EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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Patient Health Protection

EMA Human Scientific Committees' Working Party with Patients' and Consumers' Organisations (PCWP) meeting

Meeting minutes - 6 June 2013 – chaired by Isabelle Moulon

Role	Name
Co-chair	Isabelle Moulon (EMA)
Present:	**PCWP members**: European AIDS Treatment Group (EATG), European Consumers' Organisation (BEUC), European Federation of Allergy and Airways Diseases Patients' Associations (EFA), 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), European Public Health Alliance (EPHA), International Diabetes Federation Europe (IDF Europe) **Representatives from patient and consumer organisations**: European Institute of Women's Health (EIWH) **Representatives from the Agency's Scientific Committees**: Committee for Herbal Medicinal Products (HMPC), Committee for Human Medicinal Products (CHMP), Committee for Orphan Medicinal Products (COMP) **Observers**: Management Board, Co-ordination Group for Mutual Recognition & Decentralised Procedures – Human (CMDh)
Apologies:	**Co-Chair**: Lise Murphy (Eurordis) **PCWP members**: European Cancer Patient Coalition (ECPC), European Federation of Neurological Associations (EFNA), Health Action International-Europe (HAI), International Alliance of Patients' Organizations (IAPO), International Patient Organisation for Primary Immunodeficiencies (IPOPI) **Representatives from the Agency's Scientific Committees**: Paediatric Committee (PDCO)

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Introduction

Isabelle Moulon (co-chair) welcomed the participants to the meeting and the draft agenda was adopted with no additions.

Involvement of patient/consumer organisations in EMA activities

Isabelle informed the participants about a research study being carried out by the University of Twente in the Netherlands, in cooperation with the EMA. The focus of this research is on patient views concerning benefit-risk evaluations at the EMA. The objective of this survey is to evaluate the possible use of quantitative patient preferences in the benefit-risk assessments of the CHMP. A questionnaire has been prepared to be tested by PCWP members volunteering to provide feedback; Barbro Westerholm (AGE), Hildrun Sundseth (EIWH) and Richard West (EURORDIS) volunteered to have a look at the questionnaire.

Isabelle also advised the group that a revised PCWP mandate has recently been approved by all EMA committees and we have been able to expand the membership of patient and consumer organisations to 20. A call for expression of interest to be PCWP members will be sent to all eligible patient/consumer organisations, including current PCWP members, so that all members will start the new term of 3 years at the same time.

1. Preparation for election of PCWP co-chair 2013-2016

Nathalie Bere (EMA) explained that as the current co-chairs' 3 year mandate finalises this year; elections for the new co-chair will take place during the PCWP meeting on 25 September 2013. She presented an overview of the procedure and rules, according to the PCWP "mandate and rules of procedure" (see presentation). A call for candidates will be sent out in July.

One participant enquired whether all eligible organisations could also vote for the PCWP co-chair.

The chair clarified that the co-chair is elected among and by the PCWP members to represent the PCWP.

2. Draft annual report on interaction between EMA and patients/consumers (2012)

Nathalie Bere (EMA) presented an overview of the involvement of patients and consumers in EMA activities during 2012. The figures demonstrate that an extensive collaboration between EMA and PCOs was again achieved throughout 2012, which is still increasing year on year (see presentation).

Patients and consumers were involved 525 times compared to 423 in 2011 and 75 in 2007 (note: in some cases the same patient/consumer participated in more than one activity).

The involvement of PCOs continues to be extremely beneficial and they are a recognised and integral part of the Agency's work. With the passing years, their involvement continues to increase and expand, but also evolves ensuring it occurs in the most optimal manner possible allowing patients to engage with the EMA to share their real-life experiences and in doing so, they provide valuable feedback which ultimately contributes to the quality of the decision-making process.

This information, included within the "Sixth annual report on the interaction with patients' and consumers' organisations", will be presented to the EMA Management Board and published on the EMA website once adopted.

The chair thanked all the participants for their hard work and valuable input throughout the year.

3. EMA Training

3.1. Strategy

Nathalie gave a summary of the finalised training strategy which has been previously presented and now includes information related to training for patient members in the committees.

Patients and consumers who are called-upon to be involved in a wide range of activities at the EMA, either as individual patient experts or as representatives of their organisations, need to receive appropriate support and training, prior to, and during their participation in any EMA activity. This training strategy describes the specific training activities and material that will be made available to patients and consumers when taking part in EMA activities and events and takes into account feedback from PCOs, as well as experience from training already provided during previous years in the different areas.

3.2. Webpage

In line with the training strategy, and in order to compile training materials, a draft dedicated 'training webpage' is being developed where patients/consumers can find all information, in different formats, in terms of support and training separated into the different activities.

3.3. Agenda – annual training day

The EMA proposed several topics for inclusion within the upcoming annual training day agenda for all eligible patient/consumer organisations, to be held at the Agency on 10 December 2013.

After discussion the following topics were agreed for inclusion on the agenda: training on relevant information on the EMA website and how to navigate and find such information (including EudraCT), and also training on involvement in scientific advisory group meetings and in scientific advice procedures, which would include experience from patients who have participated and from organisations on locating suitable patients.

The agenda will be sent out as soon as possible.

4. Feedback from EUPATI

David Haerry (EATG), part of the coordinating group of EUPATI, provided an overview of the project to date (see presentation).

EUPATI, an IMI-funded consortium project, aims to provide comprehensive information to patients on pharmaceutical research and development through training, tools and an internet-based library. Members include European patient organisations, academic and not-for profit organisations and EFPIA (European Federation of Pharmaceutical Industries and Associations) member companies.

