11 April 2014
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Stakeholders and Communication Division

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

25 February 2014 – 09:00hrs to 12:00hrs, room 4A – Co-chaired by Isabelle Moulon (EMA) and David Haerry (PCWP)

Role	Name
Co-chairs	Isabelle Moulon and David Haerry
Present:	**PCWP members**: AGE Platform Europe (AGE); 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 Federation of Neurological Associations (EFNA); European Heart Network (EHN); European Institute of Women's Health (EIWH); European Organisation for Rare Diseases (EURORDIS); European Patients' Forum (EPF); European Public Health Alliance (EPHA); Europa Uomo-The European Prostate Cancer Coalition (EUomo); Health Action International Europe (HAI Europe); International Alliance of Patients' Organizations (IAPO); International Diabetes Federation European Region (IDF Europe); International Patient Organisation for Primary Immunodeficiencies (IPOPI); Patients Network for Medical Research and Health (EGAN) **Representatives from the Agency's Scientific Committees**: Committee for Advanced Therapies (CAT); Committee on Herbal Medicinal Products (HMPC); Committee for Medicinal Products for Human Use (CHMP); Committee for Orphan Medicinal Products (COMP) **Observers**: European Food Safety Authority (EFSA); EMA Management Board (MB); Medicines and Medical Devices Agency of Serbia (ALIMS)

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Introduction

Isabelle Moulon (co-chair) welcomed the participants to the meeting and introduced the agenda.

No conflicts of interests were disclosed in relation to the agenda items.

The draft agenda was adopted with no additions.

Isabelle welcomed two new participants; Leire Solis Garate (IPOPI) and Simon O'Neill (IDF Europe), as well as two observers: Lucia de Luca from the European Food Safety Authority (EFSA) and Pavle Zelic from the Medicines and Medical Devices Agency of Serbia (ALIMS).

1. Training

1.1. Questionnaire results 2013 and proposals for training session 2014

Nathalie Bere (EMA) presented the results of a survey questionnaire sent to all participants who attended the training session for patients held at the EMA in December 2013 (see presentation). 27 participants completed the questionnaire (out of 65).

Nine areas were covered:

- Quality of the presentations
- Sufficiency of the given information
- Time allocated for questions & answers
- General understanding of EMA's key roles
- General understanding of patients/consumers involvement in EMA activities
- Duration of the training session
- Usefulness of the training session

In general, the majority of respondents gave very good feedback from the December training session. They found it very well organised, useful and comprehensive, with sufficient time allocated. There were one or two negative scores however as no specific details were given, the reasons were not clear; Nathalie highlighted that it would be very helpful to receive more details with any negative scores so that they can understand what needs to be improved for future sessions (respondents are anonymous).

Some written comments/suggestions were included, such as a recommendation to increase the time for discussion after each presentation.

Following the presentation, the members were asked for their thoughts as to future training sessions. Several proposals were made by different participants, one being that the day of the training session could be divided into two parts; one for new-comers in the morning explaining EMA's activities and the second part focusing on more in depth topics, such as biosimilars or health technology assessments. After discussion it was decided to keep the training session mainly on general activities and in terms of information sessions for the regular more experienced patient representatives, it was proposed to look at holding two joint workshops (patient & HCP) per year on different topics, as required (e.g. biosimilars).

2. Patients and consumers involvement in EMA activities

2.1. Incorporating patient views in EMA's benefit-risk evaluation of medicines; feedback from CHMP

Isabelle Moulon briefly presented the document ""Proposal to incorporate patients' views during evaluation of benefit-risk by the EMA Scientific Committees". This has been discussed previously and has been updated following feedback from the PCWP. The document was agreed by all participants.

In line with the above, Harald Enzmann, (CHMP member) presented a new initiative to involve patients in CHMP activities. So far patients have participated in SAG meetings and scientific advice procedures and it is felt their involvement could be further enriched, specifically within the benefit/risk discussions at CHMP where they can share valuable insights and judgements from the patient viewpoint.

In this respect a working group of CHMP members, together with EMA, looked at different possibilities to include patients within such discussions and it was proposed to initiate a pilot phase whereby two patient representatives with experience of the disease/condition to be discussed would be invited to participate in product-specific oral explanations with the pharmaceutical company, where it is foreseen that their involvement can bring added value (e.g. likely negative CHMP recommendation or restriction of an indication where a significant impact is expected). The patients would be accompanied by a "mentor"; an experienced patient representative (a PCWP member) who would support the patients during their involvement (same mentor each time).

Harald emphasized the necessity of patients' value judgment for benefit/risk assessments and would ideally like patients that are sufficiently outside of the regulatory system but who have some experience of treatment options so not too intimidated by the discussion.

The pilot phase should last at least one year in order to gather sufficient evidence to fully assess the feasibility of including patients'. This proposal will be presented to the CHMP during its meeting in March and an outcome report presented once the pilot is finalised.

Following the presentation some participants pointed out that the selection of the patients should be done carefully as the value judgement can differ depending on factors such as age and gender.

Another question raised was potential conflicts of interest of the patients' organisations and here it was clarified that patients would participate as individuals and not as representatives of any organisation and that they would need to comply with the EMA policy on conflicts of interest, as any other expert. Patients will have the option to follow the company's presentation outside of the room, returning once they have finished.

It was also mentioned that it is important to allow sufficient time to find suitable patients.

Another member mentioned that it was also important to manage patient expectations; the Agency agreed and that it would prepare 'rules of participation' to ensure the patient role is clearly defined.

Overall the PCWP very much welcomed this initiative and felt that it was an important move forward.

3. EMA framework for interaction with patients and consumers

3.1. Presentation on the revision of the framework of interaction

Isabelle presented the proposals for a revision of the framework of interaction (already highlighted at the December meeting).

The objectives within the original framework, which was adopted by the Management Board (MB) in 2006, have been fulfilled as well as those highlighted within the subsequent reflection paper on the further involvement of patients and consumers in the Agency's activities (2009).

Much has been achieved since 2006 and it is time for a revision to reflect future needs and expectations. The revised framework will take stock of the current situation, identify gaps and areas for improvement and will propose the way forward. It will also provide an overall picture of the interaction between the EMA and patients and consumers within one document, demonstrating the patients' voice throughout the life cycle of medicines.

Building on experience gained and the solid structure already in place, we now need to:

- Ensure that comprehensive and appropriate training and support are provided, looking to join existing initiatives where feasible and explore possibilities for additional financial support for patients working with the EMA.
- Have in place a communication plan on the EMA model of interaction; for eligible organisations to be "ambassadors" at national and European level, EMA speakers to participate in organisations' conferences and provide increased social media material, etc.
- Reflect on the value of evidence gathered from patients; look at the individual voice compared to the wider community perspective; how such evidence is obtained and how to integrate the different views within the evaluation process?
- Investigate how to further involve patients at early stages of medicine development, e.g. IMI PROTECT, EMA scientific advice, EMA/HTA scientific advice.

Following Isabelle's presentation there followed a general discussion on the revision of the framework but generally all participants agreed with the proposals.

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

Close of meeting

Next PCWP meeting: 3 June 2014