European Medicines Agency
Post-authorisation Evaluation of Medicines for Human Use

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MINUTES OF THE SIXTH MEETING OF THE EMEA HUMAN SCIENTIFIC COMMITTEES' WORKING PARTY WITH PATIENTS' AND CONSUMERS' ORGANISATIONS (PCWP) EMEA, 30 SEPTEMBER 2008

CO-CHAIRPERSONS: ISABELLE MOULON (EMEA) - NIKOS DEDES (EATG)

MEETING PARTICIPANTS

Representatives of: European AIDS Treatment Group (EATG), European Cancer Patient Coalition (ECPC), European Patients Forum (EPF), European Federation of Neurological Associations (EFNA), European Organisation for Rare Diseases (EURORDIS), European Patients Forum (EPF), European Public Health Alliance (EPHA), Health International Alliance of Patients' Organizations (IAPO), International Diabetes Federation (IDF), International Patient Organisation for Primary Immunodeficiencies (IPOPI), The European Consumers Organisation (BEUC).

Committee for Medicinal Products for Human Use (CHMP), Committee for Orphan Medicinal Products (COMP), Co-ordination Group for Mutual Recognition and Decentralised Procedures–Human (CMD(h)), European Medicines Agency (EMEA) secretariat and Healthcare Professionals Working Group (HCP WG) observer.

I. MORNING PLENARY SESSION – GENERAL ISSUES

I.1 Welcome and introduction

The co-chairs welcomed the participants to the meeting.

I.2 Adoption of the agenda

The agenda was adopted with minor changes. Mr N. Dedes asked to report back from the Drug Information Association (DIA) Innovation Forum that he attended. This point was added under A.O.B.

I.3 Minutes of the previous meetings

The minutes were adopted with minor changes. Since the PCWP meets only four times a year, it was decided that, in future, all minutes will be adopted by written procedure unless requested otherwise by the members. This will make the publication of the minutes on the EMEA website faster.

I.4 PCWP 2009 work plan

The work plan of the PCWP for 2009 continues to include the following topics: product information, pharmacovigilance, transparency/dissemination, and interaction with committees. However, the work plan will also focus more on monitoring the activities put in place, i.e. the *Recommendations and proposals for action EMEA/149479/2004 Final* that are already in the final phase of implementation. The relevance of the work to be done next year to further involve patients' and consumers' organisations in EMEA activities was underlined. The work plan will be sent to the members for comments and then adopted by written procedure.

7 Westferry Circus, Canary Wharf, London, E14 4HB, UK
Tel. (44-20) 74 18 84 00 Fax (44-20) 75 23 71 29
E-mail: mail@emea.europa.eu http://www.emea.europa.eu

II. INVOLVEMENT OF PATIENTS AND CONSUMERS IN EMEA ACTIVITIES

II.1 Questionnaire on performance indicators for 2008

All of the experts from patients' and consumers' organisations (PCOs') who have taken part in any EMEA activities during 2008 will be asked to fill in a questionnaire on their degree of satisfaction with their interaction with the Agency. The questionnaire, which has now been produced as an electronic form, continues to include some of the topics from the 2007 questionnaire, but also includes some questions specifically related to the review of package leaflets and European Public Assessment Report (EPAR) summaries. The members agreed to the addition of a question investigating the interaction between PCOs and healthcare professionals within the initiatives carried out at the EMEA. The questionnaire, once updated, will be circulated for further comments and then sent to all experts at the end of 2008. Results will be analysed and presented in the first quarter of 2009.

II.2 Progress report of the re-evaluation of eligible organisations

During the PCWP meeting, the members expressed a desire that the outcome of the evaluation of the organisations compliance with the EMEA eligibility criteria should be kept up to date (*7 December 2007 meeting minutes EMEA/604758/07 point IV.3*). It was decided that organisations should be evaluated against these criteria every two years after their initial application.

The EMEA presented the status report of the first round of re-evaluation, initially performed on 9 organisations. The members expressed their satisfaction in seeing that many organisations have increased their level of transparency and have demonstrated that they continue to fulfil the EMEA's criteria.

Information on the re-evaluation procedure and outcome, once completed for all organisations, will be made available on the EMEA website.

