28 July 2010
EMA/405307/2010
Patient Health Protection

Minutes of the tenth EMA Human Scientific Committees' Working Party with Patients' and Consumers' Organisations (PCWP) meeting of 16 June 2010

Role	Name
Chairpersons:	Isabelle Moulon (EMA-Head of Medical Information) and Nikos Dedes (EATG)
Present:	*PCWP members:* European AIDS Treatment Group (EATG), European Cancer Patient Coalition (ECPC), European Federation of Allergy and Airways Diseases Patients' Associations (EFA), European Federation of Neurological Associations (EFNA), European Heart Network (EHN), European Multiple Sclerosis Platform (EMSP), European Older People's Platform (AGE), European Organisation for Rare Diseases (EURORDIS), European Patients' Forum (EPF), Health Action International Europe (HAI), International Alliance of Patients' Organizations (IAPO), International Diabetes Federation (IDF) and The European Consumers' Organisation (BEUC). *Representatives of Agency's scientific committees:* Committee for Advanced Therapies (CAT), Committee for Medicinal Products for Human Use (CHMP), Committee on Herbal Medicinal Products (HMPC). *Observers:* Co-ordination Group for Mutual Recognition and Decentralised Procedures- Human (CMD(h)), European Medicines Agency Management Board, Healthcare Professionals' Working Group (HCP WG) and experts from the European AIDS Treatment Group (EATG).
Apologies:	Committee for Orphan Medicinal Products (COMP), Paediatric Committee (PDCO), European Public Health Alliance (EPHA), International Patient Organisation for Primary Immunodeficiencies (IPOPI) and Pharmacovigilance Working Party (PhVWP) observer (patient representative).

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

Introduction

Isabelle Moulon welcomed the participants, stating that this would be the last meeting with the current co-chairs. She thanked everyone for their contribution to the significant achievements that the PCWP has made to date.

The new members were introduced; the European Federation of Allergy and Airways Diseases Patients' Associations (EFA), the European Heart Network (EHN), the European Multiple Sclerosis Platform (EMSP), the European Older People's Platform (AGE) and Health Action International (HAI), as well as the new observer from the Co-ordination Group for Mutual Recognition and Decentralised Procedures-Human (CMD(h)).

The Co-Chairs asked members to declare any potential conflict of interest they may have in relation to any topic in the Agenda. No issue was raised at this time.

The agenda was adopted with the addition of " Eligibility criteria" requested by a PCWP member, to be included under point 1.1.

1. Area of involvement of patients and consumers organisations (PCOs) in EMA activities

1.1. Revision of mandate and rules of procedure of PCWP

The EMA secretariat presented a draft revision of the mandate and rules of procedure of the PCWP which was adopted. The revision refers to the work of the PCWP in the coming years. It accommodates the new composition of the group and will allow more flexibility to incorporate additional participants as observers. The mandate will be circulated in the post-mail and, once adopted by the EMA scientific committees, then published on EMA website.

Eligibility criteria

A PCWP member enquired whether the current "eligibility criteria" could be more flexible and could allow some organisations at national level to participate directly in EMA activities. An example is when there is no European organisation on a certain disease, but there are several national ones. He asked whether these organisations could network and one of them, acting on behalf of the network, could interact directly with the EMA. The EMA secretariat clarified that so far national organisations participate with the EMA through European and Umbrella organisations. The current "eligibility criteria" itself will be looked at as part of the ongoing revision of the framework of interaction between the EMA and PCOs.

The need to extend the interaction at a national level was also considered. An activity where this is especially relevant is 'direct patient reporting'. It was proposed that somehow the EMA eligibility criteria model could be promoted and used as a European screening process.

1.2. New PCWP mandate – the next three years

The role of chairs / Procedure for election of new co-chair

The mandate of the current co-chairs of the PCWP has come to an end. Elections of the new co-chair will take place during the next meeting on 8th September 2010. Nikos Dedes gave a brief overview of

his experience as co-chair over the past three years. He referred to it as a very positive and enriching experience and he thanked everyone in helping to promote the role of patients within the Agency activities. He praised the work of the EMA secretariat in supporting the role of the Chair, but reminded that it is up to the candidate to promote initiatives, as they feel appropriate.

One important aspect is to collaborate to increase awareness of the PCWP activities and to further promote it European-wide.

The EMA secretariat presented the responsibilities of the chairpersons, as detailed within the mandate and rules of procedure above. He also presented the procedure for election of the new co-chair.

A PCWP member commented that it would be preferable if candidates have at least 2-3 years experience at the level of the PCWP.

