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

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MINUTES OF THE FIFTH MEETING OF THE EMEA HUMAN SCIENTIFIC COMMITTEES' WORKING PARTY WITH PATIENTS' AND CONSUMERS' ORGANISATIONS (PCWP)
EMEA, 28TH FEBRUARY 2008

CO-CHAIRPERSONS: NOËL WATHION (EMEA) - NIKOS DEDES (EATG)

MEETING PARTICIPANTS

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 Diabetes Federation (IDF), International Patient Organisation for Primary Immunodeficiencies (IPOPI), Standing Committee of European Doctors (CPME).

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

Welcome and introduction

Noël Wathion, Head of EMEA Human Post-Authorisation Unit, replaced Isabelle Moulon as co-chair during this meeting. The co-chairs welcomed the participants to the meeting.

I.1 Adoption of agenda

The agenda was adopted with minor changes.

I.2 Minutes of the previous meeting

Some members provided comments on the minutes of the PCWP meeting of the 7th December 2007.

Post meeting note: after having implemented the agreed changes, the minutes were circulated again and were adopted by written procedure.

I.3 Proposals for further interaction between Patients' and Consumers' Organisations, and the CHMP Pharmacovigilance Working Party (PhVWP)

After the initial agreement on the principles, the EMEA has drafted a proposal describing the aim and modalities for the participation of patients and consumers in the activities of the PhVWP. This initial proposal is still under discussion at the PhVWP. Once finally agreed by both Working Parties, the proposal will be put forward to the CHMP.

I.4 Training on the review of PI: Package Leaflets and EPAR summaries

The group was informed about the second training held at the EMEA on the review of product information directed to patients (namely EPAR summaries and Package Leaflets) by patients' and consumers' organisations. New experts from both new organisations and organisations already involved in the review process have been invited to participate in the project. Some of the experts that attended last year's training participated again to share the experience gained so far.

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After introducing and describing the details of the procedure, the EMEA presented an overview of the outcome and experience gained. The training provided a good occasion to get an insight into the point of view of patients' and consumers' organisations on Package Leaflets and EPARs summaries and on some of the issues they are concerned with. The training, both from the EMEA and from the point of view of patients' and consumers' organisations, has been considered useful and productive.

The material circulated during the training will be published on the EMEA's website together with a summary report of the training.

I.5 EC public consultation on 'Legal proposal on information to patients'

In July 2007, the PCWP provided comments on the 'Report on current practices with regard to provision of information to patients on medicinal products', as published by the European Commission (EC).

The Commission has launched a public consultation on the key ideas of a legal proposal on information to patients. In addition to individual organisations sending their own comments directly to the Commission, the EMEA offered the opportunity to organise a meeting with those interested members, and which could serve as forum for discussion and exchange of ideas on this topic.

I.6 Report on the progress of the EMEA interaction with Patients' and Consumers' Organisations and analysis of performance indicators for 2007

A revised and final version of the report was circulated to the group before being presented to the EMEA Management Board.

Post meeting note: the report has been discussed during the June meeting of the EMEA Management Board and has been published on the EMEA's website. The report is available here: http://www.emea.europa.eu/pdfs/human/pcwp/47881407en.pdf.

I.7 Preparation of the plenary meeting with all Patients' and Consumers' Organisations working with the EMEA - 6 June 2008

The draft agenda was presented for comments and the members confirmed the interest of having a general presentation on the EMEA's mission and activities targeted to the new organisations and its respective representatives, as well as an overview on the way the interaction with patients' and consumers' organisations have been progressively developed.

Post meeting note: the draft agenda was circulated for further input and the EMEA invited to the meeting all the patients' and consumers' organisations eligible to participate in EMEA activities, according to the established criteria.

I.8 Preparation of the joint meeting with Healthcare Professionals' Working Group - 5 June 2008

The agenda for the joint meeting with the representatives of the Healthcare Professionals' Working Group had been drafted and was presented for comments and/or suggestions.

Post meeting note: the draft agenda was circulated after the meeting for further input.

II. TRANSPARENCY AND DISSEMINATION OF INFORMATION

II.1 EC report on the progress of the Pharmaceutical Forum

A representative from the EC provided the group with an update on the activities of the Pharmaceutical Forum, informing that a final High Level Pharmaceutical Forum is foreseen for the second semester of 2008. The various objectives achieved so far by the 'Working Group on Information to Patients' which includes getting a common understanding on needs and challenges in the field, defining a set of core quality principles on information to patients and to develop an example of an information package, in the form of a Diabetes Fact Sheet which contains essential information on the condition and treatment options, were covered during the presentation.

One of the next steps for 2008 is to explore ways to improve the access to and dissemination of information in healthcare settings: pharmacies, hospitals and general practitioners. A Strategic Paper

identifying the possible mechanisms to overcome the existing barriers to access to information will be developed.

As far as the quality of information is concerned, a methodology to use the quality principles will be defined.

In the area of partnerships and collaborations for information to patients, the working group will also explore a number of initiatives involving different partners at the national level. The aim is to create an overview on the structures of existing partnerships. In parallel, the working group aims at developing ethical guidance for public-private partnerships. Finally, the working group will develop a "wish list" for what could be the key elements for a European level core information.

Outcomes from the Forum include elements which can be used for an overall strategy on information to patients on diseases and treatments. Additionally, it is being considered to establish a virtual network on information to patients in which EMEA would be involved.

II.2 Strategy to better protect public health by strengthening and rationalising EU pharmacovigilance

A representative from the EC provided an overview of the European Commission strategy to strengthen and rationalise the EU pharmacovigilance system, which had been subject to a recent public consultation. He emphasized key points of particular interests for patients' and consumers' organisations. The rationale of the new proposal came after an extensive assessment of the actual system of pharmacovigilance that had been initiated by the EC in 2004, and which revealed weaknesses in the system.

