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, 07TH DECEMBER 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 Public Health Alliance (EPHA), European Organisation for Rare Diseases (EURORDIS), International Alliance of Patients' Organizations (IAPO), International Patient Organisation for Primary Immunodeficiencies (IPOPI).

Committee on 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

The Co-Chairs welcomed the participants to the meeting. The new observer from the CMD(h) group was introduced to the group as well as the member of the Health Care Professionals' Working Group, nominated to attend as observer.

I.1 Adoption of agenda

The agenda was adopted with minor changes. In particular, members were made aware of the European Commission's public consultation on the proposals for amending the pharmaceutical legislation to strengthen the pharmacovigilance system. Individual patients' and consumers' organisations may send their comments until the 01st of February 2008. A presentation of the proposal, focussing on those sections more interesting for patients' and consumers' organisations, will be given in the future.

I.2 Minutes of previous meeting

The minutes from the 21st September meeting of the PCWP were adopted.

I.3 Proposals for further interaction between Patients' Organisations, Scientific Committees and Working Parties

As a way to explore how patient's representatives can be more involved in the scientific activities of the EMEA, an outline of the current Working Parties of the Committee for Medicinal Products for Human Use (CHMP) operating at the EMEA was presented. Special emphasis was given, this time, to the functioning and tasks of the Pharmacovigilance Working Party (PhvWP). The representative from the Committee on Herbal Medicinal Products (HMPC) also introduced the role and functioning of this Committee in greater detail.

Members asked for additional individual presentations of the different working parties in the future. This would provide detailed description of their tasks, in order to identify what kind of input patients' and consumers' representatives can provide.

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Ways to interact with the PhVWP were discussed in greater detail. Finally, it was proposed to explore the feasibility of the participation of one PCWP representative to the meetings of the PhVWP. This would increase the insight of patients and consumers into its method of work, contents of the discussions and structure of the meeting. This proposal will be put forward to the PhVWP for discussion at their next meeting.

I.4 Information on specific obligations for products under conditional marketing authorisation: follow up

As per the patients' recommendations and proposals for action, previous discussions held during the 21st September meeting focussed on how to improve access to information on specific obligations for products under conditional marketing authorisation or authorised under exceptional circumstances.

After having considered comments from patients' and consumers' representatives, the EMEA secretariat has created new symbols to identify the relevant products on the website. An explanatory text will also be included in the pages dedicated to patients' groups, describing the different types of marketing authorisations.

I.5 1st EMEA meeting with centres on ENCePP (European Network of Centres in Pharmacoepidemiology & Pharmacovigilance)

In line with the EMEA Road Map and the European Risk Management Strategy (which is a joint initiative of the EMEA, the European Commission and the Heads of Medicines Agencies (HMAs)) of the Member States, the EMEA is working on the establishment of the European Network of Centres for Pharmacoepidemiology & Pharmacovigilance or ENCePP, a network of Pharmacoepidemiology Centres, Medical Care Centres, automated Health Care Databases and electronic Registries, which will significantly contribute to identify, characterise and assess risks relating to medicinal products marketed in Europe, thus enabling a more proactive conduct of Pharmacovigilance. A member of the PCWP attended on the 28th June 2007 the above-mentioned meeting and reported back to the group on the experience. The EMEA gave an update on the progress made after the June meeting on this topic.

A report of the progress to date was later circulated to the group and is available on the EMEA website.

A representative from the PCWP will be invited to attend to next meetings of the group.

I.6 EMEA workshop on naming, labelling and pack design of insulin containing medicinal products

A representative from the PCWP, member of the International Diabetes Federation, was invited to participate and to give his contribution to the above-mentioned meeting held at the EMEA on the 19th November 2007. The experience brought together different stakeholders from different environment such as, regulators, clinicians and industry representatives. It was considered to be an important initiative which has offered the opportunity to share different points of view and identify problematic areas. An overview of the issues discussed at the meeting and the general conclusions were given, and it was informed that additional meetings would be periodically held in the future. A written report will be published soon and it will be then circulated to the group.

I.7 Draft NRG (Name Review Group) recommendations on the naming/labelling of medicinal products for paediatric use

A proposal for naming/labelling of medicinal products for paediatric use was presented during the 21st September meeting of the PCWP. Comments provided by PCWP members are being considered together with other comments received from different stakeholders involved in the process. Further update on the outcome will be provided at future meetings.

I.8 HCPWG (Health Care Professionals' Working Group) meeting of 24 October 2007

The PCWP observer participating in the HCP WG described the progress done so far by the working group in setting up a framework of interaction between the healthcare professionals and the EMEA.
It was described how alternative ways in achieving an appropriate and fruitful framework of interaction, compared to the one currently used by patients and consumers, are currently being sought after.

The observer from the HCPWG, on the other hand, pointed out the usefulness of participating in the PCWP meetings. This experience has been helpful in gaining familiarity with the work done by the patients and consumers in the past, and it could be shared with the rest of the HCPWG. It was also underlined that the two groups have various areas of common interest including pharmacovigilance, information on medicines and interaction with Scientific Committees.