II.3 Brainstorming on further involvement of PCOs in EMEA activities

Currently, PCOs are involved in the Agency's work on a number of levels, as members of the Management Board, the Committee for Orphan Medicinal Products (COMP) and the Paediatric Committee (PDCO). In addition, they will be members of the Committee for Advanced Therapies (CAT) in the near future and they have been proposed, subject the agreement of the HMA (Heads of Medicines Agency), to participate during a pilot phase as observers in the Pharmacovigilance Working Party (PhVWP). Building on the existing experience, further progress of this interaction will need some considerations before being taken further.

The members discussed various activities that may contribute to the work of the Agency but recognised the need for establishing a set of priorities in order to make the best use of the current resources from the EMEA and the PCOs.

The EMEA secretariat will prepare a questionnaire describing the additional activities where PCOs could contribute. The answers to this questionnaire should stimulate a more in-depth discussion during upcoming meetings of the PCWP.

III. TRANSPARENCY AND DISSEMINATION

III.1 Outcome of the 'Workshop on the EMEA on-line strategy and website design' held on the 29th September

Members of the PCWP, together with representatives from healthcare professionals' organisations, were invited to participate in a workshop as part of the initiatives put in place by the EMEA management for restructuring the EMEA website. During the workshop, participants were involved in exercises to further define who the potential users of the EMEA's website are and what their needs might be.

A representative from the EMEA secretariat fed back to the PCWP on the project, underlining the productive outcome of the workshop. Members will be kept informed of the progression of the work on the restructuring of the EMEA website and on the outcome of the first phase of the project, which is intended to define the expectations of the EMEA's stakeholders.

III.2 Public consultation on the data fields contained in the 'EudraCT' clinical trials database to make public

In the past, the PCWP was informed of the legislative proposals regarding the publication of some fields of the database EudraCT (European Clinical Trials Database), with specific provisions for paediatric clinical trials. Patients' representatives were also invited to participate in related initiatives and, since the publication of this information will be managed by the EMEA, to a 'Consultation for the New EudraCT Paediatric Clinical Trial Public Web Site'.

The EMEA secretariat reminded all members about the:

- 'Public consultation on the data fields of the clinical trials database (EudraCT) and the information on trial results for paediatric clinical trials to be made publicly available',
- 'Public consultation on the data fields contained in the 'EudraCT' clinical trials database to be included in the 'EudraPharm' database on medicinal products and made public'.

The consultations were launched by the European Commission in June/July 2008. PCOs were invited to submit comments to the European Commission before the deadlines.

The EMEA representative gave some background information on the project on the publication of fields from the database and foresaw the future involvement of patients in the implementation of the new transparency measures.

III.3 Introduction to the EudraVigilance system in the context of access policy

According to article 26, paragraph (3) and article 57, paragraph (1d) of *Regulation (EC) 726/2004*, the EMEA shall ensure the dissemination of information on adverse reactions to medicines authorised in the Community, by means of a database permanently accessible to all Member States. Healthcare professionals, companies and the public shall have appropriate levels of access to the database provided personal data protection is guaranteed.

EudraVigilance is a European Union (EU) database created by the EMEA. It contains individual case safety reports (ICSRs) for medicines licensed in the EU. These reports are received from national competent authorities (NCAs) and pharmaceutical companies. The purpose of EudraVigilance is to support the public health of EU citizens by collecting safety information on medicines and making this available for scientific assessment.

The EMEA is now working on an access policy to the information contained in EudraVigilance. The general terms of this policy with some practical examples and the planned level of access to the public were presented. The members welcomed this initiative and appreciated this further step towards transparency. The speaker said that the policy will be sent to the members for comments once it is made available.

IV. AFTERNOON PLENARY SESSION – PHARMACOVIGILANCE AND PRODUCT INFORMATION

IV.1 Benefit-risk communication

As part of the ongoing discussion on how to best communicate issues related to the benefits and risks of medicines, the EMEA has, together with topic leaders from the PCWP and the HCP WG, co-ordinated a qualitative survey among patients', consumers', healthcare professionals' organisations, as well as regulators. A questionnaire was distributed in March-April 2008, and answers were discussed at the joint meeting with healthcare professionals on 05 June 2008. The discussion focussed on general principles.

An extensive, consolidated document was drafted, containing both written contributions and details of the subsequent discussion.

The group agreed that the report should focus on the main messages (in particular similarity between patients' and HCPs' expectations, differences between benefit-risk at the population level and at an individual level, and the subsequent need for clear information on benefits and risks) and that the contributions received should be annexed to the report.

