6 February 2013
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Patient Health Protection

Minutes of EMA Human Scientific Committees' Working Party with Patients' and Consumers' Organisations (PCWP) meeting with all eligible organisations

30 November 2012 – 09:00hrs to 16:30hrs, room 4B, – Co-chaired by Isabelle Moulon (EMA) and Lise Murphy (EURORDIS)

Role	Name
Co-chairs	Isabelle Moulon and Lise Murphy
Present:	PCWP members and eligible organisations: Alzheimer Europe (AE), European AIDS Treatment Group (EATG), European Cancer Patient Coalition (ECPC), European Consumers' Organisation (BEUC), European Federation of Allergy and Airways Diseases Patients' Associations (EFA), European Heart Network (EHN), European Institute of Women's Health (EIWH), European Liver Patients Association (ELPA), European Organisation for Rare Diseases (EURORDIS), European Patients' Forum (EPF), European Public Health Alliance (EPHA), Global Alliance for Mental Illness Advocacy Networks (GAMIAN-Europe), Health Action International Europe (HAI), International Alliance of Patients' Organizations (IAPO), International Diabetes Federation European Region (IDF Europe), Myeloma Patients Europe (MPE) Representatives from the Agency's Scientific Committees: Committee for Orphan Medicinal Products (COMP) External speakers: European Patients' Academy on Therapeutic Innovation (EUPATI), Innovative Medicines Initiative (IMI), Pharmacovigilance Risk Assessment Committee (PRAC) Observers: Co-ordination Group for Mutual Recognition and Decentralised Procedures- Human (CMDh)
Apologies:	PCWP members and eligible organisations: AGE Platform Europe (AGE), DEBRA International, European Federation of Neurological Associations (EFNA), European Gaucher Alliance (EGA), European Genetic Alliances' Network (EGAN), European Headache Alliance (EHA), European Multiple Sclerosis Platform (EMSP), European Network of Fibromyalgia Associations (ENFA), European Parkinson's Disease

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Role	Name
	Association (EPDA), European Prostate Cancer Coalition (EUomo), Fabry International Network (FIN), International Bureau for Epilepsy (IBE), International Confederation of Childhood Cancer Parents Organisations (ICCCPO), Insulin Dependent Diabetes Trust (IDDT), International Patient Organisation for Primary Immunodeficiencies (IPOPI), Pain Alliance Europe (PAE), Rett Syndrome Europe (RSE), Thalassaemia International Federation (TIF) Representatives from the Agency's Scientific Committees, Working Parties and Working Groups: Committee for Advanced Therapies (CAT), Committee for Medicinal Products for Human Use (CHMP), EMA Management Board, Healthcare Professionals' Working Group (HCP WG), Committee on Herbal Medicinal Products (HMPC), Paediatric Committee (PDCO)

Introduction

Isabelle Moulon and Lise Murphy (co-chairs) welcomed the participants to the meeting and thanked all those who had participated in the successful training session the day before.

It was also mentioned that it has been 10 years since the first meeting of the EMA working group with patients/consumers and that this interaction has since progressed enormously and become a very successful collaboration!

The draft agenda was adopted with no additions.

Nathalie Bere (EMA) provided an overview of the work carried out so far during 2012, after which the chair thanked all the participants for their hard work and input throughout the year, emphasising that the key task is to refine the current involvement to ensure that the patient/consumer participation is optimised.

1. Involvement of patient/consumer organisations in EMA activities

1.1. Experience following implementation of the new policy on conflicts of interest

Noel Wathion (EMA) joined the meeting by telephone, and explained that following recent feedback from several patient organisations the EMA is committed to further engaging in discussions on issues related to the implementation of the EMA policy on conflicts of interest, specifically regarding patient representatives' involvement in the Agency's work.

Sheila Kennedy (EMA) presented the group with an overview of the experience gained to date on the implementation of the policy since its introduction in September 2011, including future steps (see presentation). Sheila stressed that the policy aims to establish a robust system able to identify potential conflicts, while providing enough flexibility to ensure input from the best available expertise.

Following the presentation, there were several comments and questions from the meeting participants. Several expressed their concerns that the new policy has had a significant impact on their participation as committee members, which they feel is now more restricted. They feel that the policy has not fully addressed the particularities of patient's representatives.