II. TRANSPARENCY AND DISSEMINATION OF INFORMATION

II.1 Pharmaceutical Forum: update from the 6th meeting of the working group on information to patients on pharmaceuticals

The Co-chairpersons of the PCWP group reported back from the 6th meeting of the Working Group on Information to Patients following release of the Progress Report and the conclusions of the Second meeting of the Pharmaceutical Forum.

The Pharmaceutical Forum Workplan 2007 - 2008 was presented during the meeting, highlighting the three objectives of the Working Group on Information to Patients: access to and dissemination of information, quality principles, and practical implementation of the partnership for information.

A group will prepare a methodology to develop and validate the information to patients and a feasibility study will be carried out as part of the impact assessment. Additional input and expertise will be requested from the Member States, the EMEA and the stakeholders for the impact analysis.

EMEA and the PCWP will be consulted for the impact assessment regarding a proposed legislation following the Commission Report on Article 88 (a) of the Directive. The minutes of the meeting will be circulated to the group, as soon as they are published.

II.2 PCOs' involvement in promotional activities linked to pharmaceutical companies

The occasional experience of patients' organisations being approached by a pharmaceutical company for the launch of a newly marketed product has given the opportunity to open the discussion about patients' organisations and their policies/codes of conduct regarding their relationships with pharmaceutical companies.

Each member reported on their experience as to their respective organisations, and of any written rules/position paper available.

Members recognised however that a common policy is missing.

It was then proposed to reflect on a possible document addressing this issue. It was requested to the members to circulate any existing related policies from patients' and consumers' organisations. The EMEA welcomes the initiative but proposes to limit its contribution only in providing logistic support to the initiative, since the policy to be agreed amongst PCOs falls out the Agency sphere of activity.

III. AFTERNOON PLENARY SESSION

III.1 Report on patients' involvement in EMEA activities 2007 and performance indicators analysis

As specified in the adopted "Framework on the interaction between the EMEA and patients' and consumers' organisations" a report will be presented to the Management Board on the outcome and progress made on the work undertaken in the Agency's interaction with Patients' and Consumers' Organisations. The report will be accompanied by performance indicators, jointly developed by the EMEA and Patients' and Consumers' Organisations.

A first draft report was presented to the group. They welcomed it very much, and appreciated the progress made so far in involving patients' and consumers' organisations representatives at various levels within the Agency. Many suggested improving the dissemination and visibility of the document especially at national level to promote national competent authorities awareness about this successful experience. The report will be circulated for further comments to the PCWP members, before it is transmitted to the Management Board for their next meeting in March 2008.

IV. UPDATE ON PREVIOUS ACTIVITIES

IV.1 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, 03 October 2007

The EMEA secretariat informed the group of the final report of the conference being now available at the EMEA website. The co-chair, who participated at the conference as speaker, highlighted how the input from patients' and consumers' representatives was really welcomed during the whole meeting and how they were regarded as prominent stakeholders. This is reflected on the report that hosts a dedicated section summarising all the issues raised during the meeting by patients' representatives.

IV.2 Published EPAR summaries

An updated list of all new EPAR summaries was presented to the group. It was pointed out that the update during the meeting is the only way to be aware of the newly published EPAR summaries for products that have obtained a marketing authorisation in the past years (backlog) and, in general, patients may need more information on the progress of the work. EMEA explained that now all products approved trough centralised procedure will have in the next few months their respective EPAR summary.

IV.3 Fulfilment of EMEA criteria for PCOs: follow-up after the initial assessment

During previous meetings, attention was called to the fact that organisations assessed according to the EMEA criteria need to update the documentation provided for the initial assessment. This is of the most importance especially for ensuring that outcomes of evaluation criteria are kept up to date.

The EMEA has proposed to review the documentation two years after the initial application of each organisation, and has requested them to provide an update of the questionnaire they sent the first time.

IV.4 Training on the review of PI: Package Leaflet and EPAR summaries

EMEA informed the group of a second training for patients and consumers who are to be involved in the review of Package Leaflets and EPAR summaries. The training will be held at the EMEA on the 29th of January 2008 and will focus on the procedure as well as on the experience gained so far by experts who have already participated in the procedure.

IV.5 New wording for the PL of the antidepressant medications

A final wording proposal was presented to the group (Annex I). This wording has been agreed at the level of the PhVWP after having considered comments provided by the PCWP. The text will be proposed for implementation by each Member State.

V. A.O.B

V.1 Report from the Telematic Implementation Group (TIG) of the 03 December 2007

The PCWP representative invited to attend the TIG meeting on 03rd December 2007 reported back to the group. The TIG is responsible of the implementation of the EudraPharm project. They welcome the interaction with patients and value the contribution from the PCWP to the work that they undertake.

The main conclusion during this meeting concerned a new user testing consultation involving patients' and consumers' representatives, which will be requested in a short timeframe. In addition, patients and consumers will also be involved through another consultation procedure on issues concerning the information to be displayed in EudraPharm. Further discussions during next meetings will also explore new ways to support to the process, especially at national level.

V.2 Report from the conference from Health Security Agencies: agencies and democratization, November the 16th, Liege

Postponed to the next meeting.

Closure of the meeting