9 December 2013
EMA/618027/2013
Patients and Healthcare Professionals

Patients/Consumers Working Party (PCWP) and Healthcare Professionals Working Party (HCPWP) joint meeting

Meeting minutes – 25 September 2013 - chaired by Isabelle Moulon

Present

Representatives from Healthcare Professionals' Organisations: European Association for Clinical Pharmacology and Therapeutics (EACPT), European Aids Clinical Society (EACS), The European Academy of Paediatrics (EAP), European Association of Hospital Pharmacists (EAHP), European Association of Urology (EAU), European Federation of Internal Medicine (EFIM), European Society of Cardiology (ESC), European Society of Medical Oncology (ESMO), European Society of Endocrinology (ESE), European Society of Radiology (ESR), Pharmaceutical Group of the European Union (PGEU), Standing Committee of European Doctors (CPME), The European Specialists Nurses Organisations (ESNO), United European Gastroenterology (UEG).

Representatives from Patients' and Consumers' Organisations: Alzheimer Europe (AE), European AIDS Treatment Group (EATG), European Cancer Patient Coalition (ECPC), The European Consumers' Organisation (BEUC), European Federation of Allergy and Airway Diseases Patients Associations (EFA), 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), Health Action International (HAI), International Alliance of Patients' Organisations (IAPO), International Diabetes Federation Europe (IDF-Europe), International Patient Organisation for Primary Immunodeficiencies (IPOPI), Patients Network for Medical Research and Health (EGAN).

Representatives and observers from the Agency's Scientific Committees: Committee for Human Medicinal Products (CHMP), Committee for Orphan Medicinal Products (COMP), Pharmacovigilance Risk Assessment Committee (PRAC).

Observers: Management Board, Co-ordination Group for Mutual Recognition & Decentralised Procedures – Human (CMD(h)), European Forum for Primary Care (EFPC).

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Introduction

The chair welcomed all participants to the joint meeting and provided an overview of the topics of commons interest to be addressed.

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

The agenda was adopted with no additions.

1. Organisations' common position on product shortages

Following discussions at the previous PCWP/HCPWP joint meeting where a drafting group of seven patients', consumers' and healthcare professionals' representatives was identified to prepare a common position on product shortages, François Houÿez (EURORDIS) presented the draft document (see presentation). He outlined the structure of the document explaining that some topics for which organisations had not been able to agree or needed additional thinking had been kept outside the scope of the document. As further input is received from organisations, the document could be refined and updated.

The document was generally well received and praised by all members. The example from some countries where public lists on on-going shortages are made available was particularly welcome. There was a suggestion to expand focus from rare diseases to other more general therapeutic areas.

The chair clarified that the document goes beyond the remit of EMA responsibilities and therefore could not be considered as a PCWP/HCPWP position but rather one from all signatory organisations. The aim was to have the document endorsed by as many organisations as possible before 14 October 2013, when it will be presented at the EMA workshop. Members were asked to provide comments or to endorse the document by 10 October 2013.

2. Communication on additional monitoring of medicines

Christopher Gadd (EMA) provided an update on the communication campaign for medicines under additional monitoring (see presentation). He informed the meeting that, further to the publication of the first list of medicines under additional monitoring in April 2013, it was now time to launch a coordinated communication on the inclusion of the black inverted triangle in package leaflets.

Information material (including translations) was being prepared to support the communication and would be made available in advance of 1 October to Member States and to patients', consumers' and healthcare professionals' organisations. This includes a 'fact sheet', a video, a website banner and a press release which members of the PCWP and HCPWP are encouraged to use to further disseminate information through their websites and other channels of communication.

The EMA will carry out a survey to collect organisations' feedback on dissemination at a later stage.

3. Public hearings: draft rules of procedure

Monika Benstetter (EMA) presented the draft rules of procedure on the organisation and conduct of public hearings (see presentation). She explained that the rules of procedure would be discussed and adopted by the EMA's Pharmacovigilance Risk Assessment Committee (PRAC) and then would go for public consultation. In advance of PRAC's adoption, the EMA would like to discuss the proposed rules of procedure with the PCWP and HCPWP and capture their views.

A discussion followed where specific points were raised regarding the rules to restrict and or prioritise participation of individuals and groups of stakeholders. Views were split on whether or not industry should participate in the hearings. There was general agreement that balance had to be ensured in order to bring the societal perspective into the hearings, rather than single individuals' experience. Reimbursed participation and language were also highlighted as critical factors that had to be taken into consideration.

A group of volunteers was identified among PCWP and HCPWP members and will be invited to join a virtual group for discussing in further detail the draft rules of procedure.

