' and consumers' representatives work on a voluntary basis for their organisation. It was also added that it could be very useful if the Agency could organise training sessions for patients/consumers on regulatory activities.

The EMA secretariat agreed on the need to widen patients'/consumers' participation, which will be achieved in 1Q2010 with the enlargement of the PCWP. It was also noted that the possibility for a large number of observers to attend the PCWP meeting will be explored. The importance of the annual PCWP meeting with all eligible patients'/consumers' organisations has been highlighted in this context.

The draft reflection paper will be presented to the EMA Management Board for endorsement in December 2009.

It was agreed to wrap up this discussion in the afternoon towards the end of the meeting, when conclusions and proposals would be agreed upon.

1.2. Involvement of patients and consumers in preparation and dissemination of EMA communications – overview and analysis of comments received

This topic has been postponed to the next PCWP meeting (08 December 2009).

1.3. Enlargement and renewal of PCWP composition

The PCWP has been established in 2006, and according to its "Mandate, objectives and rules of procedure", its membership is valid for three years and is renewable. In the view of the need to renew the present composition of the PCWP, the EMA secretariat presented an overview of the current

composition, together with a proposal for its enlargement. With regard to the current composition, it was communicated that all current PCWP members have renewed their interest in continuing to be members of the working party, as resulted from a call for expression of interest launched at the end of August 2009. The EMA secretariat reminded the group that new co-chairs will be nominated; one chairperson will be nominated by the EMA, the second will be elected by the PCWP once the new group has been established (1Q2010).

With regard to the enlargement of the PCWP, the criteria and the procedure for the selection of the new members were presented, together with a timeframe for its finalisation. PCWP members expressed the need to review the mandate of the working group, maybe allowing for the presence of more alternate members and observers who could rotate, to give more patients/consumers the opportunity to participate to the meetings of the PCWP.

The EMA secretariat communicated that the invitations to become members on the PCWP would be sent out to the selected organisations by the end of the year 2009.

1.4. Preparation of training session for the experts' review of EMA product information

The EMA secretariat presented the draft agenda of the training session on the review of documents addressed to the general public by patients/consumers experts, which will take place on 07 December 2009. The training session will include an introduction to the review procedure, with practical examples and exercises. The training manual will be extensively updated. The EMA illustrated the statistics relative to the review of documents by patients/consumers during the years 2008/2009. The review procedure will be streamlined with the aim to increase the rate of participation of the experts.

2. Area of transparency and dissemination

2.1. Work Plan for 2010

The EMA secretariat presented the PCWP work plan for 2010. The document covers all the areas of activity in which the PCWP will be involved during the next year. The work plan will focus on how to develop further involvement of patients and consumers in benefit/risk considerations at the level of scientific committees. Organisational matters to be addressed are the enlargement of the PCWP, the renewal of its composition and the election of new co-chairs, and also the need to strengthen the interaction with healthcare professionals represented by the Healthcare Professionals' Working Group (HCP WG). The EMA secretariat also noted that after the new framework is finalised, new performance indicators will be put in place to measure the level of satisfaction of the patients'/consumers' organisations involved in the activities of the agency.

PCWP members expressed the need to link the work plan to some of the activities included in the EMA Road Map to 2015 that has been illustrated by Noël Wathion, Head of the Human Post-authorisation Unit.

PCWP members were asked to review the work plan and forward their comments and suggestions for additional activities to the EMA secretariat within ten days from this meeting.

2.2. EMA published information on generics

The EMA secretariat presented how the information on generics is published by the agency, and asked for feedback on the new questions & answers document on generics, which has been reviewed; new elements have been added to the document (e.g. the use of different salts, use patents, information on hybrid generics), and the agency is interested in knowing the views of patients/consumers on this issue.

The PCWP will give feedback to the EMA secretariat in two weeks from this meeting.

3. Area of pharmacovigilance

3.1. Draft report on the outcome of the pilot phase

The EMA secretariat presented the draft report on the outcome of the pilot phase in which two members of the PCWP participated for three months in the meetings of the Pharmacovigilance Working Party (PhVWP). The purpose of this pilot phase was to analyse various aspects in order to be in the position to formulate a clear proposal for involving patients and consumers in the meetings of the PhVWP. From the analysis of the pilot phase emerged that the participants to the PhVWP should preferably have some previous experience in other EMA activities (e.g. through participation in the PCWP). If this is not possible, training should be foreseen for prospective members. The PCWP members who participated in the pilot phase expressed a good level of satisfaction with the way their contribution was taken into account, and noted that it has been an important commitment which involved a challenging preparation, given the workload for each meeting. The EMA secretariat communicated that a call for expression of interest for the PCWP observer and alternate in the PhVWP will be open in January 2010 once the proposal had been endorsed by the EMA Management Board and the Heads of Medicines Agencies, and the PCWP will be timely informed about this procedure.