Potential candidates should send their expressions of interest, together with a CV and letter of motivation. The EMA secretariat advised that it would be preferable to receive candidatures by 31 August to enable all members to review the applications, even though applications will be accepted until the start of the next meeting on 8 September.

1.3. Guidance on how to complete the 'declaration of interests' of patients' and consumers' organisations' representatives

Following a recent publication by the Corporate Europe Observatory it became clear that patients and consumers representatives within the Agency have difficulties in filling in their declaration of interest.

The current form was created to be used by scientists and does not fully take into account the specific circumstances of patients' representatives, who are very often volunteers. The EMA and the PCWP, acknowledging this aspect, prepared in the past a guidance to help patients and consumers representatives to complete the form. The EMA secretariat advised that the guidance is perhaps not sufficiently followed.

The Agency is also currently revising the declaration of interest forms, to adjust for different scenarios and affiliations and thus facilitating completion of the forms.

The EMA secretariat concluded that they would ensure that the guidance is included every time a declaration of interests form is sent out and would additionally explore producing 'frequently asked questions' and/or an online tutorial on how to complete the form.

1.4. EMA interaction with 'health technology assessment' bodies (HTAs)

The EMA secretariat presented this topic giving an overview of the new joint collaboration between the EMA and the European network for Health Technology Assessment (EUnetHTA). This collaboration has, specifically focused on the European Public Assessment Report (EPAR) and its contribution to relative effectiveness assessments. Following on the conclusions of the high level Pharmaceutical Forum, the EMA is working on improving the information contained within the EPAR, in order to address the HTAs need for specific information.

PCWP members requested clarification on the role of the PCOs in this process and emphasised the need to open the interaction to PCOs. The opinion is that PCOs working alongside regulators during the evaluation process would facilitate the impact of regulatory decisions and help their smooth integration within society.

1.5. Revision of the framework on the interaction between the EMA and patients' and consumers' organisations

Patient perspective in drug development in the past 20 years and future priorities

A PCWP member presented an overview of how patient involvement within the development and authorisation of medicines has evolved in the last 20 years.

Process for PCOs involvement in benefit/risk evaluation

The EMA secretariat presented a draft procedure to consult PCOs during benefit/risk considerations within the Agency.

PCWP members welcomed the proposal, and added that they would also like PCOs representatives to attend the CHMP meetings, in a similar manner to the current participation of the PhVWP meetings.

The current practice of involving PCOs in consultations on specific issues related to medicinal products, where their input is of particular benefit, will allow for the analyses of this experience from both perspectives and will lead to proposals on the revision of the framework.

It was requested that the PhVWP observers provide the PCWP with feedback on their experience at the PhVWP meetings.

Role of PCOs as members within scientific committees

This topic was postponed until the plenary meeting in September.

Additional training

It has been proposed to develop a training programme destined for any patient and consumer involved within EMA activities. PCWP members are invited to propose areas where they feel extra training would be beneficial and additionally what would be the ideal format(s). This will be added to the agenda of the PCWP meeting in September.

2. Area of pharmacovigilance

2.1. Direct patient reporting of adverse drug reactions

A representative from a PCWP organisation presented a 15-country survey on patient reporting of adverse drug reactions.

Comments received from the PCWP members included the fact that PCOs should be in contact with the health authorities on this issue. Although all routes of reporting should be available, an electronic system would potentially be most advantageous. It was also suggested that it would be potentially useful to include in the package leaflet details on how and where to report adverse events.

The EMA responded that the new legislative proposal on pharmacovigilance may imply the development of guidelines, for which consultation with PCOs will be critical. The EMA emphasised its role as facilitator and coordinator. However, implementation of this activity will be up to national agencies, in collaboration with the pharmaceutical industry. They suggested the utility of an awareness campaign in this area. The group will be kept informed on any 'next steps' on this topic.

3. A.O.B

3.1. 3rd annual report – activities during 2009

The EMA secretariat presented the annual report from 2009, giving a detailed overview of the involvement of PCOs in the Agency activities. The report, once presented to the EMA Management Board, will be published on the EMA website.

3.2. 2011 PCWP meeting dates

It was suggested that, depending on the agenda, future PCWP plenary meetings may take place over a day and a half. The meeting dates will be revised to include the day before in case they are needed.

HMPC – The report from the joint meeting between the PCOs and the HMPC regarding how to improve information on herbal products was published on the EMA website on 14 June 2010.

The chairpersons thanked the participants for their contribution and participation in the meeting.

Close of meeting

Next meeting: 08 September 2010