07 February 2011
EMA/790515/2010
Patient Health Protection

Minutes of the EMA Human Scientific Committees' Working Party with Patients' and Consumers' Organisations (PCWP) together with all other eligible organisations - meeting of 30 November 2010

Role	Name
Chairpersons:	Isabelle Moulon (EMA-Head of Medical Information) and Lise Murphy (Eurordis)
Present:	PCWP members: Alzheimer Europe (AE), Debra International-Global Network of Epidermolysis Bullosa Support Groups, 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 Genetic Alliances' Network (EGAN), European Headache Alliance (EHA), European Heart Network (EHN), European Institute of Women's Health (EIWH), European Organisation for Rare Diseases (Eurordis), European Patients' Forum (EPF), Global Alliance for Mental Illness Advocacy Networks (GAMIAN-Europe), Health Action International (HAI), Insulin Dependent Diabetes Trust (IDDT), International Alliance of Patients' Organisations (IAPO), International Diabetes Federation (IDF), International Patient Organisation for Primary Immunodeficiencies (IPOPI), Myeloma Euronet (ME), Rett Syndrome Europe (RSE), The European Consumers' Organisation (BEUC), The European Older People's Platform (AGE), The European Prostate Cancer Coalition (Europa Uomo). Representatives of Agency's scientific committees: Committee for Medicinal Products for Human Use (CHMP), Committee for Orphan Medicinal Products (COMP), Committee for Advanced Therapies (CAT), Paediatric Committee (PDCO), Committee on Herbal Medicinal Products (HMPC). Observers: EMA Management Board.
Apologies:	Co-ordination Group for Mutual Recognition & Decentralised Procedures – Human (CMD(h)), European Commission, European Myeloma Platform (EMP), European Multiple Sclerosis Platform (EMSP), European Parkinsons Disease Association (EPDA), European Public Health Alliance (EPHA), Healthcare Professionals' Working

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Role	Name
	Group (HCP WG), Pharmacovigilance Working Party (PhVWP), Thalassaemia International Federation (TIF), The International Confederation of Childhood Cancer Parent Organisations (ICCCPO).

Introduction

Isabelle Moulon welcomed the participants to the meeting, especially the newcomers. Lise Murphy thanked all those who participated in a successful training session the day before.

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 no additions.

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

1.1. Benefit/risk communication by the European Medicines Agency: a study of influential stakeholders' expectations and attitudes

Frederic Bouder gave a presentation on the results of a research project he carried out at the Agency during 2009/2010 (3 case studies) on the way that it communicates benefit/risk. The study involved 102 different stakeholders and at least 77 in-depth interviews were carried out. The final study report should be published shortly and the EMA will be looking into how it can take the recommendations forward.

Following Frederic's presentation participants discussed the added value of having an advisory board which could be established to evaluate each case, as each issue is different and lessons can be learnt from previous cases; PCOs expressed interest to be involved within such an advisory board.

A further participant mentioned that older people should be specifically targeted within benefit/risk communications.

Additional comments from the floor highlighted the fact that benefit/risk communication is not just about giving information but about interaction with various key players. Any committee has not only an informative role but also needs to work towards providing credibility to the general public in the provision of information. PCWP is of the opinion that further discussions on benefit/risk communications should involve PCOs, HCPS, regulators, industry and also risk communication experts.

- the EMA confirmed that PCOs are regularly included in the preparation of the Agency safety communications.

1.2. Feedback from 3rd foresight regulatory affairs training (benefit/risk and HTA)

A PCWP member presented an overview from a regulatory affairs forum held in September 2010 organised by the Gianni Benzi Foundation. He focused his presentation on two topics; B/R and health technology assessments (see presentation).

The EMA highlighted that these are very important issues that the group will be re-discussing. The Agency will be looking at the ongoing activities in these areas and will provide a general overview.

1.3. New policy on conflicts of interest – presentation of impact analysis on PCOs

The EMA gave a presentation on the final policy on conflicts of interest (see presentation) which was endorsed by the EMA Management Board in October 2010.

The draft policy had been presented to the PCWP at their meeting in September 2010 and PCOs had submitted comments which were considered for the finalisation of the document.