David highlighted some achievements made so far, such as a website in 8 languages, intranets for consortium & advisers, external communications including publications and newsletter articles. There have been presentations at conferences and material distributed at events. EUPATI is on Twitter, Facebook, LinkedIn, etc. The Patients' Academy is up and running and held a Workshop in Sept 2012 and a "National Platforms" Workshop in March 2013. There are currently 650 EUPATI Network Members and 600 Newsletter subscribers.

There has also been some negative publicity, mainly related to the fact that the project involves pharma funding. This is one of several challenges to overcome, including convening volunteer advisory boards, organising constructive consultations with advisors, the delay in recruiting project staff at some public institutions.

The group will be kept up to date on future developments.

5. Guidance on eligibility for double daily allowance

Renata Tapley (EMA) gave a short presentation on the rules regarding eligibility for patients/consumers to receive double the daily subsistence allowance (see presentation).

These rules were adopted by the Management Board in December 2012 within the existing EMA reimbursement rules. Only experts working on voluntary basis (i.e. who don't receive any financial support or income from the organisation they represent) are eligible to receive the doubled allowance. It is not granted for participation in training sessions or workshops that do not require preparatory work from participants, unless they would be contributing, e.g. presenting, participating in break-out sessions.

A specific request form needs to be completed by the expert and the original given to the EMA, together with written confirmation (email from the organisation they represent).

The final decision will be made by the EMA Authorising Officer following recommendations or information from the meeting organiser.

6. Public summary for herbal medicines

Federica Castellani (EMA) gave a presentation and explained that in previous discussions, PCO representatives felt there was a need for more information on herbal medicines adapted to the general public, and expressed interest in being involved in the preparation of this information.

The Committee on Herbal Medicinal Products (HMPC) established in 2004 following new legislation (Directive 2004/24/EC) which introduced a simplified registration procedure for traditional herbal medicines in EU Member States. HMPC activities aim at assisting harmonisation on use of herbal medicines by preparing scientific opinions on herbal medicines (monographs).

The EMA will now start preparing herbal summaries for the general public, similar in structure, content and style to other documents prepared for the general public (e.g. EPAR summaries, summaries of orphan designations). It will be based on the adopted monograph and HMPC assessment report.

Around 20 herbal summaries to be prepared per year (translated in all EU languages) and the involvement of patients and consumers in their preparation is very welcomed by the HMPC.

It was felt that the best way for the involvement to occur would be similar to the current review procedure of other documents, such as EPAR summaries. A call for expression of interest will be sent out for patients with interest/expertise in herbal medicines, and a specific pool of reviewers will be established.

The HMPC representative PCWP member highlighted the importance of the summaries; citing that herbal medicines are widely used and the HMPC is very keen for PCOs to review these lay documents.

7. EU Clinical Trials Register: presentation of results information

Noémie Manent (EMA) presented proposals on how clinical trial results information will be published within the European clinical trials register (see presentation). Currently only protocol related information is published, the results information will be launched towards the end of 2013 for sponsors to populate.

A small group including patient organisations (members of the EudraCT JOG) will be asked to review the proposed display of the results to assess usability, with further testing once the system has been launched and real data are available. Any additional PCOs wishing to review the proposals should advise the PCWP secretariat.

There were a few questions from the floor, for example whether interim results are also published. Noemie responded that sponsors have to provide results information within one year of the end of the trial (6 months for paediatrics) but it is up to them if they wish to provide interim data. It was also asked whether they have to report ADRs and causality of serious adverse reactions. It was clarified that this information is included within the study report. It is important to try and avoid mis-interpretation of this data, so a disclaimer will be included.

8. Workshop on Patient Support Programs

Gilles Touraille (EMA) provided an overview of the workshop to be held the next day (7 June) on the management of safety data from Patient Support Programmes (PSPs) and Market research Programmes (MRPs) (see presentation).

PSPs are a service that involves direct interaction with patients and/or carers to support patient care and may be conducted by MAH or by a third party on behalf of MAH. MRPs involve the systematic collection, recording and analysis of data and findings concerning medicinal products, relevant for marketing and business development.

Good Vigilance Practices (GVP)-Module VI addresses legal requirements regarding the collection, data management and reporting of suspected adverse reactions associated with medicines in the EU including the management and reporting of safety data arising in PSPs and MRPs, when made aware of them.

Since release of this module, pharmaceutical companies have raised concerns about the difficulty to implement the requirements on management of safety data originating from PSPs and MRPs and have suggested simplifying and harmonising the reporting to competent authorities.

The aim of the workshop is to bring together stakeholders to understand the spectrum of programmes that fall under the terms of PSPs and MRPs and the type of safety information which is collected in those programmes and to assess the optimum way of collecting safety data from PSPs and MRPs while ensuring compliance with EU legal obligations and ICH guidelines on management of ADRs.

The patient representatives participating in this workshop will provide feedback at the next meeting.

9. Patient representation on EMA Management Board

Two new patient representatives have been appointed to the EMA management board in March 2013; Wim Wientjens (IDF) and Nikos Dedes (EATG).

Wim addressed the group highlighting that it is excellent that patients are included within the MB and have been for years, and equally that members of the MB are invited to the PCWP meetings. He also explained that his previous experiences at the EMA are very useful and his goal will ultimately be to shorten the medicines evaluation time. He also mentioned his involvement in the telematics group to try and have more EU IT harmonisation.

Nikos highlighted that this was the beginning of a 3 year term and will take a little time to get used to the group and hopes to be able to participate often in the PCWP meetings.

Next meeting: 25/26 September 2013