



European Medicines Agency

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EMEA/CHMP WORKING GROUP WITH HEALTHCARE PROFESSIONALS' ORGANISATIONS

Wednesday, 24 October 2007

MINUTES

Chairperson: N. Wathion

The fourth meeting of the EMEA/CHMP Working Group with Healthcare Professionals' Organisations (HCP WG) was held at the EMEA on 24 October 2007.

The HCP WG welcomed the newly appointed observer from the EMEA Committee on Herbal Medicinal Products (HMPC) to the meeting.

Organisational matters

The HCP WG adopted the draft minutes from the joint meeting with the EMEA Working Party with Patients' and Consumers' Organisations (PCWP) held 1 June 2007. The group was informed that the document will be published on the EMEA website.

The HCP WG reflected on the progress made during its 1st year of existence, and reconsidered how the interaction between EMEA and healthcare professionals' associations should continue to be developed in the most effective way.

The EMEA expressed some concerns about the continuous decline in the number of participants to HCP WG meetings. It was questioned whether the current structure of the group's work, which mirrors that of the PCWP, is the appropriate format for interaction with healthcare professionals' organisations.

The participants of the meeting expressed their satisfaction with the progress achieved so far and welcomed discussions on how to further optimise the interaction. It was agreed that the EMEA will prepare a questionnaire for distribution to the HCP WG to explore the members' views on this issue. The results of this questionnaire will form basis for a brainstorming discussion on the further development of the interaction at the HCP WG meeting scheduled for 31 January 2008.

HCP WG recommendations and proposals for action

Building on the work undertaken by drafting groups at the meeting held 16 March 2007, and the progress achieved via written procedures since then, the group reviewed revised versions of the draft documents outlining the recommendations and proposals for action in the future interaction between the EMEA and healthcare professionals' organisations. This document only reflects the discussion on issues arisen since the above-mentioned meeting. A more detailed report on the contents of the recommendations can be found in the published [minutes](#) dated 1 June 2007.

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In the area of '*information on medicines*' the group in particular discussed the relevance and target audience of the European Public Assessment Report (EPARs). It was clarified that healthcare professionals regard the EPARs as relatively specialised documents, which are only consulted when in-depth information on a given evaluation outcome is needed.

In terms of easily accessible information on new developments during a product's lifecycle, e.g. safety updates, it was acknowledged that EPARs may not be an expedient tool, and the group agreed to explore other possibilities, e.g. newsletters with brief overviews aimed at busy clinicians.

Issues concerning the SPC were also discussed, including the possibility of introducing a summary section. The EMEA will explore different possibilities and discuss further with the group in January 2008.

In the area of '*pharmacovigilance activities*' the group had a discussion on how to establish a better coordination in the general communication of safety signals. Authorities are often aware that information on safety issues are about to be published via e.g. studies in scientific journals. However, the communication on conclusions and questions arising are often channelled via the media, and from the Agency's point of view, a preview of this information would be beneficial in terms of preparing for an appropriate response to any media queries.

On their side, healthcare professionals expect an increasing transparency in the area of EMEA's evaluation processes, which could possibly include consultations on safety communications prepared by the Agency. But it was also acknowledged that the lack of time for review before publication constitutes a problem. In addition, the participants found it a good suggestion to develop a procedure for consultation of healthcare professionals' organisations in the preparation of communication to healthcare professionals.

In the area of '*involvement in EMEA activities*' the main discussion was on how to best develop the interaction with healthcare professionals as experts and benefit from their capacities in the work of the EMEA. It is clear that the current structure of the EMEA's scientific committees and working parties, as well as the general confidentiality requirements, create a barrier for full involvement of healthcare professionals' organisations in the EMEA's scientific tasks. It was agreed to further consider how to find an appropriate balance between these interests.

Following these discussions, a consolidated set of recommendations for the future work in each of the areas covered by the drafting groups will be presented for adoption at the HCP WG meeting scheduled for January 2008.

Coordination issues

ENCePP network

The group heard a presentation on the European Network of Centres for Pharmacovigilance & Pharmacoepidemiology (ENCePP), an EMEA-led project in the context of the European Risk Management Strategy. The network's objective is to contribute to the improvement of public health by, among several other initiatives, enabling a more rapid detection of new adverse drug reactions, developing risk management and improve the communication of safety information to users.

The HCP WG was represented at the inaugural meeting in July 2007, and the group agreed that it is important to follow the further developments of ENCePP closely.

Monthly e-mail updates on EMEA activities

The group was introduced to the EMEA monthly e-mail sent to patients' and consumers' organisations, which provides these organisations with a regular overview of the EMEA's activities, e.g. new marketing authorisations, published guidelines, safety updates, etc.

Both the mailing and its format were very well received by the HCP WG. It was suggested that the group together with the EMEA should identify which pieces of information healthcare professionals could be more interested in and to explore the possibilities for developing a parallel newsletter tailored for healthcare professionals.

HCP WG observer to the PCWP

As a follow up to the outcome of the joint meeting with the EMEA Working Party with Patients' and Consumers' Organisations (PCWP), the HCP WG appointed an observer to the PCWP.

Conclusions

The Chair reflected on the positive outcome of the meeting, thanking the participants for their active contribution. The next meeting of the HCP WG is scheduled for 31 January 2008, where it will be a priority to finalise the HCP WG recommendations and proposals for action.

LIST OF PARTICIPANTS

HEALTHCARE PROFESSIONALS' ORGANISATIONS

Standing Committee of European Doctors CPME

European Association for the Study of Diabetes EASD

European Society for Medical Oncology ESMO

Pharmaceutical Group Of The European Union PGEU

CHMP Members & Experts

PCWP & HMPC Observers