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

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MINUTES OF THE SEVENTH MEETING OF THE EMEA HUMAN SCIENTIFIC COMMITTEES' WORKING PARTY WITH PATIENTS' AND CONSUMERS' ORGANISATIONS (PCWP) EMEA, 27 NOVEMBER 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 Organisation for Rare Diseases (EURORDIS), European Patients Forum (EPF), Health Action International (HAI), Health International Alliance of Patients' Organizations (IAPO), 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 Commission, European Medicines Agency (EMEA) secretariat, Healthcare Professionals' Working Group (HCP WG), and Paediatric Committee (PDCO).

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 of the meeting was adopted.

I.3 Published minutes of previous meeting

The published minutes of the last meeting were circulated for information.

I.4 CMD(h) consultation on a proposed new wording for a package leaflet: update

The PCWP, on request of the CMD(h), examined a new wording to be added in a package leaflet. The Chair of the CMD(h) reported back on the actions taken following these recommendations. The input of the PCWP was largely taken into account by the CMD(h) who documented the added value of this cooperation. At the same time members were grateful of the feedback received and would be pleased to be involved in such consultations in the future.

I.5 Consideration on a template for facilitating PCWP consultation by other groups (i.e. CMD(h), PhVWP) on product information review

During the past two years both the PhVWP and the CMD(h) have involved the PCWP in the review of new text recommended for the package leaflet of some medicines. Following this experience, PCWP members had requested to develop a template to facilitate the consultation of the working party by third parties.

A first proposal was put forward by the EMEA secretariat. Members will comment on this first draft and the template will be presented both to the PHVWP and to the CMD(h).

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I.6 Benefit risk communication

The EMEA presented the draft report "*Communication on benefits and risks of medicines: patients' and healthcare professionals' expectations*", resulting from the survey and discussions recently held with PCWP and Healthcare Professionals' Working Group (HCP WG). As previously agreed, the report focuses on main consensual messages and makes proposals for improvement to be developed by the groups in the coming years. Compilations of answers to the survey will be annexed to the report.

The PCWP welcomed the report and recommended that it is disseminated as broadly as possible and used as a basis for training. A workshop could also be organised.

The report was circulated to the PCWP and to the HCP WG for final comments within three weeks. The final document will then be presented to the EMEA scientific committees at the beginning of 2009, before publication.

II. AREA OF PRODUCT INFORMATION

II.1 Report from the Pharmaceutical Forum

The PCWP has always been updated, in the past, of the progress of the work of the Pharmaceutical Forum. This time a representative from the European Commission presented the 'Final Conclusions and Recommendations of the High Level Pharmaceutical Forum' to the group.

In particular the PCWP heard about the conclusion of the 'Information to patients' working group that had the objective of improving information to patients on their treatments and related health issues in the existing legal framework. The outcome of the working group has been summarised in four recommendations:

- enhance the quality of information
- increase accessibility and dissemination of information
- information generation by making the best use of all actors
- continued momentum on information to patients

The speaker explained in detail these recommendations and listed the tools that could be used to implement them. A public conference for the dissemination of the outcomes toward patients and the health community will take place on the 25th of March 2009.

Since the PCWP expressed their view adding some remarks on the initiative and on its final outcome, they were made aware that the final conclusions and recommendation, for any further details, are available on the website of the Pharmaceutical Forum (http://ec.europa.eu/pharmaforum/docs/final_conclusions_en.pdf). Furthermore, the EC representative reminded that any suggestions from patients and consumers organisations, on the implementation of the recommendations, are particularly welcome in view of the public conference to take place.

II.2 Activities of the HMPC: assessment report summary for the public

A representative of the EMEA secretariat presented to the PCWP a new initiative from the HMPC in order to promote access to their documents.

The Committee has proposed to create a summary of the assessment report of the herbal medicines they evaluate, addressed to the public, in addition to the documents already published on the EMEA website (Community herbal monographs) or on the European Commission website (Community list of herbal substances, preparations and combinations thereof for use in traditional herbal medicinal products).

The representative of the HMPC showed some examples and explained the objectives to be achieved with the creation of the documents. In addition, the speaker described the target audience that the Committee would like to address.

The group will look at the proposal, nevertheless they agreed that a more in depth discussion on the structure and the contents of the summaries was needed. It was considered to set-up a drafting group on the subject, in the margin of the next meeting of the HMPC, to work on the topic. Some members expressed their willingness to participate anticipating that, among the organisations they represent,

some may have a more specific interest for herbal medicines and may be willing to give their contribution as well.