4. Road map to 2015

4.1. The European Medicines Agency Road Map to 2015: The Agency's Contribution to Science, Medicines, Health

Noël Wathion, Head of the Human Post-authorisation Unit, presented the EMA Road Map to 2015. The draft document has already been circulated internally for comments to all EMA Scientific Committees and correspondent Working Parties. Comments from the PCWP are expected by 16 October 2009.

The Road Map to 2015 is a continuation of the Road Map to 2010, building on current achievements, and provides the Agency's vision on how it will further develop itself as a public health Agency. The Road Map will be complemented with a document, "From Vision to Reality," which will be made available at a later stage, in view of the launch of a public consultation in January 2010. The EMA Road Map to 2015 focuses on four strategic areas: Further improving the operation of the core business, Addressing Public Health Needs, Facilitating Access to Medicines, and Optimising the Use of Medicines. All these areas where illustrated to the PCWP, for each one indicating long-term objectives and result indicators. PCWP members welcomed the document and expressed great appreciation for the goals outlined in it.

References to the role and interaction with Health Technology Assessment bodies were mentioned, as well as the attention given to new therapies and to emerging science. With regard to information to

patients, it was made clear that the EMA aims at having an important role in the provision of "regulatory" information. This implies that the EMA does not intend to reach individual patients, but rather to ensure that good quality and timely information is provided to patients and healthcare professionals in a coordinated manner through the EU Regulatory System Network.

PCWP members found the Road Map to be an excellent document, as it highlights many challenging areas for the EMA. However, it was noted that the Road Map is very ambitious, and the EMA would have to give priority to some actions/initiatives. The Road Map will be accompanied by a multi-annual planning, which will equally have a five years timeframe. Moreover, the "From Vision to Reality" document will consider different aspects of the Agency's operation, such as workload, human resources etc., and is expected to facilitate the implementation of the Road Map to 2015.

5. A.O.B

5.1. Wrap-up discussion on future patients/consumers interaction with EMA

The co-chairs lead the wrap-up discussion about the draft reflection paper (see 1.1), and about how to plan the future strategy aimed at involving patients/consumers in EMA activities. The PCWP welcomed in general terms the content of the draft reflection paper, with these observations:

- Make clearer in the text the need to widen the representation of patients'/consumers' organisations at the EMA:

- Cover more therapeutic areas;
- Explore further participation at PCWP level, and in a more flexible manner.

- Highlight the need for further training, on two levels:

- General training program;
- Induction material for new patients/consumers taking part in EMA activities.

It was agreed to circulate the draft reflection paper for comments to all participants after the meeting.

5.2. Update on the activities of the Working Group on clinical trials in third countries

The EMA secretariat introduced to the PCWP the activities of the Working Group on clinical trials in third countries. This working group is currently composed of four sub-groups, each one working on a different issue; each sub-group will produce a document, and the resulting four documents will be merged into a consolidated single document which will be released for public consultation in 1/2Q2010. A workshop will be organised later in 2010. Patients'/consumers' organisations representatives will be invited to this workshop.

5.3. Feedback on patients'/consumers' organisations consultations by the Pharmacovigilance Working Party

The EMA secretariat presented a summary of the various consultations by the PhVWP in which the PCWP members have been involved in the year 2009. Final documents were presented to show the

level of implementation of the comments received from patients'/consumers' organisations representatives.

5.4. Preparation of plenary meeting with all eligible organisations

The draft agenda for the annual PCWP meeting open to all eligible patients'/consumers' organisations has been presented by the EMA secretariat. The agenda is still in its development phase and comments from the PCWP on additional topics are welcome.

5.5. Update on the European Network of Centres for Pharmacoepidemiology and Pharmacovigilance (ENCePP)

The EMA presented an update on the work of the European Network of Centres for Pharmacoepidemiology and Pharmacovigilance (ENCePP). The main goal for 2009 was to have in place an operational network system that would allow the conduct of "ENCePP studies"; another objective was to define a Code of Conduct setting out rules for transparency and scientific independence in pharmacovigilance and pharmacoepidemiology research; and finally, to agree on the mandate which will enable the appointment of the ENCePP Steering Group, which will see the participation of a patients'/consumers' representative as a member. The EMA proposed to have a more extensive presentation on ENCePP during the next PCWP meeting in December 2009.

5.6. MRI Product Index

The observer from the Co-ordination Group for Mutual Recognition and Decentralised procedures - Human (CMDh) briefly summarised a proposal to update the MRI Product Index database for products approved through the Decentralised and Mutual Recognition procedures that is currently available on the Heads of Medicines Agencies website. The MRI Product Index will be re-developed to allow for the inclusion of veterinary products and will be made more-user friendly. The PCWP members were asked to provide feedback on the current layout and features of the MRI Product Index.

5.7. PCWP meeting dates for 2010

The PCWP meeting schedule for 2010 has been presented. The meeting dates (subject to change) are as follows:

05 March	Joint meeting with HCP WG
16 June	Plenary meeting
08 September	Plenary meeting
29 November	Training session on the review of product information
30 November	Meeting with all eligible organisations

Close of the meeting

The Chairpersons thanked all the participants for their active participation and fruitful discussions.