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

London, 30 October 2008
Doc. Ref.: EMEA/591309/2008

MINUTES OF THE SIXTH MEETING OF THE EMEA/CHMP WORKING GROUP WITH *HEALTHCARE PROFESSIONALS' ORGANISATIONS*
EMEA, 30TH OCTOBER 2008

Chairperson: Juan García Burgos

MEETING PARTICIPANTS

Representatives of:
European Association for Clinical Pharmacology and Therapeutics (EACPT), European Union Geriatric Medicine Society (EUGMS), European Union of General Practitioners (UEMO), European Society of Cardiology (ESC), Pharmaceutical Group Of The European Union (PGEU), European Specialists Nurses Organisations (ESNO), United European Gastroenterology Federation (UEGF), European Society for Medical Oncology (ESMO), Standing Committee of European Doctors (CPME), European Cancer Organisation (ECCO), International Diabetes Federation (IDF)

Committee for Herbal Medicinal Products (HMPC), Committee for Medicinal Products for Human Use (CHMP), Co-ordination Group for Mutual Recognition and Decentralised Procedures–Human (CMD(h)), European Medicines Agency (EMEA) Secretariat.

Welcome and introduction

Juan García Burgos presented N. Wathion's apologies for being absent and replaced him as chair during this meeting. He welcomed the participants to the meeting.

The agenda was adopted without changes.

Minutes of the previous meeting

The HCP WG endorsed the minutes from the joint PCWP - HCP WG meeting held on 5th June 2008 (EMEA/301606/2008). The group was informed that the document is publicly available on the EMEA website.

DRAFT HCP WG WORK PLAN FOR 2009

The HCP WG Work Plan for 2009 was presented. The main task for 2009 will be the development of a framework for interaction between EMEA and healthcare professionals' organisations, which will define the extent of the planned interaction and the objectives to be achieved. In addition 2009 will see the start of the implementation of the HCP WG recommendations. These recommendations are focused in three main areas: information on medicines, pharmacovigilance and involvement in activities of EMEA Scientific Committees. Following agreement by the group, the Work Plan will be transmitted to the CHMP in November for adoption and subsequently will be published on the EMEA website.

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

HCP WG RECOMMENDATIONS AND PROPOSALS FOR ACTION

Draft "Recommendations and proposals for action" were prepared by the HCP WG based on discussions held by the group in the three areas above mentioned. The document was released for 3-month public consultation and comments have been received from 14 different individual sources, mainly industry and healthcare professionals' organisations. Comments had been reviewed and were presented and analysed during the meeting, together with proposals for amendments of the current text. In general, all the third parties who participated in the consultation welcomed and largely supported the proposed interaction and encouraged EMEA to progress in its formal establishment. However, it was also pointed out the need to ensure that the process does not become too complex and that it does not increase the workload of EMEA and other stakeholders. In addition, it has been requested to guarantee equal opportunities of interaction and participation to different HCPs' organisations. With regard to the provision of information, it was agreed that EMEA should be regarded as a source of validated and official information on medicines.

The amended version integrating the outcome of the discussion held during the meeting will be circulated for adoption by written procedure. The updated final version will be sent to the CHMP for final adoption likely in its December 2008 meeting and subsequently it will be published in the EMEA website.

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 patients and healthcare professionals in May 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 received contributions should be annexed to the report.

DISSEMINATION OF CONSULTATION DOCUMENTS

EMEA secretariat gave a presentation on EMEA guidelines, explaining their objective and how they are prepared, as well as outlining their different scope compared to therapeutic guidelines.

Prof. Ian Weller from University College of London, Chair of the SAG HIV/Viral Disease participated in the discussion and presented the results of a survey he had recently carried out in relation to the public consultation of the *"Guideline on clinical development of medicinal products for the treatment of HIV infection"*. In this survey, which was addressed to members of a specific scientific network in HIV (NEAT) as well as other individual experts in the HIV field, questions were asked regarding the awareness about EMEA guidelines and respective consultation procedures. This survey showed a limited awareness by the academic and scientific communities of EMEA documents when they are subject of public consultation, despite expressing at the same time, clear interest on them. The members of the group reported on the experiences of their societies and discussed on how better engage academic

community in consultations. Action at two levels was considered: on one hand EMEA informed of initiatives already in-place to actively disseminate consultation documents targeting organisations related to the document's area of interest; on the other hand, the responsibility relies also on the organisation first reached by the EMEA, which would have to properly distribute the document using their own organisation's network to allow it to be read and commented on by those many individuals with a potential interest. EMEA secretariat stressed the importance of getting the comments from academia and scientific organisations on their scientific guidelines.

