31 January 2014
EMA/792279/2013
Patients and Healthcare Professionals Department

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

11 December 2013 – 09:00hrs to 16:30hrs, room 4B, – Co-chaired by Isabelle Moulon (EMA) and David Haerry (EATG)

Role	Name
Co-chairs	Isabelle Moulon and David Haerry
Present:	**PCWP members**: AGE Platform Europe (AGE); The European Consumers' Organisation (BEUC); 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 Heart Network (EHN); European Institute of Women's Health (EIWH); European Multiple Sclerosis Platform (EMSP); European Organisation for Rare Diseases (EURORDIS); European Patients' Forum (EPF); European Public Health Alliance (EPHA); Europa Uomo-The European Prostate Cancer Coalition (EUomo); Patients Network for Medical Research and Health (EGAN); 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) **Representatives from patient and consumer organisations**: European Haemophilia Consortium (EHC); European Foundation for the Care of Newborn Infants (EFCNI); European Liver Patients Association (ELPA); Global Alliance for Mental Illness Advocacy Networks (GAMIAN-Europe); International Bureau of Epilepsy (IBE); Myeloma Patients Europe (MPE); Pain Alliance Europe (PAE); SMA Europe (SMA E) **Representatives from the Agency's Scientific Committees**: Committee for Advanced Therapies (CAT); Committee for Medicinal Products for Human Use (CHMP); Pharmacovigilance Risk Assessment Committee (PRAC) **Observers**: Co-ordination Group for Mutual Recognition & Decentralised Procedures – Human (CMD(h)); EMA Management Board; Medicines and Medical Devices Agency of Serbia

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Role	Name
Apologies:	**PCWP members**: Alzheimer Europe (AE) **Representatives from patient and consumer organisations**: Debra International; European Gaucher Alliance (EGA); European Headache Alliance (EHA); European Network of Fibromyalgia Associations (ENFA); European Parkinson's Disease Association (EPDA); Fabry International Network (FIN); The International Confederation of Childhood Cancer Parent Organizations (ICCCPO); InDependent Diabetes Trust (IDDT); Thalassaemia International Federation (TIF) **Representatives from the Agency's Scientific Committees**: Committee on Herbal Medicinal Products (HMPC); Committee for Orphan Medicinal Products (COMP); Paediatric Committee (PDCO)

Introduction

Isabelle Moulon (co-chair) welcomed the participants to the meeting and introduced three new eligible patient organisations; the European Foundation for the Care of Newborn Infants (EFCNI), the European Haemophilia Consortium (HC) and SMA (Spinal Muscular Atrophy) Europe.

The draft agenda was adopted with no additions.

1. Involvement of patient/consumers in EMA activities

1.1. Overview of activities

Nathalie Bere (EMA) provided an overview of the different activities where patients/consumers have been involved in EMA activities during 2013, including comparison to previous years (see presentation).

Isabelle congratulated the members for their impressive work and input throughout the year.

A meeting participant enquired about the process for observers to attend PCWP meetings and it was explained that a call for interest is sent out prior to each meeting and places are allocated on a first-come-first-served basis, depending on budgetary limitations.

Another participant asked whether qualitative aspects of patient/consumer involvement were also evaluated. The EMA described that several qualitative measures were available, for example the feedback that on average around 40-50% of comments on the review of documents are taken into account, as well as information obtained via performance indicator surveys (with qualitative questions). However it was acknowledged that this was perhaps not sufficient and that for the next annual report the EMA would be looking at the way in which patient/consumer involvement is presented and the feasibility to include additional aspects of qualitative assessment.

1.2. Revision of the framework of interaction between EMA and patients/consumers

Isabelle Moulon presented an overview of the initial framework between the Agency and patient/consumer organisations (Framework of interaction - 2006), as well as the subsequent reflection paper (Reflection paper - 2009). She explained that the objectives within the initial framework have

been fulfilled and that a systematic involvement of patients and consumers across several areas of the agency's work has been achieved (see presentation).

A revision of this framework, to be adopted in 2014, will not only provide information on the outcome of the previous objectives, including the role of patients in EMA committees, details of their involvement in benefit/risk discussions and the training necessary to support them, but will also provide a complete picture of the interaction with patients and consumers within one umbrella document.