There followed a second presentation by the EMA giving an overview of the specific impact of the new policy on PCOs, including some Question & Answer examples (see presentation).

Following these presentations the participants had several questions/comments.

Several members expressed concerns on the impact of the policy regarding the participation of patients in the EMA scientific committees.

- the Agency responded that patient representatives acting as members of the scientific committees have the same rights and obligations as the other committee members. Therefore it is not possible to apply double standards and the EMA cannot treat patient representatives differently than any other committee members.

An additional participant asked what the rules were for observers at the committees as this did not seem to be covered within the policy.

- the Agency will look into this and come back with a response at a later stage.

There was a further question requesting clarification on the rules for grants/funding given to an organisation, specifically whether there are any differences if the funding is for research or non-research purposes?

- the Agency responded that no distinction is made; the rules apply to any funding, whether it is given for research work or not. It was highlighted that all kinds of funding/grant should be declared.

It was requested whether the policy can allow for exceptions in some circumstances?

- the EMA explained that the concept of waivers has been abandoned in the revised policy as experience has shown that it may lead to inconsistency in the handling of conflicts of interests.

Several participants thanked the EMA for their clear presentations and praised its efforts to increase trust and transparency by creating a stricter, clearer policy.

The EMA informed that the implementation of the new policy will be closely monitored and a report will be prepared as per agreement at the Management Board.

1.4. Revision of eligibility criteria

Following recent discussion on the level of transparency of PCOs involved in EMA activities, the EMA management board assessed the process in place for the evaluation of eligibility. The board concluded that the current practice is acceptable but that there is a need to increase transparency on the Agency's procedures.

As an outcome of the Board discussions the EMA will prepare a standard operating procedure which will describe in detail the procedure for the review and monitoring of the eligibility criteria for PCOs. The EMA will also revise its eligibility criteria; especially the section on 'transparency'.

The EMA presented a proposed new draft of the criteria which will be circulated post-meeting for comments in preparation for re-discussion at the February 2011 PCWP meeting.

There followed several comments from the floor:

A question was raised with regards to the monitoring of individual (national) organisations within the umbrella 'eligible' organisations.

- the EMA responded that the current criteria usually only accepts 'European' organisations as eligible organisations and that it is up to each organisation to monitor their national affiliate organisations; the EMA cannot request the financial details of all the individual organisations, although it does recommend that the financial details of all organisations are published and made available to the general public.

A further question pertained to which annual report should be provided to the Agency at the time of evaluation.

- the response was that the latest financial report is preferred; this is usually the report from the previous year.

The EMA reiterated that the draft document would be circulated for comments and that this is a good opportunity to make any other changes to other sections, in addition to the section on transparency.

1.5. Performance indicators for 2010

The EMA circulated the draft revised performance indicator questionnaire which will be sent out for completion to all those who have participated in the EMA activities during 2010. The outcome data will be included within the annual report for 2010.

The draft document, which has been updated to bring it in line with new procedures, will be circulated for comments until mid-December.

1.6. Review of the new EMA website

The EMA gave an overview of the new corporate website, which PCOs have contributed to through user-testing. PCOs are encouraged to provide any additional feedback now that the website is up and running.

1.7. Role of PCOs as members within scientific committees

The EMA presented an overview of the draft document "The role and responsibilities of patients' representatives within EMA Human Scientific Committees". The co-chairs proposed that the document elaborates further on the added value of patients in the committees' discussions.

The document will be circulated for comments until mid-January and will be re-discussed at the next PCWP meeting in February 2011.

1.8. Value and preferences for health states amongst patients

An EMA representative gave a presentation on a benefit/risk methodology research study which will be carried out at the Agency in 2011. The study will look at patient preferences and values for efficacy and safety attributes for different treatments. The study method will involve interviews and questionnaires and will involve different stakeholders.

The EMA will be sending out more information in the near future with a call for expression of interest to include patients and consumers in this study.

1.9. The use of IVRS (Interactive Voice Response System) – patient perspective

This topic was postponed until a future meeting.

2. A.O.B

The Agency would like to further open participation at PCWP meetings and include more observers from patient organisations during 2011. A call for expression of interest to attend will be sent out prior to each meeting.

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

Close of meeting

Next meeting: 22-23 February 2011