III. AREA OF INVOLVEMENT OF PATIENTS AND CONSUMERS IN EMEA ACTIVITIES

III.1 MMS-e (External Meeting Management System) - pilot phase

The EMEA is going to adopt a new on-line system for the management of invitations to the EMEA meetings and travel arrangements for EMEA experts. A representative of the EMEA responsible for setting up the electronic system invited some members from the PCWP to participate to the pilot phase of this project, intended to test its functionalities. Some members expressed their interest in participating.

III.2 Acceptance of clinical trials conducted in third countries for evaluation of MAA

The EMEA strategy paper: '*Acceptance of clinical trials conducted in third countries, for evaluation in Marketing Authorisation Applications General-EMEA/228067/2008'* was circulated to the Management Board of October 2008 and to the September 2008 meetings of the EMEA scientific committees including the CHMP (Committee for Human Medicinal Products). This strategy paper states that "These activities need to be further developed and expanded and this requires a plan of action extending beyond 2008. The strategy set out in this paper will be translated into an itemised action plan set out over three years".

Amongst the activities set out in the paper there is the creation of an "EMEA Working Group on Third Country Clinical Trials". The group to be established will include a representative from the PCWP. The EMEA speaker explained how an expertise in the realm of bioethics in the context of clinical trials, and contact with patients/patient groups in the international context (third countries/low and middle income countries) would be particularly useful and added that the Working Group will be asked to develop practical proposals for tasks and procedures, or guidance, in the action areas identified in the strategy paper.

The members of the PCWP were invited to submit their candidacy to be nominated as members of the new working group. Follow-ups on this topic will be given at a future PCWP meeting.

III.3 Report from the involvement of PCOs in EMEA activities in 2008

A representative from EMEA presented some preliminary data of the involvement of patients and consumers in EMEA activities during 2008. Patients and consumers are involved in EMEA activities at several levels: they are members of some EMEA scientific committees (COMP, PDCO) as well as the Agency's Management Board. Furthermore, during 2008, patients and consumers have given their important contribution to several other workshops, conferences and new initiatives organised by the EMEA. During the presentation it was highlighted how the PCWP has strengthened its interaction with other working parties and groups at the EMEA. EMEA underlined once more the value of the involvement of experts from patients' and consumers' organisations in the review of package leaflets and EPAR summaries and the members stressed the importance to maintain feedback on their input in all activities.

Updated figures, comprehensive of all the EMEA activities where patients and consumers were involved, will be shown at the next PCWP meeting together with a report drafted on the results of the performance indicators for 2008 (results from the questionnaire on the degree of satisfaction of patients and consumers participating in EMEA activities), including some details of the progression of the interaction in comparison to 2007, as recommended by some members.

III.4 Further involvement of patients and consumers in the EMEA activities

Some preliminary results were shown at the meeting about an on-line survey, to patients and consumers organisations eligible to participate in EMEA activities. This survey was set up in order to better define the areas where patients and consumers would be more inclined to be involved at the Agency. The members requested to have updated figures as soon as available and asked for more detailed descriptions to investigate any difference in the cluster of answers provided from

organisations that are not part of the PCWP. Those results will be the basis to explore the way forward for a further involvement of PCOs in EMEA activities.

III.5 Enlargement and renewal of PCWP composition: definition of criteria for selection

The EMEA secretariat explained that the next renewal of the membership for the PCWP is due for the end of 2009. The EMEA will decide on the organisations that will be represented in the group on the basis of their appropriateness to the subjects covered within the scope of the PCWP's mandate. The areas where representation is lacking were shown to the group and it was mentioned that this will be taken into consideration for the next nominations (for example: cardiology, rheumatology, gastroenterology, nephrology, etc). All eligible organisations to be involved in EMEA activities will be informed in due time in order to propose their candidacy. The speaker also reminded that the nomination of the Co-chair is due for the 1st quarter of 2010. EMEA will invite the organisations' contact persons to propose any candidacy.

III.6 Draft revision of rules for involvement of EMEA stakeholders

The EMEA secretariat presented a draft revision of the "*Rules of involvement of members of patients' and consumers' organisations in committees related activities*" (EMEA/483439/2008) previously adopted in January 2006. The revision was made to cover for Healthcare Professionals when participating in EMEA activities and the document defines the different types of consultation with patients, consumers and healthcare professionals and defines the specific conditions for each type consultation. Furthermore the document sets up rules for members of the organisations that can participate in the activities either as experts or as representatives of their organisations. The members welcomed these further steps in preparing the grounds to strengthen the interaction with healthcare professionals.