V. AOB

V.1 CMD(h) consultation on package leaflets: proposed new wording

The Co-ordination Group for Mutual Recognition and Decentralised Procedures – Human, CMD(h), requested comments from the PCWP for new wording that might be proposed for some medicines. The group took the opportunity to underline the need for a template to be used when other groups consult the PCWP, considering the increasing number of interactions of this kind that are being received.

V.2 Antiepileptic medications: feedback from the Pharmacovigilance Working Party on the consultation for the new wording of the package leaflet

A representative of the EMEA secretariat gave some background information on this consultation that took place after the June PCWP meeting. The new wording, regarding some additional information to be added to the package leaflets of some antiepileptic medicines, was based on the outcome of a safety evaluation of the medicines that are considered to harbour a potential risk of suicidal thoughts and behaviour. The EMEA representative listed the comments received and presented the final wording to the members, as agreed by the PhVWP during its July 2008 meeting. The group stressed once more the importance of being involved in these types of consultation and expressed appreciation for this request for co-operation from the PhVWP.

V.3 ENCePP (European network of centres for pharmacoepidemiology and pharmacovigilance) project: update

The ENCePP

The ENCePP coordinator gave an update on the most recent developments of the project. He explained how the ENCePP, according to a preliminary inventory, included 83 research organisations in 20 European countries as of September 2008. The main objectives and deliverables of the ENCePP have now been agreed in a draft implementation strategy and 4 working groups have been established.

The speaker emphasised that there will be a continued representation of PCOs in the project through the representative of the PCWP at the ENCePP plenary meetings and at the Working Group 'Independence & Transparency'. Regular updates on the ENCePP will be provided at the next PCWP plenary meetings and the group is likely to be involved in the consultation of guidance documents as well.

The EMEA and the Innovative Medicines Initiative

Since members of the PCWP were invited during the 6th June meeting to express their interest to work together with EMEA in the EMEA-led Consortium (PROTECT) for the Call topic 6 (Strengthening the Monitoring of Benefit/Risk) of the public IMI (Innovative Medicines Initiative) consortium, the EMEA speaker informed that it is preparing a proposal for IMI topic no. 6 "Strengthening the Monitoring of Benefit/Risk".

The EMEA is also involved in a consortium (Eu2P), led by the University of Bordeaux, submitted under Call no. 18 (Training Programme in Pharmacovigilance) to develop a Master in Pharmacovigilance and Pharmacoepidemiology and a short course in Risk Communication for non-specialist (e.g. journalists, patients, venture capitalists, etc). The EMEA is asked to explore the feasibility of a cooperation of the PCWP on this topic, which is also part of the work plan of the working party for 2008.

V.4 DIA-EMEA-CMD(h) Workshop on User Testing

The EMEA, jointly with the Drug Information Association and with the CMD(h), has organised a workshop on user testing of package leaflets. This will take place on 5 December 2008 in London. A member of the PCWP has been invited to present the patients' viewpoint under a specific topic. EMEA staff highlighted that input from any other members willing to take part in this workshop would be welcomed and invited members to express their interest.

V.5 EURORDIS summer school: feedback

A representative from Eurordis fed back on the most recent Eurordis Summer School for patient advocates, concerning training in clinical trials and drug development. The members complimented Eurordis on the organisation of the course and noted its value in promoting interaction with other PCOs, regulators, academic partners and industry and the opportunity for learning on both sides.

V.6 PCWP meetings dates for 2009

The final dates of the meeting were agreed as follows:

March - Plenary - Thursday, 5 March

June - Joint meeting with HCP WG - Tuesday, 9 June

September - Plenary - Wednesday, 30 September

December - Meeting with all eligible organisations - Tuesday, 8 December

V.7 Drug Information Association (DIA Innovation Forum)

Mr. Nikos Dedes reported back from the conference where he was invited to participate in a panel on Innovation and the challenges of the future. In his presentation he defined Innovation from the patients and consumers organisations' perspective as anything that contributes to better health outcomes and sustainable healthcare. That would include innovation on better utilization of existing interventions including generics and prevention. He stressed the need for subtle but forceful regulations, investments in EU public research, transparency and leadership. Reward, fairness & equity to access and sustainability are not mutually exclusive.

Close of the meeting