More importantly the revision of the framework will serve to identify gaps and areas for improvement and more specifically lay out the way forward.

PCOs were invited to provide comments and input by the end of January, followed by a teleconference with some volunteer organisations early in February. The aim is to have a draft proposal for presentation at the PCWP meeting in February and then to the EMA management board later in 2014.

1.3. Funding of patient/consumer organisations

Juan Garcia (EMA) presented an update on the proposal for evaluation of financial information from patients, consumers and healthcare professional organisations for assessment of eligibility.

The EMA criteria for eligibility requires that any organisations working with the 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.

This topic has been discussed several times; with different options proposed and deliberated but an agreed conclusion has not yet been reached. The Agency has re-examined the different elements and feedback received, together with its legal team, and has put together a proposal it feels best fits the scope and requirements.

It was emphasised that eligible organisations are involved with the Agency on matters of general interest, but which are not directly related to any specific medicines under evaluation. Rather it is individual patient representatives who are involved in product-specific activities, and the EMA conflicts of interest policy is therefore applicable in these cases.

It was also highlighted that the Agency encourages organisations to make public their annually audited accounts and to have in place a code of conduct/policy regulating the relations and financial independence of the organisation with the pharmaceutical industry.

After the presentation there followed several comments from the floor; it was proposed that all eligible organisations should make public their sources and level of funding, as well as their activities reports. This proposal was unanimously supported by all organisations.

A code of practices relating to organisations' involvement with industry was mentioned (called "Code of Practices between Patients' Organisations and the Healthcare Industry") and some members suggested that organisations could adhere to such a code (some organisations already do).

Following further discussion it was agreed that the EMA would prepare an updated document for circulation early 2014.

1.4. Update on conflicts of interest policy

Noel Wathion (EMA) presented the outcome and follow-up from the EMA public workshop "Best expertise vs. conflicts of interests – striking the right balance", held on 6 September 2013. The aim of

the workshop was to gather the views from all stakeholders to contribute to the proposals for the revision of the policy in 2014.

Noel explained that the revision focuses on defining a methodology for identifying the best expertise within the EU and will ensure that the nature of any declared interest is assessed before determining when the interest would no longer be a concern.

The draft principles for the revision will be discussed at the December 2013 MB meeting, hopefully followed by a revised CoI policy for endorsement at their March 2014 meeting.

An update will be presented at PCWP meeting in February 2014.

1.5. Update on preparation for Public hearings

Monika Benstetter (EMA) gave an update on the preparations for the introduction of public hearings at the Agency (see presentation).

Explanations on how, when and why to hold public hearings were presented and it was explained that the draft rules of procedure would be sent out for public consultation in February 2014.

The link to the public consultation will be sent to PCOs once published.

1.6. Medicine shortages; feedback from workshop and common position paper

Francois Houyez (Eurordis) gave an overview on the common document prepared by patients, consumers and healthcare professionals' organisations on "supply shortages of medicines in Europe" (see presentation).

Organisations were invited to contact Francois to sign the common document (currently 22 organisations have signed).

2. Involvement of patient representatives in EMA committees

2.1. Committees' representatives' role in the PCWP

Harald Enzmann (CHMP) gave feedback from the CHMP, especially highlighting the importance of the patient/consumer input and the need to take more account of the impact on patients (e.g. HTAs, legal issues, classifications, etc.). He would like to see an increase in interactions between CHMP and patients, especially as there is no current formal CHMP patient member.

Kieran Breen also gave a brief feedback as a very new member of the CAT. He explained that the work carried out by the CAT is slightly different, focusing more on innovation and industry sponsors.

2.2. One year's experience of PRAC (Experience, impact on patients, communication)

Peter Arlett gave an overview of the new pharmacovigilance legislation and its first year of operation.

He explained what has been done so far; the activities that have been implemented and the challenges involved. Peter demonstrated what has been delivered and achieved so far with examples of improvements and also highlighted what remains to be done and how best to move forward together.

Albert van der Zeijden (IAPO), PRAC patient member, also gave a presentation on his long experience as a patient representative, both in the previous PhVWP and the new PRAC.