The strategy, in summary, aims to: clarify and codify the tasks and responsibilities of involved parties and establish standards; establish an EMEA committee structure for pharmacovigilance scientific assessment and decision making coordinating activities and making recommendations on the safety of medicines at the EU level; rationalise the EU pharmacovigilance referral procedures; increase drug safety transparency; improve EU coordination of communication about major new or changing safety issues and establish an EU portal on the safety of medicines; introduce better product information; introduce a "Pharmacovigilance System Master File" to ensure robust but un-bureaucratic oversight of companies pharmacovigilance systems; provide for a clearer legal basis for risk management plans for new and authorised products with safety concerns, including post-authorisation safety studies; codify guiding principles and oversight for the conduct of non-interventional post-authorisation safety studies; simplify ADR reporting using the EU Eudravigilance database as a central tool; introduce scanning of the scientific literature by the EMEA with a clearly defined scope; exchange of data on medication errors that result in an adverse reaction; removal of the current routine requirement for industry periodic safety reports (PSURs) for low risk, old and established products; provide the legal basis for the new EMEA pharmacovigilance committee structure to require submission and coordinate assessment of PSURs and make consequent recommendations for product labelling; provide for the legal basis for patients to report suspected adverse drug reactions.

The proposals to strengthen transparency and communication and to rationalise the adverse drug reaction reporting, were particularly welcomed by the patients' and consumers' representatives.

The public consultation ended on the 1st of February 2008 and now comments are being processed in order to have proposals for legislation in the 4th quarter of 2008.

II.3 Report from the CHMP Pharmacovigilance Working Party (PhVWP) on direct reporting of adverse reactions by patients

The PhVWP, after having been presented with the experiences of patient reporting of adverse drug reactions in some countries of the EU (namely Denmark, France, the Netherlands, Sweden and the United Kingdom), agreed to prepare a summary report in line with one of the key recommendations issued in March 2005 by the working group with patients' and consumers' organisations (http://www.emea.europa.eu/pdfs/human/pcwp/14947904en.pdf).

The report summarises the results obtained in the various Member States and draws some general conclusions. According to these conclusions patient reporting appears as a further source of safety

information that may offer an added value to the spontaneous reporting system. Therefore, the PhVWP agreed to consider direct patient reporting further in co-operation with the PCWP.

III. UPDATE ON PREVIOUS ACTIVITIES

III.1 Published EPAR summaries

The EMEA secretariat presented an updated list of the new EPAR summaries for medicines approved in the past that did not have a summary yet. The remaining EPAR summaries to be written were also listed. In a very short timeframe all centrally authorised medicines would have their own EPAR summary.

III.2 Update on the PCOs dedicated section on the EMEA's website

The Q&A document on generic and biosimilar medicines have been translated into all EU languages, and they are now available on the EMEA's website (http://www.emea.europa.eu/Patients/generic.htm). The dedicated section of the website for patients' and consumers' groups has been updated appropriately to improve access to these documents.

IV. A.O.B

IV.1 Relationships between Patients' and Consumers' Organisations and the Pharmaceutical Industry (outside the remit of the PCWP)

Various patients' and consumers' organisations have met to agree on a 'code of practice between patients' organisations and pharmaceutical companies'. The outcome of a preliminary discussion held on the previous day to the PCWP meeting was presented to the group, explaining in summary which are the next steps to be taken as well as the expected timeframe to conclude the work.

IV.2 Meeting of the Telematic Implementation Group (TIG) – EudraPharm of the 3 December 2007: possible actions for the PCWP

The TIG has proposed the participation of patients and consumers in a test environment for new developed areas of the database. Participants will be given a comfortable timeframe to perform the test on-line and send back their comments during the next months. Further discussion and feedback would take place during the joint meeting with representatives of healthcare professionals' organisations in June 2008.

IV.3 New Wording for Section 4 (frequency definition of side effects) in PL

After the recommendation proposed by the PCWP for a common wording to express the frequencies of adverse drug reaction in the Package Leaflet**,** the Quality Review of Documents Group (QRD) had asked the PCWP whether the table including explanation for each numerically expressed frequency (as already discussed by the PCWP during its 21st September 2007 meeting, see below) should be provided systematically in every leaflet. The PCWP after having considered various options agreed that the table (see below) should be provided systematically, as a reference for the patient/reader.

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

IV.4 Report from the conference from Health Security Agencies: Agencies and Democratization, November the 16th, Liege

A member of the group participated to the conference on 'Cross-national and European perspectives on health safety agencies' and reported back on his experience. The conference is part of MEDUSE project, funded by the European Commission that aims setting up a dialogue between social scientists and non-academic actors.

Some members pointed out their participation to another conference organised as part of the MEDUSE project relevant for the PCWP: "the Dynamics of Patient and Health Organisations in Europe" that has taken place in Paris, July 2007. A report will be sent to the group for information.

IV.5 PCWP representative for the next 02nd EMEA meeting with research centres and interested parties on ENCePP

The EMEA is organising a second meeting with 'Research Centres and Interested Parties on the European Network of Centres for Pharmacoepidemiology and Pharmacovigilance (ENCePP).

The objective of the meeting is to give an update on the recent developments and current status of the project, including the proposed Working Model, and the establishment of an interim Advisory Group and 4 Working Groups.

A representative of the PCWP who already participated in previous meetings will attend, and will report back during the next PCWP meeting.

IV.6 PCWP proposed meeting dates for 2009

The calendar with the 2009 meeting dates has been prepared and will be circulated to the group for further comments.

Close of the meeting