- The EMA responded that they are looking at this issue in the context of a future revision of the current policy. In the meantime an interim measure is proposed whereby there would be no restrictions in relation to funding received by an organisation if the committee member (patient organisation representative) is a volunteer, and not an employee for the organisation. This measure is applicable in the context of the current policy.

Some participants responded that although this may alleviate the situation in terms of participation in the committee, this might not be a suitable long term solution.

- The Agency emphasized that this is an interim proposal that can be introduced under the current policy and that it will explore further any viable proposals which would be presented to the EMA Management Board later in 2013. It also highlighted that the Agency needs to maintain a robust system, giving the same rights and obligations to all its committee members.

It was proposed to hold a teleconference in January to discuss concrete suggestions on the best way forward. The outcome of this teleconference will be used as a basis for further discussion at the PCWP joint meeting with healthcare professionals in February 2013; the aim being to procure tangible proposals, achieving a balance between consideration of the complexities related to patient representatives working in a regulatory environment and the management of any potential conflicts of interest.

1.2. Funding of organisations

Juan Garcia (EMA) presented an update of the document relating to conflicts of interest (COI) of organisations in relation to their funding (see presentation).

The EMA criteria for eligibility requires that any organisations working with EMA must disclose all sources of funding, including names of individual providers and their percentage in terms of the overall income. This information is requested annually by the Agency; however the criteria do not currently include details on how this information is used.

The aim of this document is to outline how financial information is used to assess whether an organisation is 'eligible' or not and also how to identify and handle potential conflicts of interest a particular organisation may have when they are involved in a specific product-related evaluation or discussion.

The document proposes that patient/consumer organisations (PCOs) demonstrate diversity of funding. The EMA would also encourage organisations to regularly audit their accounts, to have a policy on its code of conduct in this respect, and to publish income information on their website.

After the presentation there followed several comments from the floor; some participants discussed the possibility of establishing a threshold and that the EMA could require organisations to publish their accounts. However no agreement was reached on this point, with various voices preferring that EMA continues to strongly encourage such transparency. EMA highlighted that following implementation of eligibility criteria in 2005 more organisations have increased their levels of transparency in this respect.

Following further discussion it was agreed that the EMA would update the document, for re-discussion at the meeting with healthcare professionals in February 2013.

1.3. Training strategy

Nathalie Bere presented the proposed training strategy for patients and consumers which describes the specific training that is provided when they take part in EMA activities to aid and optimize their involvement (see presentation).

This has been highlighted previously and takes into account feedback obtained during discussions held in the margin of PCWP meetings. This strategy will be part of the revised "framework of interaction with patients and consumers' organisations".

After the presentation there followed a discussion concerning the annual training day and the possibility to hold it earlier in the year (currently held end November) - The EMA agreed to investigate for implementation in 2014. PCOs were also asked to propose topics for the training day.

In terms of the strategy document there were no comments and once information on training provided to committee members has been included it will be tabled for adoption.

PCOs were then shown a video which has been specifically developed for patients who are invited to take part in SAG meetings. This was well received with a few proposed minor amendments which will be incorporated. It will be circulated to all organisations prior to its publication on the EMA website, as well as on YouTube.

1.4. Involvement of young people in the work of the paediatric committee

This topic was postponed until the meeting with healthcare professionals in February 2013.

1.5. Patient/consumer involvement in benefit/risk evaluations

Juan Garcia (EMA) introduced the topic, highlighting that a document providing an overview of how PCOs are, and can, be involved in benefit/risk evaluations at the level of the CHMP (Committee for Medicinal Products for Human Use) has been prepared. The document builds upon the experience of many years of involvement with the CHMP and its working parties, and also incorporates more recent experience following systematic participation of patient representatives in SAG (scientific advisory group) meetings.

The complete reflection of patients involvement in benefit/risk cannot be finalised until the PRAC (Pharmacovigilance Risk Assessment Committee) is fully operational and representatives of patients have been nominated as PRAC members, as this will have an impact on the way patients will participate in benefit/risk discussions at the Agency from now on (see presentation).

There followed a presentation by June Raine, the PRAC chair (see presentation). June explained that patient representatives were previously involved within the Pharmacovigilance Working Party (PhVWP) as observers, and that this interaction had provided very useful experience which could be built upon through the PRAC.

