20 October 2010
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Patient Health Protection

Minutes of the eleventh EMA Human Scientific Committees' Working Party with Patients' and Consumers' Organisations (PCWP) meeting of 08 September 2010

Role	Name
Chairpersons:	Isabelle Moulon (EMA-Head of Medical Information) and Lise Murphy (Eurordis)
Present:	PCWP members: European AIDS Treatment Group (EATG), European Cancer Patient Coalition (ECPC), European Federation of Allergy and Airways Diseases Patients' Associations (EFA), European Multiple Sclerosis Platform (EMSP), European Older People's Platform (AGE), European Organisation for Rare Diseases (EURORDIS), European Patients' Forum (EPF), European Public Health Alliance (EPHA), 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 for Orphan Medicinal Products (COMP), Paediatric Committee (PDCO). Representative from the European Commission. Observers: Co-ordination Group for Mutual Recognition and Decentralised Procedures- Human (CMDh), Pharmacovigilance Working Party (PhVWP).
Apologies:	European Federation of Neurological Associations (EFNA), European Heart Network (EHN), International Patient Organisation for Primary Immunodeficiencies (IPOPI), Committee on Herbal Medicinal Products (HMPC), EMA Management Board, Healthcare Professionals' Working Group (HCP WG).

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 to this important meeting which would include the election of the new co-chair of the PCWP.

A 'tour de table' followed whereby all those present introduced themselves, including the new participants.

Members were asked 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 "feedback from the benefit/risk conference" requested by a participant, to be included under point AOB.

1. Organisational matters

Election of the new PCWP co-chairs

The group was advised that Dr Isabelle Moulon, Head of Medical Information sector of the EMA, was nominated by the EMA Executive Director as co-chair of the PCWP for a second three year term.

The EMA secretariat presented the procedure for election of the new co-chair.

All potential candidates had been requested to send their expressions of interest, together with a CV and letter of motivation prior to the meeting.

Two candidatures were received; one from Eurordis and one from IAPO. Each candidate briefly presented themselves to the group. Thereafter the votes were cast and the majority of 10 out of 16 votes, with no abstentions, was won by Lise Murphy from Eurordis.

Isabelle Moulon congratulated Lise on behalf of the group and wished her a fruitful co-chairpersonship. On behalf of the PCWP, Isabelle thanked the previous co-chair, Nikos Dedes, for his outstanding contribution to the PCWP.

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

2.1. New policy on conflicts of interest

The EMA presented the new draft policy on conflicts of interest which has been drafted on the basis of the key principals adopted by the Management Board at its June 2010 meeting. It was clarified that some aspects of the policy are still being finalised. The new draft policy will be discussed at the 7th October 2010 Board meeting.

A comment from the group highlighted the fact that this new policy will need very clear instructions, especially for those not very familiar with medicines regulation (e.g. patient representatives).

A further statement by a participant expressed concern that this revision could be partly in response to external pressures and that it could affect the capacity of patients and consumers to be involved in the Agency activities in the future. The EMA responded that the current policy has been in place since 2006 and its revision, in any case necessary, has been initiated for some time. Experience obtained has

highlighted the need for a more robust, efficient and transparent process. The aim is to find the right balance between strengthening the handling of conflicts of interests and ensuring that the best scientific expertise is involved in the assessment process.

An impact analysis has been carried out to determine the impact of the proposed changes and this was presented to the Board in June.

The EMA co-chair advised that, once the policy is finalised, the EMA will look more in depth at the impact on patients and consumers.

There were further questions from the group concerning the policy, many regarding individual situations. These points will be further investigated once the policy is finalised. The policy will be presented at the meeting with all eligible organisations at the end of November.

In the meantime, it was recommended that any further comments be sent to the EMA secretariat as soon as possible, prior to the finalisation of the policy.

2.2. Role of PCOs as members within scientific committees

The co-chair thanked the members for their work in preparing the document.

The EMA presented an overview of the draft document "The role and responsibilities of patients' representatives within EMA Human Scientific Committees".

Representatives from each of the committees (PDCO, COMP & CAT) gave a presentation on the work carried out within their committee and their personal experience as a patient representative member within that committee.

Following the presentations one participant asked the presenters what they considered challenging in their work. It was then recommended to include these challenges within the document.

It was also proposed to include the level of workload in order to provide a thorough overview for any future patients' representatives who become a member of any committee.

The document will be finalised and will be presented at the meeting with all eligible organisations in November.

2.3. HAI report on financial disclosure of patients' and consumers' organisations working with the agency

The purpose of putting this item on the agenda was not to discuss HAI's report but to issue some recommendations in particular on the transparency aspect.

The issue of transparency of PCOs will be brought to the meeting with all eligible organisations on 30 November, and this would be a good opportunity to discuss the current eligibility criteria in place for PCOs working with the EMA. The participants were requested to reflect on the current eligibility criteria and how they could be revised to request more on funding and activities.

The EMA will prepare and circulate a summary on these issues, so that PCOs can identify questions/issues to be addressed.

Members of the PCWP requested that the Commission explore ways to support the provision of public funding for these organisations. – As this topic is not for discussion at the PCWP, it was advised that any request(s) should be made directly to DG Sanco.

2.4. PCWP work plan 2011

The EMA presented the proposed work plan for 2011.

The participants requested the following inclusions:

- A glossary of acronyms;
- To extend the duration of plenary meetings; 1.5 - 2 days
- PROTECT (Pharmacoepidemiological Research on Outcomes of Therapeutics by a European Consortium);
- To be kept up to date on work with health technology assessment bodies;
- To elaborate further on the support provided to the development of the EudraCT public interface.

The work plan will be updated accordingly.

2.5. SAG pilot phase

The proposal for patient representatives to participate in SAG meeting foresees a 1 year pilot phase which will start in October.

The proposal has already been discussed and in principal agreed. Up to two patient/consumers, selected among eligible organisations, will be invited to the SAG meetings, unless it is deemed that the discussion would be too technical and/or does not involve benefit/risk assessment. A questionnaire will be given to both the patient representative and the regulators after each meeting for analysis of the experience. Following the one year period a report will be prepared.

3. Area of pharmacovigilance

3.1. EudraVigilance Access Policy

In line with pharmaceutical legislation, aggregated information on reported adverse events recorded in the EudraVigilance database will, in the near future, be made available to the public.

The EMA gave a presentation on the new Access Policy (see presentation).

For information, a user group, including patient/consumer and healthcare representatives, has recently been created, with the aim to define the requirements for the access policy.

Following the presentation, the group asked several questions concerning the exact nature of the information to be made public, and specifically if in addition to adverse events information such as population / indication, etc would be available. - The EMA clarified that this type of information is not reported and therefore will not be available, and for this reason clear guidance on the interpretation of the data will be provided. The EMA highlighted that the user group has an important task in contributing to the preparation of such guidelines for use by the public once the information becomes available.

4. A.O.B

The feedback from the benefit/risk conference was postponed until the next meeting in November.

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

Close of meeting

Next meeting: 30 November 2010