04 March 2010
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Minutes of the second PCWP meeting with all eligible patients' and consumers' organisations

08 December 2009

Role	Name
Chairpersons:	Isabelle Moulon (EMA) and Nikos Dedes (EATG)
Present:	PCWP members: European AIDS Treatment Group (EATG), European Cancer Patient Coalition (ECPC), European Federation of Neurological Associations (EFNA), European Organisation for Rare Diseases (EURORDIS), European Patients' Forum (EPF), European Public Health Alliance (EPHA), The European Consumers' Organisation (BEUC), International Alliance of Patients' Organizations (IAPO), International Patient Organisation for Primary Immunodeficiencies (IPOPI). Representatives of other eligible organisations: European Federation of Allergy and Airways Diseases Patients' Associations (EFA), European Genetic Alliances' Network (EGAN), European Heart Network (EHN), European Myeloma Platform (EMP), European Older People's Platform (AGE), Global Alliance for Mental Illness Advocacy Networks (GAMIAN-Europe), Health Action International (HAI), Insulin Dependent Diabetes Trust (IDDT), Myeloma Euronet (ME), Rett Syndrome Europe (RSE). Representatives of Agency's scientific committees: Committee for Medicinal Products for Human Use (CHMP), Committee for Orphan Medicinal Products (COMP), Committee on Herbal Medicinal Products (HMPC), Paediatric Committee (PDCO). Observers: Co-ordination Group for Mutual Recognition and Decentralised Procedures- Human (CMD(h)).

Introduction

The second PCWP meeting with all eligible patients' and consumers' organisations was held at the Agency on 8 December 2009.

The Co-chairs welcomed participants and highlighted the importance of this meeting, which constitutes an excellent opportunity for all eligible patients' and consumers' organisations to exchange views and information and to have an inside look at the PCWP activities.

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The participants were also informed about the launch of the new Agency corporate identity and of the new Agency organisational structure.

The draft agenda was adopted without any amendments.

1. Area of advanced therapies

1.1. Advanced therapies, nanotechnologies and genomics

The Agency secretariat gave an overview on advanced therapy medicinal products and innovative methods. Patients' and consumers' organisations were informed about the current status and the obstacles in the development of these medicines as well as the most relevant initiatives aimed at boosting the scientific research in this field. It was noted that the strong patients´ demand for safe and better targeted therapies is one of the key drivers for the development of these medicines. Their therapeutic potential was illustrated with some examples such as cell therapy, engineered tissues, or the use of monoclonal antibodies as antineoplastic and immunomodulating agents. Another promising therapeutic area is nanomedicine, which advantages are derived from the unique properties of the nanoparticles.

Special attention was paid to "personalised medicines" which are based on knowledge of individual genetic susceptibilities. It was stressed that genomic biomarkers would play a crucial role in the differential diagnosis and development of tailored medicines to individual patients.

Participants welcomed this presentation and raised some questions on the availability of these new medicines, the legislation on data protection and the need for increasing awareness and better education of patients and healthcare professionals over this promising area.

At the request of PCWP, it was decided to organise a Webinar on innovative medicines which would be open to all members of eligible patients' and consumers' organisations and all HCPWG organisations.

1.2. Access to medicinal products containing stem cells

This topic was postponed to the next meeting which will be held on 5 March 2010.

2. Area of involvement of patients and consumers in Agency's activities

2.1. The involvement of patients' and consumers' organisations at the European Medicines Agency: the way forward

The Agency secretariat gave an overview of the participation of patients' and consumers' organisations in the Agency's activities since its creation. Acknowledging the important benefits derived from this participation, the Agency has prepared a reflection paper which includes specific actions on how to further progress towards a more structured involvement of these stakeholders. The analysis of the experience gained so far shows that patients' and consumers' involvement contributed to enrich the regulatory process, while strengthening the trust in its results. The main difficulties that have to be addressed concern the lack of resources, the considerable organisations' efforts in supporting their participation in the Agency activities, and the time that patients need to get familiarised with the regulatory procedures.

It is concluded that the current framework of interaction with patients' and consumers' organisations has been implemented and there is a need to revise it to reflect new aspects of patients' involvement

in the Agency's activities such as their participations in PhVWP, the involvement in benefit risk evaluation, in safety communication. The framework will also describe the role of patients in Agency's Scientific Committees.

After its adoption by the Management Board, the reflection paper will be published on the Agency website.

2.2. Patients' and consumers' organisations and the Agency Code of Conduct: confidentiality aspects

The Agency secretariat gave a presentation on the confidentiality aspects of patients' and consumers' involvement in the Agency's activities. It was explained that patients and consumers can be involved as representatives of their organisation, or as individual experts. In both cases, like all experts of the Agency, they should adhere to the Code of Conduct and to the provisions defined in the Policy on the handling of conflict of interests. In accordance with the legislation into force all experts and representatives have a life-long duty of confidentiality with the Agency.

It was clarified that the PCWP meetings' discussions are not confidential.

