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

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MINUTES OF THE FOURTH MEETING OF THE EMEA HUMAN SCIENTIFIC COMMITTEES' WORKING PARTY WITH PATIENTS' AND CONSUMERS' ORGANISATIONS (PCWP)

EMEA, 21 SEPTEMBER 2007
CO-CHAIRPERSONS: ISABELLE MOULON (EMEA) - NIKOS DEDES (EATG)

PARTICIPANTS TO THE MEETING

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

Committee for Herbal Medicinal Products (HMPC), 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 (EC), European Medicines Agency (EMEA) Management Board & Secretariat.

I. GENERAL ISSUES

I.1 Welcome and Introduction

The Co-Chair welcomed the participants to the meeting.

I.2 Adoption of Agenda

The agenda was adopted with minor changes.

I.3 Report of Previous Meeting

The minutes from the 1st of June joint meeting between the PCWP and the Working Group with Healthcare Professionals were adopted.

I.4 Work Plan 2008

The Work Plan for 2008 was presented and discussed. Some members proposed to further develop the sections dedicated to the patients' involvement in EMEA activities and also some changes were suggested in the area of Pharmacovigilance. A revised version will be circulated and if no further comments are received, it will be adopted by written procedure. The document will be then sent to the EMEA Scientific Committees for final adoption before it is published.

I.5 Information on Specific Obligations: overview of current practice

EMEA secretariat presented to the group how information on specific obligations is currently presented in EMEA documents. Examples of some centralised product under conditional marketing authorisation or authorised under exceptional circumstances were given. Related information available in the European Public Assessment Report (EPAR) and in the Product Information was shown, highlighting those sections of the documents where information on specific obligation for the marketing authorisation holder could

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be found. After discussion and identification of some areas for improvement, it was decided to elaborate some proposals such as adding clear references (e.g. graphic identifiers) under each product at the EPAR webpage for products under conditional marketing authorisation or authorised under exceptional circumstances. The possibility to make more visible this information in the package leaflet will also be explored. The topic will be further discussed during the next meeting.

I.6 European Commission-EMEA Conference on the Operation of the Clinical Trials Directive (Directive 2001/20/EC and 2005/28/EC) and Perspectives for the Future

The EMEA has organised a workshop together with the European Commission to discuss the above mentioned directives and their impact so far in the operation of clinical trials. The PCWP has been invited. The PCWP Co-chair and a member of the group will present the PCWP common point of view during the Conference on 03rd October 2007.

A representative from the EMEA secretariat explained to the group the detailed programme and the scope of the conference, specifying that the contribution from the PCWP, will be part of a report published following the workshop.
During the discussion several aspects of the directive were considered:

- the need to cover for non-interventional clinical trials in the directive;
- the composition of the Ethics Committees, which was found to be very heterogeneous across EU, and where the participation of patients is highly recommended;
- the current problems deriving from a lack of harmonised approach across the EU both in terms of contents and structure of the “informed consent”;
- request from the group for public access of information on ongoing clinical trials for medicines in Europe.

Some comments from the group were classified as aspects that can be remedied within the present legal framework while others referred to what a new legal framework should look like. Feedback from the conference will be provided during the next meeting.

II. TRANSPARENCY AND DISSEMINATION OF INFORMATION

II.1 EU Health Portal Initiative

A representative from Health and Consumer Protection Directorate-General at the European Commission presented the Health-EU Portal initiative (the official public health portal of the European Union). It provides a wide range of information and data on health-related issues and activities at both European and international level. The main objective of this thematic Portal is to provide European citizens with easy access to comprehensive information on Public Health initiatives and programmes at EU national level. The portal is intended to help meet EU objectives in the Public Health field. It is an important instrument to positively influence behaviour and promote the steady improvement of public health in the 27 EU Member States.

The European Commission representative went through the different steps in the development of the project, and described its structure, its editorial board, its objective, and gave also some preliminary statistics post launch.

Access to the information is possible via a simple theme structure which presents health-related aspects affecting individuals and their environment.

The sections on “News”, “Events” occurring across Europe and “Press Releases” give the opportunity to keep up to date and get involved in major decisions and events in the health field at national, cross border and international level. A newsletter has also been put in place to effectively target the audience through periodical updates.

The group very much welcomed the initiative and recognised the importance of promoting education in the health related field.

II.2 Draft Document on Risk/Benefit Communication

The document will explore and analyse the general perception amongst EMEA stakeholders regarding current practice on benefit/risk communication in EMEA documents.