3. Pharmacovigilance

3.1. Guideline on ADR reporting; outcome of PCWP drafting group

Nathalie Bere presented the draft 'patient guidance on ADR reporting', which has been prepared in collaboration with several PCWP members and EMA medical writers. The aim is to provide a high level, concise explanation to patients that is applicable across Europe to inform that: 1) they can now report side effects of medicines themselves, 2) why it is important that they report these possible effects and, 3) how to report side effects.

These key messages were included on the front of the guidance with more information (frequently asked questions) on the back page, including a link to the respective country website for reporting.

Some draft proposals in terms of artwork to make the guideline more attractive to its audience were also proposed.

There were several comments from participants on the pictures and the colour of the background. Several suggested cartoon figures, and that both male, female and child representations should be included.

PCOs were invited to send final comments on the text by Wednesday 18 Dec and new artwork proposals would be circulated to PCOs for comments as soon as available.

3.2. Survey on communication on additional monitoring of medicines

Daniel Glanville (EMA) gave a presentation on the survey results. The survey aimed at collecting feedback from patient, consumer and healthcare professional organisations as well as from national competent authorities regarding the overall communication campaign uptake, the communication channels used, the working processes and the quality of the EMA materials.

Overall feedback was positive both from a cooperation/ coordination perspective and usefulness of materials prepared by the EMA (e.g. press release; factsheet and video).

4. Projects

4.1. EMA's collaboration with HTAs

Hans-Georg Eichler (EMA) presented the current initiatives aimed at promoting cooperation between medicines regulators and Health Technology Assessment (HTA) bodies, including the parallel scientific advice initiative and the EMA-EUnetHTA collaboration.

Health Technology assessment is a multidisciplinary field of policy analysis. It studies the medical, social, ethical, and economic implications of development, diffusion, and use of health technology.

Collaboration with HTA bodies has the potential to increase access to new medicines that receive marketing authorisation but may fail to be reimbursed or used as expected.

Although it cannot be expected that EMA–HTA collaboration will address affordability of medicines it will hopefully align the information needs of regulators and HTA's, make pre- and post-licensing evidence generation more efficient, and enable timely availability of beneficial drugs to patients.

4.2. Feedback from HTA SA workshop

This topic was postponed.

4.3. Update on EUPATI

Maria Mavris, from Eurordis gave a presentation update on the EUPATI project.

This IMI-funded consortium project aims to produce reliable, comprehensive training tools to patients on pharmaceutical research and development to 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. EMA is a member of the project's regulatory advisory panel.

The project will develop a certificate training programme (face-to-face courses), an educational toolbox (e-learning platform) and an Internet library.

The content for the training course syllabuses is under development and EUPATI would welcome content authors and reviewers. An application form is also being finalised for the face-to-face training and will be circulated to all eligible organisations as soon as it is available.

4.4. Collaboration at national level

David Haerry explained that in the context of EUPATI's project, work package 7 would be looking into aspects of sustainability, including encouraging involvement of patients at national level.

Considering experience so far, it was felt that proposing concrete areas for collaboration to the national competent authorities where there is a shared interest (e.g. national registries; compassionate use; gaps in clinical trial assessment; reporting of adverse drug reactions; risk perception of vaccines; antimicrobial resistance) could be an appropriate next step to follow up prior contact made at Heads of Medicines Agencies (HMA) level and with individual national agencies.

4.5. ADVANCE project – studies on vaccines safety & effectiveness

Peter Arlett (EMA) gave an update focusing on the outcome of the project's kick-off meeting organised on 13 November 2013. The main objective of this first workshop was to discuss and confront the needs and perceived challenges and barriers expressed by stakeholders regarding a future system for benefit-risk monitoring of vaccines.

Patient and healthcare professional organisations who expressed an interest in the project will be invited to comment on the minutes of the workshop and to participate in a survey (Feb 2014) on possible models for a vaccine benefit-risk monitoring framework. There will be also opportunity to provide input during the different stages of developing best practice guidance.

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

Close of meeting

Next PCWP meeting: 25 - 26 February 2014