2.3. Involvement of patients and consumers in preparation and dissemination of European Medicines Agency communications – overview and analysis of comments received

EURORDIS gave a presentation on the involvement of patients and consumers in the preparation and dissemination of EMA communications in critical situations, such as an unexpected adverse reaction, product defect, supply shortage or withdrawal of marketing authorisation. These situations were illustrated with concrete examples. The presentation raised questions on the time and the way in which patients could be involved, and the areas in which their contribution might be valuable. Based on received comments and discussions held within PCWP on this issue, it was suggested that eligible organisations could appoint contact persons who might be consulted by the Agency on the preparation of communications in critical situations.

It was decided to elaborate a proposal, which should be presented in future PCWP meetings, and it was agreed that François Houÿez (EURORDIS) will be the topic leader.

2.4. The activities of the PCWP

The Co-chair outlined the history of PCWP and its main achievements to date. He said that in the past years PCWP activities were focused on the implementation of the final 'Recommendations and Proposals for Action' (EMEA/149479/2004/Final) and mentioned some of the forthcoming activities as presented in the Work Plan for 2010. He underlined the exponential growth of patients and consumers that have been participating at the Agency, in recent years, and the increasing number of activities in which they have been involved. Their successful contribution to the Agency was illustrated with some examples such as the PCWP representatives participation as observers in PhVWP, the PCWP participation in the elaboration and implementation of the Agency Transparency Policy, the new web site construction and EudraCT public interface project.

The Co-chair highlighted the Agency monthly newsletter as a tool to provide updated information on human medicines to patients, consumers and healthcare professionals' organisations, and urged all eligible organisations to disseminate this newsletter using their internal communication channels.

3. Area of product information

3.1. Recommendations and users' views on the Package Leaflet

BEUC presented the results of a survey carried out in eight European countries (Belgium, Italy, Spain, Portugal, Czech Republic, Poland and Romania) on the use of the package leaflet (PL) by patients. It demonstrated that PL is read by the majority of the population in these countries, and they are in general satisfied with the information that it provides. However, the study concludes that its readability should be improved by using straightforward language and more patient-friendly tools, such as pictures and pictograms. Participants welcomed the results of the survey and asked some questions on the methodology and the comparability of the results.

3.2. How to improve the information on the Package Leaflet

The Agency secretariat gave two presentations on the improvement of the information on the PL. It was highlighted that PCWP plays an important role on bringing to the Agency the patients' view and concerns on the readability of the PL information. In line with the report elaborated by PCWP and HCP WG - Information on benefit-risk of medicines: patients', consumers' and healthcare professionals' expectations - it was said that the PL should include more patient-oriented information on benefits, clearer estimation of the risk of undesirable effects, including additional information on selected adverse reactions or specific populations, and patterns which may modify the benefits or risks of the medicine.

The second presentation was focused on the revision of the QRD (Quality Review of Documents) template. This revision would be based on the experience achieved until now and the results of discussions held at different fora. It is motivated by the update of relevant European guidelines and the introduction of new legislation on Advanced Therapy products. Participants were informed about the actions carried out so far, and the main changes that would be introduced in the new template. The draft revised template is expected to be released for a public consultation in the first quarter of 2010.

Participants welcomed both presentations, and expressed some concerns over the accuracy of the translations of PL in certain countries. It was agreed to send the Agency examples of imprecise or erroneous translations. It was proposed to invite experts in social sciences and communication, who have worked specifically on the PL, to comment on the template. If necessary they could be invited to further discussion.

4. Area of clinical trials

4.1. EudraCT public interface construction

The Agency Secretariat gave an update on the development of the EudraCT public interface, which is expected to be publicly available in the second/third quarter of 2010.

It was agreed that representatives of patients' and consumers' organisations would be invited to attend a dedicated meeting on EudraCT, at the beginning of 2010, during which a mock-up of the public interface will be showed. These patients' and consumers' organisations interested should inform the Agency secretariat.

5. Area of pharmacovigilance

5.1. Update on ENCePP

This topic was postponed.

6. A.O.B

6.1. European Medicines Agency new corporate identity

The Agency presented its new visual corporate identity which launch-day coincided with the meeting. Participants were informed about its basic components, such as the new logo and slogan, and the rationale for their selection. It was explained that this project had been undertaken in order to improve the quality and consistency of communications with the Agency's partners, stakeholders and the public, and to increase awareness about its work. It was underlined that this is not only the Secretariat new identity but also the shared identity of every member of the Agency's Committees, Working Parties and the Management Board.

It was said that the Agency corporate identity is related to other projects, in particular, the creation of a new Agency web site which would be operative in the first quarter of 2010.

The Agency secretariat thanked all patients' and consumers' organisations for their kind support and contribution to the realisation of this ambitious project.

6.2. Meeting dates for 2010

- 05 March Joint meeting with HCP WG
- 16 June PCWP plenary meeting
- 08 September PCWP plenary meeting
- 29 November Training session on the review of documents
- 30 November PCWP meeting with all eligible organisations

Close of the meeting

The Chairpersons thanked all the organisations for their active participation and fruitful discussions.