For information purposes, EMEA secretariat gave an update of the EMEA copyright policy for public documents

EUDRAVIGILANCE

EMEA secretariat gave a first introduction to this group to the Eudravigilance database. The presentation came timely as Eudravigilance access policy is to be released for public consultation shortly.

According to article 26, paragraph (3) and article 57, paragraph (1) (d) 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 presentation went also through the access policy and gave some practical examples on the planned level of access to healthcare professionals. The members welcomed this initiative and appreciated this further step towards transparency. It was agreed to circulate the access policy to the members of the group for comments once it is made available.

COORDINATION ISSUES

Outcome of the 'Workshop on the EMEA on-line strategy and website design' held on the 29th September 2008

Members of the HCP WG, together with representatives from patients and consumers' organisations, had been invited to participate in a workshop as part of the initiatives put in place 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 HCP WG on the project, underlining the productive outcome of the workshop. She also informed that as part of this project, "user personas" profiles had been developed. These "user personas" aim to represent users of the EMEA website, and are expected to provide specific details of typical users that help to make user requirements and preferences tangible.

Members of the HCP WG as well as patients' and consumers' representatives will be consulted on the appropriateness of these" user personas"

Members will be kept informed of the progression of the work on the restructuring of the EMEA website and could be consulted to test early phases of the project.

Rules for Involvement of EMEA Stakeholders

EMEA secretariat presented a draft revision of the "Rules of involvement of members of Patients' and Consumers' Organisations in Committees related activities" (EMEA/48439/2008), which was initially adopted in January 2006. The document has been revised in order to also cover members of healthcare professionals' organisations when interacting with EMEA Scientific Committees, its Working Parties, Scientific Advisory Groups, and with the Rapporteurs.

The document aims to define the different types of consultation with patients, consumers and healthcare professionals and the specific conditions for each type of consultation. In this aspect, it sets up rules for members of the organisations coming either as experts or as representatives of their organisations. During the revision, some aspects with regard to "declaration of interest", "confidentiality undertaking" and "adherence to EMEA Code of Conduct" have also been clarified.

After agreement at both the Patients'/Consumers' Working Party (PCWP) and the Healthcare Professionals Working Group (HCP WG), it will be sent for adoption by the EMEA Human Scientific Committees.

NRG recommendations on the naming/labelling of medicinal products for paediatric use

The Chair of the Name Review Group (NRG) of the EMEA updated on the recommendations that this group has prepared with regard to the naming/labelling of medicinal products for paediatric use. Several groups, such as PCWP and HCP WG have been consulted in the past on this subject, and the main issues focused on the best use of qualifiers for prescription/ selection of the correct medicine. Despite general agreement in main principles and recommendations, the discussion at the level of the NRG still needs to finalise some"non-consensus" issues, and it was informed that HCP WG would be involved and updated on any progress at all times.

Feedback from the Pharmacovigilance Working Party on the HCP WG consultation regarding class wording revision of antiepileptic medicines

A representative of the EMEA secretariat gave background information on this consultation that took place after the June HCP WG meeting. The new wording, regarding some additional information to be added to the Product Information of antiepileptic medicines, was based on the outcome of a safety evaluation of the medicines that are considered to bear a potential risk of suicidal thoughts and behaviour. The EMEA representative listed the comments received from the HCP WG and presented the final wording to the members, as agreed by the PhVWP during its July 2008 meeting. The interest and relevance of HCP WG being involved in these types of consultation coming from the PhVWP was stressed.

Monthly e-mail to patients', consumers' and HCPs' organisations

A communication tool by means of a monthly e-mail has been developed using the feedback received from representatives of patients and healthcare professionals' organisations through various discussions at the PCWP and HCP WG. An updated version was presented to the group. The objective is to put in place a system for monthly updating patients and healthcare professionals' organisations on key information on human medicines produced and published by the EMEA. The tool is to be called "human medicines highlights" Participants agreed on

the proposed structure and seemed very satisfied. Some informed of having already disseminated it within their own organisations and having received a very positive feedback.

This final draft will be presented to the PCWP in November 2008 and since early 2009, every new issue will be widely disseminated among EMEA's interested parties and will become publicly available on the EMEA website. Users will also be offered the possibility to subscribe to it.

Report from PCWP meeting on 30th September 2008

PCWP representative attending as observer to the meeting reported back from the PCWP meeting held on 30th September 2008.

HCP WG proposed meeting dates for 2009

Meeting dates for 2009 were agreed as follows:

- 11th March, Wednesday – Plenary meeting
- 9th June, Thursday – Joint meeting with patients' and consumers' organisations
- 29th October, Thursday – Plenary meeting

Close of the meeting