Following the presentations, previous patients who were observers at the PhVWP offered to provide support to the new patient representative members of the PRAC, once they are nominated.

The PCWP was highlighted as the best forum to find patient and consumer expertise within a range of different therapeutic areas and could be consulted very quickly when necessary.

2. General

2.1. IMI (Innovative Medicines Initiative) : Highlights to date & longer-term perspectives

Hugh Laverty, from IMI, gave a presentation on this initiative which is a public/private partnership between the pharmaceutical industry and the European Commission (see presentation). Some of the patient organisations present are involved in IMI projects.

Research activities are performed through collaborative projects involving both industry and non-industry partners, following open calls and peer review. All research is pre-competitive, enabling different companies to collaborate and share expertise among themselves and with non-industry partners. IMI aims to accelerate the discovery and development of new medicines.

Hugh provided an overview of the main intents, what has been achieved to date, including examples of on-going projects and programs, and also future steps, including a move towards more societal needs.

After the presentation there were a few comments from the participants, namely why there was not more involvement by patient organisations.

- Hugh responded that in line with the current system, applications are dealt on a first come/first served basis and only one can become involved (top-ranked). It was suggested that perhaps PCOs could pool resources rather than submit competing applications. He also suggested that PCOs could discuss directly with the Commission and EFPIA with regards to the future PPP which is planned as part of Horizon 2020 and the role that PCOs could play in this.

PCOs were encouraged to visit the website and provide feedback.

2.2. European Patients' Academy on Therapeutic Innovation (EUPATI)

Jan Geissler, EUPATI Director, gave a presentation on the EUPATI project.

This IMI-funded consortium project, coordinated by the European Patients' Forum (EPF), aims to provide reliable, comprehensive information to patients on pharmaceutical research and development. This will increase the capacity of patients to be effective advocates and advisors, e.g. in clinical trials, with regulatory authorities and in ethics committees. Members include a consortium of European patient organisations, academic and not-for profit organisations and EFPIA member companies.

Within the next 5 years, EUPATI will provide training, tools and an internet-based library for meaningful patient involvement in medicines research and development. It will inform the lay patient community how the development process of new treatments works. PCOs are welcome to cooperate with the EUPATI consortium.

3. New pharmaceutical legislation

3.1. Urgent Union Procedure - "Stakeholders' submission form"

Vanessa Seguin (EMA) gave a presentation on the Urgent Union Procedure (Art.107i), introduced by the new pharmacovigilance legislation (see presentation). Within the framework of this procedure, all stakeholders (e.g. healthcare professionals, patients' organisations, general public) may submit data relevant to the procedure. Accordingly, the Agency has developed a Stakeholders' submission form and system to allow for the provision and receipt of such information. The template form was shown and demonstrated how to submit data.

Meeting participants had been sent the draft form and support system for testing prior to the meeting and some had provided their initial feedback and comments. The Agency advised that there was still time to provide additional comments after the meeting (+ 10 days) and that they will be kept up to date on the final outcome.

A.O.B

Follow-up on Workshop on access to clinical trial data

Francois Houyez (Eurordis) attended the workshop which was held at the Agency in November. He advised PCOs that 5 advisory groups would be created including patient representatives.

The EMA is committed to publishing clinical-trial data once the marketing-authorisation process is finalised. This event marked the first step in the process to publication of this data, as there are practical issues and other considerations that need to be addressed. The workshop gathered the views, interests and concerns from a broad range of institutions, groups and individuals and the next step will be to establish policies in close dialogue with stakeholders in five different areas identified during the workshop; protecting patient confidentiality; clinical-trial-data formats; rules of engagement; good analysis practice and legal aspects.

Advisory groups with broad representation from all parties, including PCOs will be formed and will start working on these topics in early 2013 with final advice from each group expected by the end of April 2013. The proactive publication of clinical-trial data is expected to come into force on 1 January 2014.

Francois encouraged organisations to join the advisory groups and the EMA advised they will circulate the call for expression of interest once it is published on the Agency website.

PCO involvement in scientific advice procedures

The EMA advised that from 2013 PCOs would also be invited to participate in scientific advice procedures (patient representatives are already involved in scientific advice for orphan medicines (protocol assistance) with the assistance of Eurordis.

More details will be provided once the procedure has been fully implemented.

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

Close of meeting

Next PCWP meeting: 27-28 February 2013