4. ADVANCE project – studies on vaccines safety and effectiveness

Malgorzata Leszczynska (EMA) gave a presentation on the 'Accelerated Development of Vaccine benefit-risk collaboration in Europe - ADVANCE' project. The project is funded under the umbrella of the Innovative Medicines Initiative (IMI) and the EMA is one of the participating partners. The Agency's role will be to support the development of best practice and a code of conduct for benefit-risk monitoring of vaccines, including a communication strategy around vaccine benefit-risk. The EMA would like to involve patients', consumers' and healthcare professionals' organisations in this work through participation in three dedicated workshops. The first one will take place on 13 November 2013.

Safety and effectiveness of vaccines was considered a critical topic and the communication dimension of the project was generally welcome. There was a suggestion to cover both preventative and therapeutic vaccines within the scope of the project.

More information on the project kick-off workshop on 13 November 2013 will be sent out and organisations are encouraged to express their interest to participate.

5. PCWP/HCPWP work plans 2014

Nathalie Bere and Ivana Silva (EMA) outlined the key areas covered by the work plans for the PCWP and the HCPWP for 2014 (see presentation).

It was clarified that aspects related with adaptive licensing, patient direct reporting and the EudraCT registry were included in the work plan.

Members were asked to provide comments on the proposed work plans by 11 October 2013, after which these would be considered adopted by the working parties and would be put to the adoption by the EMA's human scientific committees.

6. Workshop "Best expertise vs. conflicts of interests: striking the right balance"

Noël Wathion (EMA) and Nikos Dedes (EATG) gave an overview of the main outcome of the workshop (please refer to the published report on the EMA website). As the topic was one of high interest and not all questions had been addressed within the time allocated for the workshop it was felt important to allow for additional discussion with PCWP and HCPWP.

Members were asked to reflect on three main questions: how to make it more attractive for experts to participate in EMA activities; whether rules should be more or less restrictive; and what other practical considerations would need to be looked at.

Several ideas were suggested on how the EMA, national competent authorities and organisations could provide further public recognition of experts involved in EMA activities. In addition the possibility to have more layers of risk-levels that capture experience gained with participation of patients and healthcare professionals in decision-making bodies (i.e. scientific committees) and consultative bodies (e.g. scientific advisory groups) could be explored. The involvement of experts who due to their niche of scientific expertise have been involved in discussions with pharmaceutical companies needs further consideration (i.e. use of the concept of expert witness).

The input collected will be feedback into potential proposals to review the current policy on conflicts of interest which will be discussed by the Management Board in December 2013.

7. AOB

7.1. New call for PDCO members

Members were reminded of the European Commission's Call for Expression of Interest for the position of member for the European Medicines Agency's Paediatric Committee ('PDCO').

The deadline for submission of applications is 8 November 2013 and submissions should be sent directly to Sanco-pharmaceuticals-D5@ec.europa.eu.

7.2. Report from EnprEMA

Jose Drabwell (IPOPI) PCWP representative at the European Network of Paediatric Research at the European Medicines Agency (Enpr-EMA), gave an update on the ongoing activities of this network, highlighting initiatives intended to involve children and young adults in medicines evaluation.

7.3. Training agenda and participation

Nathalie Bere (EMA) presented the draft agenda for the training day annually organised by the Agency for representatives of patients and consumers' organisations interested in becoming involved in EMA activities. The session will cover several areas where the Agency is systematically involving patients, such as the review of documents and scientific advice. The training will be organised in December and all interested organisations were invited to provide names of participants.

7.4. EMA re-organisation

Isabelle Moulon (EMA) gave an update on the new structure of the Agency following the re-organisation communicated on 16 September 2013 (see presentation), including the roles of each Division and Department.

Under the new structure, the Stakeholders and Communication Division is responsible for ensuring that the Agency has a coherent, coordinated and consistent approach to stakeholder and partner relations management and communication. It manages relations with and information to patients and healthcare professionals, and coordinates medicines information in the European medicines regulatory network. The Division also manages the Agency's online presence, external communication and press relations, as well as the information centre. In addition, this Division manages relations with the pharmaceutical industry, and provides support to micro, small and medium-sized enterprises (SMEs) through its SME Office.

7.5. HCP observers

Ivana Silva (EMA) informed on the outcome of the call for expressions of interest launched among members of the HCPWP for observer roles within the PCWP, Enpr-EMA and ENCePP.

7.6. eCV

Malika Holleyman (EMA) informed the meeting that members would be contacted in the context of a new EMA procedure where an electronic CV would be requested as part of the validation of their declarations of interest.

7.7. EU guidance on patient direct reporting

Juan Garcia Burgos (EMA) explained the Agency's initiative, in collaboration with member states, to develop European guidance on patient direct reporting. The aim is to produce a simple and practical document in lay language useful to patients, consumers and healthcare professionals across Europe on what patient direct reporting is. For that purpose it was suggested to set up a drafting group to prepare a draft proposal to be circulated among all members of the PCWP and HCPWP to 'user test' the content and format of the document. Several members volunteered for the drafting group.

The Chair thanked all participants and closed the meeting.