IV. AREA OF TRANSPARENCY AND DISSEMINATION

IV.1 EMEA copyright policy

With the aim to improve access to the information published on its website the EMEA has recently revised its copyright policy. A speaker from the Agency presented the key changes in the policy explaining that as of January 2008, provided acknowledgment of EMEA is included, a blanket permission to reproduce, distribute and/or cite EMEA public documents applies. Permission does not apply to third-party documents published on the EMEA website. Some indications for the best use of links to the EMEA website were also given. All the details can be found here: http://www.emea.europa.eu/htms/technical/dmp/copyritel.htm.

The PCWP appreciated and considered valuable the changes introduced to the policy.

IV.2 Translation of the leaflet for patients and consumers

Following a request from the group, the Leaflet "Involvement of patients' and consumers' organisations in EMEA activities" has been translated in some other languages of the European Union (Italian, French, German, and Spanish) and will be published in all of these versions on the EMEA website. The PCWP was made aware that the EMEA also stores some printed copies of the leaflet and they can be sent on request to interested patients' and consumers' organisations.

IV.3 Proposed revision of the EMEA experts' nomination form

An update on the EMEA expert's nomination form was proposed to the PCWP, according to previous requests received from some experts. The group appreciated the first proposal but proposed more extensive changes. The EMEA will amend and re-circulate the document to have a more substantial agreement and then a final proposal can be put forward to the Agency's management.

IV.4 Creation of a short summary with the main fields of expertise and activities of each organisation

During the meeting of the 6th of June of the PCWP, the creation of a short summary describing the main fields of expertise and activities of each organisation eligible to participate in EMEA activities was suggested by some members.

The summary would be helpful to understand the work of each patients' and consumers' organisation for new members at the meeting of the PCWP, as well as for organisations newly involved in the EMEA activities and in general to anyone that needs concise information about the patients' and consumers' organisations involved in the PCWP.

A few examples were sent by some members for discussion at the meeting. In order to promote the harmonisation among the examples provided, in terms of length and content, the EMEA will compile all the summaries received in a single document to be circulated among the members. A final version will be proposed again at the next meeting.

IV.5 Monthly e-mail: update of the current version

The most recent version of the monthly e-mail for patients and consumers organisations was presented to the group. It features a new title: "Human Medicines Highlights", an improved layout and a link to a permanent web-based version. The EMEA speaker explained that all the issues of the Human Medicines Highlights will be stored in an accessible web-archive. After considering the discussions that took place at the Healthcare Professionals' Working Group, it was decided that the Human Medicines Highlights will have also a broader audience - it will be no longer restricted only to patients and consumers organisations, but it will also cover some documents of interest for healthcare professionals and will be sent to anyone interested in subscribing. Members showed their satisfaction for the improved access that will be guaranteed by this version.

V. AOB

V.1 ENCePP: update on the project

The ENCePP coordinator gave a new update on the project informing the group that a website specifically dedicated to the network is currently under preparation [it has subsequently been launched]. He also anticipated some of the activities that will take place in 2009, such as the meeting of the General Assembly and a second Scientific Convention.

Actually, a first Scientific Convention on the use of EU Health Care Databases for pan-EU Pharmacoepidemiologic Research took recently place at the EMEA. The meeting, as confirmed by the PCWP representative involved, demonstrated the potential of the ENCePP in promoting the exchange of knowledge and dialogue among the experts involved in key research areas of pharmacoepidemiology in EU.

V.2 IMI Call 18 (European programme in pharmacovigilance and pharmacoepidemology)

During the 30th of September meeting, the members requested that the EMEA explore the feasibility of a cooperation of the PCWP in the consortium preparing a full proposal for IMI Call No.18. The Call No.18 aims to provide support education and training to current and future professionals involved in biomedical research and development. More specifically the PCWP considered involvement in the pharmacovigilance training program that aims to improve understanding of pharmacovigilance by non-specialists (e.g. journalists and patient organisations) to improve the communication of hazards associated with medicines.

The EMEA explored this participation and informed the group that the participation of PCWP patient organisation(s) could be welcome by the coordinators of this IMI call. The participation of the PCWP would ensure that the training material is adequately designed to address the needs of patients and the general public and should facilitate its dissemination. Members were called to express their interest, proposing their candidacy to the EMEA in a short timeframe.

Close of the meeting