Views from patients', consumers' and healthcare professionals' organisations, as well as from members of EMEA Scientific Committees' will be considered in the document.

The structure of the document was presented for comments by the PCWP members. Following agreement on its structure, a first draft will be discussed during the following meetings.

II.3 Monthly E-mail for Patients and Consumers: Final Draft

The monthly e-mail for patients' and consumers' organisations is now fully operative and it will be proactively sent to each organisation eligible to participate in the EMEA activities as well as to any organisation upon request. The possibility to subscribe to it will be offered in the EMEA website for any patients' and consumers' organisation at a later stage.

As a next step, the project will be presented to healthcare professionals' organisations to explore whether it fulfils their expectations as an information tool which could be sent to them.

II.4 Eudra Pharm: Update on the Activities

A representative from the Dutch Medicines Agency on behalf of the Telematics Implementation Group (TIG), gave an overview in the project status and referred to those issues related to its development. A demonstration of the multilingual interface (to be shortly implemented) was also shown, and other future developments were mentioned, such as its link to EudraCT and EudraVigilance. The full support from all the 48 Member State Competent Authorities for human and veterinary medicines is necessary for EudraPharm to become a completely operative and comprehensive database which includes information on all medicines marketed in the EU.

Patients' organisations re-emphasized that they are keen to see the development of EudraPharm, to continue until the system corresponds to what Regulation 726/2004 foresees, as it will provide a key tool for patients to find which products are available for which disease in which country. The responsibility of national governments to ensure adequate recourses towards the National Competent Authorities was stressed. The group agreed on the usefulness of the possibility to search by "indication", and they welcome the commitment of the project team towards reaching this goal.
Finally, the PCWP expressed their interest to be further updated and involved in the development process.

II.5 Insulin Naming, Labelling and Pack Design

The EMEA will organise on the 19th November 2007 a "Workshop on naming, labelling and pack design of insulin containing medicinal products".

The purpose of this meeting is to have a first brainstorming with stakeholders on identified practical problems including mix-ups of names, administration of incorrect dose and/or the use of incorrect type of insulin, which may have serious even life threatening consequences to the patient and to explore what initiatives could be proposed in an effort to reduce medication errors with this type of products.

The workshop foresees the participation of many stakeholders, including a representative from the PCWP that will report back to the group during the next meeting.

II.6 Published EPAR Summaries

An updated list of the new available European Public Assessment Report was circulated during the meeting.

II.7 Draft NRG Recommendations on the Naming/Labelling of Medicinal Products for Paediatric Use

The Name Review Group (NRG) has developed some recommendations on the naming/labelling of medicinal products for paediatric use. After a review of qualifiers currently in use for nationally authorised medicinal products for paediatric use, the group has come up with some points for consideration. These have been previously presented to the Paediatric Committee (PDCO) and now also to the PCWP for input. Those qualifiers that could be agreed upon will be included in the annex to the guideline on the acceptability of names for human medicinal products processed through the centralised procedure (CPMP/328/98 rev 5).
The group discussed the points to consider proposed and agreed to provide specific comments after the meeting. Comments received will be discussed at a future NRG meeting.

II.8 New Wording for Section 4 (frequency definition of side effects) in PL

The Quality Review of Documents secretariat has presented to the PCWP few proposals for some harmonised patient-friendly definition to be used in the package leaflet to describe the frequencies of adverse drug reactions. The following one was judged to be a clear and balanced way to give further explanation:

very common:	affects more than 1 user in 10
common:	affects 1 to 10 users in 100
uncommon:	affects 1 to 10 users in 1,000
rare:	affects 1 to 10 users in 10,000
very rare:	affects less than 1 user in 10,000
not known:	frequency cannot be estimated from the available data

Feedback on the implementation on this wording and the experience gained will be given in a year time.

II.9 Interaction with PhVWP (Pharmacovigilance Working Party)

The PhVWP has continued to involve the PCWP in their activities. In this aspect, the PhVWP has sought the view of the PCWP on a proposed wording to update the Package Leaflet of some medicines.

II.10 POs' involvement in promotional activities linked to pharmaceutical companies

This topic will be addressed during the next meeting.

II.11 Performance Indicators Questionnaire

A performance indicators questionnaire has been prepared to measure degree of satisfaction from patients and consumers who have been involved in EMEA activities during 2007. A report showing the results obtained will be presented during the next meeting. Each member from Patients' and Consumers' Organisations was invited to fill in a questionnaire.

Closure of the Meeting