European Medicines Agency

London, 5 June 2008
Doc. Ref.: EMEA/58588/2008

# EMEA/CHMP WORKING GROUP WITH HEALTHCARE PROFESSIONALS' ORGANISATIONS

**Wednesday, 31 January 2008**

MINUTES

***Chairpersons:*** N. Wathion and I. Moulon

The fifth meeting of the EMEA/CHMP Working Group with Healthcare Professionals' Organisations (HCP WG) was held at the EMEA on 31 January 2008.

The HCP WG welcomed the newly appointed representative of the European Specialist Nurses Organisations (ESNO), which will strengthen the representation of nurses' organisations in the working group.

## Organisational matters

The HCP WG adopted the draft minutes from the meeting held 24 October 2007. The group was informed that the document will be presented to the CHMP and published on the EMEA website.

As agreed at the previous meeting, a questionnaire was distributed to the group in December 2007 to explore the members' views on the functioning of the group after its first year of existence. The questionnaire asked member organisations about their needs and expectations to the work of the group, possible reasons for the relatively low attendance rates at meetings in the second half of 2007, as well as ways to ensure better consistency in the work of the HCP WG.

There was a good response rate from member organisations, who in general confirmed their interest in further developing the HCP WG as a platform for exchange and interaction with the EMEA. The replies also reflected the different expectations to the kind of involvement that the organisations wish to have with the Agency. Some organisations expected a more direct involvement in the scientific discussions and medicines evaluation procedures than the remit of the HCP WG makes feasible. Therefore it was deemed necessary to clarify the role of the HCP WG so that participation from healthcare professionals' organisations to the HCP WG is decided based on clear expectations. Based on this, the role of the HCP WG will be:

- To continue as a forum for exchange and discussion on issues, which are of interest to healthcare professionals and related to the EMEA's aim of ensuring appropriate support to the fostering of scientific excellence in medicines evaluation and safety monitoring.

- To work on how to best develop and structure the general involvement of European healthcare professionals' organisations in the Agency's scientific tasks related to the evaluation and monitoring of medicines.

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The main priority for the HCP WG in 2008 will be the establishment of a framework for the involvement of healthcare professionals' organisations in the work of the EMEA. The framework will ensure transparency of the involvement and provide clear remits. As part of this, the already agreed criteria for involvement will be reviewed. Once adopted, they will be implemented in 2009.

As for the future organisation of HCP WG meetings, it is foreseen to hold two plenary meetings plus a joint meeting with the PCWP[1] per year. Additional ad-hoc meetings could also be organised on a case-by-case basis.

*Post-meeting note: The HCP WG Rules of Procedure will be revised in accordance with these developments. The document will be removed from the EMEA website until a revised version has been adopted.*

**HCP WG recommendations and proposals for action**

The group adopted the following parts of the *HCP WG recommendations and proposals for action* that have been drafted during 2007:

- Recommendations in the area of *information on medicines.*
- Recommendations on the *involvement of healthcare professionals' organisations in the work of the EMEA.*

The documents will be submitted to the EMEA's scientific committees for adoption and subsequently published on the EMEA's website.

The recommendations in the area of pharmacovigilance activities will be updated as to reflect the European Commission's legislative proposals for strengthening the EU pharmacovigilance system (see below). A revised draft will be distributed to members for comments and adoption via written procedure during the second quarter of 2008.

**EU pharmacovigilance**

A representative from the European Commission gave an introduction to the European Commission's legislative proposals for strengthening the EU pharmacovigilance system. The consultation document has recently been subject to a public consultation, which ended 1 February 2008. Following the review of comments, a proposal will be made to the European Parliament and the Council. The new EU pharmacovigilance legislation is expected to be in place by 2011-2012.

**Revision of the SPC guideline**

A representative from the EMEA presented the proposals for revision of the Summary of Product Characteristics (SPC) guideline to the group. The draft guideline with proposed revisions is currently under public consultation with the European Commission as lead. Members were encouraged to particularly address the practical use of the SPC, e.g. whether the expressions are found relevant and useful. The deadline for submission of comments is 28 March 2008.

[1] The EMEA Scientific Committees' Working Party with Patients' and Consumers' Organisations

**EudraPharm**

A representative from the EU Telematics Implementation Group gave an introduction to the EudraPharm project. EudraPharm is a database intended as a source of information on all medicinal products for human and veterinary use that have been authorised in the European Union (EU) and the European Economic Area (EEA). The first version is available on the internet and can be found here.

Currently, the interface is available only in English and with limited data (only data for products that have been centrally authorised -via the EMEA- are available). A second version with a multilingual interface and more data (for products that have been authorised by national regulatory authorities) is under development and was demonstrated at the meeting. The HCP WG was invited to take part in the user testing of this new version with a view to provide feed back on the functionality of this latest version of the database.

**Coordination issues**

*Monthly e-mail updates on EMEA activities*
At the last meeting, the HCP WG had been introduced to the EMEA monthly e-mail to patients' and consumers' organisations, which provides these organisations with a monthly overview of the EMEA's activities, e.g. new marketing authorisations, published guidelines, safety updates, etc.

It was agreed that the EMEA will adapt the current format to also fit the needs of healthcare professionals. The EMEA will gradually implement these changes over the coming months, and the format and contents will be discussed again at the HCP WG meeting scheduled for October 2008.

*EC/EMEA conference on the Clinical Trials Directive*
The HCP WG was represented at this conference, which was held at the EMEA in October 2007. The group was informed that the report, presentations and written submissions to the conference are now available on the EMEA website and can be found here.

**Conclusions**

In accordance with the agreed restructuring of the HCP WG meeting organisation, the meeting scheduled for 3 April 2008 will be cancelled. Members who wish to continue their participation to the group will be invited for a joint meeting with the PCWP, which will take place in June 2008. For the remainder of 2008, the priority of the HCP WG will be to finalise the framework and criteria for interaction as well as to start the implementation of the agreed *recommendations and proposals for action*.