European Medicines Agency

London, 1 June 2007
Doc. Ref.: EMEA/129522/2007

EMEA/CHMP WORKING GROUP WITH HEALTHCARE PROFESSIONALS' ORGANISATIONS

Friday, 16 March 2007

MINUTES

Chairpersons: Noël Wathion – Giuseppe Nisticò

The second meeting of the EMEA/CHMP Working Group with Healthcare Professionals' Organisations (HCP WG) was held at the EMEA on 16 March 2007.

The meeting was co-chaired by N. Wathion and G. Nisticò. Since the last meeting, new organisations had been invited to participate in the group and representatives from the European Federation of Nurses Association (EFN) and the European Union Geriatric Medicine Society (EUGMS) were welcomed. A list of attending organisations is annexed to this report.

The HCP WG was introduced to the EMEA's senior Medical Officer, H.G. Eichler, who expressed his interest in following the HCP WG in its future work.

Organisational matters

The HCP WG adopted the draft meeting report from the meeting held 17 November 2006, and the group was informed that this and future meeting reports will be published on the EMEA website once adopted.

The HCP WG was also informed that the HCP WG Mandate & Rules of Procedure and HCP WG Work Plan 2007 have been published on the EMEA website following adoption by CHMP.

The EMEA secretariat has developed a set of draft criteria for involvement of Healthcare Professionals' Organisations in the work of the Agency. These are quite similar to the criteria already in place for involvement of patients' and consumers' organisations and emphasise a need for transparency regarding statutes, members, activities as well as financial contributions and the organisations' budgets. The HCP WG was provided with an example from a patients' organisation who had very well demonstrated to fulfil the criteria after having modified their statutes and improved their website to comply with the recommended transparency of the above-mentioned issues.

It was stressed that although the EMEA does not expect organisations to instantly make major changes to their websites, the issue of transparency is crucial to the EMEA when evaluating organisations' eligibility for involvement in EMEA activities. A list of organisations eligible for involvement will be published on the EMEA's website with links to the individual organisations' homepages, as is also done for patients' and consumers' organisations.

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Preparation for drafting group discussions

I. Moulon provided the HCP WG with an overview of the 'Recommendations and Proposals for Actions' prepared together with patients' and consumers' organisations in 2004. The purpose of the presentation was to give the HCP WG an impression on the possible context in which the group could develop their own recommendations and proposals for actions. Further in-depth discussions in the respective drafting groups established for this purpose will be held in a second phase.

Reports from drafting groups

The *HCP WG drafting group on 'Information on Medicines'* discussed issues relating to product information, in particular the Summary of Product Characteristics (SPC). The drafting group had discussions on its use by healthcare professionals, the structure and the content of the document.

During the discussions the point was raised that not all healthcare professionals are aware of the existence of the SPC as a reference document, and that some do not find the SPC particularly practical for their work. There is no gold standard reference providing healthcare professionals with validated information on medicines in EU, although it is recognised that some national publications are widely used in different Member States (as e.g. the British National Formulary (BNF) in the UK). The drafting group therefore considers the SPC a useful and relevant document for reference. However, a need was identified to better balance the extent of information provided with practicality and flexibility for professional use. In this respect, the possibility of having a more concise document in addition to the complete SPC could be further explored.

Overall, the SPC should be a comprehensive, clear and updated reference for healthcare professionals, focussing on clinically relevant information. More specifically, the group asked for clearer information on special populations and on the severity and frequency of adverse reactions.

Attention should be paid to the electronic format of product information as to facilitate dissemination of information and use of electronic tools for prescription, supporting also provision of information at dispensing points. In addition, the need for training and education of healthcare professionals in relation to the SPC was discussed.

The draft recommendations in the area of information on medicines were supported by the HCP WG. It was discussed to which extend it is possible to provide "evidence-based" information in indications for which there is no marketing authorisation. The group was reminded that it is not the role of regulatory authorities to promote off-label use. However, further discussion could be brought up at the European level, especially with regard to the information on clinical trials or compassionate use. Similarly, therapeutic guidelines and relative benefit-risk deserve a broader discussion which falls outside the scope of the SPC discussion.

The *HCP WG drafting group on 'Pharmacovigilance Activities'* discussed issues relating to risk communication, spontaneous reporting of adverse drug reactions as well as research and educational needs for healthcare professionals in relation to pharmacovigilance.

It was acknowledged that the spontaneous reporting system needs to be strengthened and complemented with more active methods of evaluation of safety of medicines under real-life conditions of use. Strengthening the link between healthcare professionals and the EU pharmacovigilance system offers great potential.

It was noted that the whole pharmacovigilance system performance in terms of measurable public health benefit is in need of evaluation, for which a possible methodology and involvement of healthcare professional's organisations should be further developed. New risk minimisation tools and the ongoing shift to active pharmacovigilance were explained as they give new opportunities for healthcare professional's organisations to play a role in education and training in pharmacovigilance activities.

The group also touched upon topics related to improvement of co-operation with scientific journals in pharmacovigilance tasks. Some members were of the opinion that pharmaco-economic factors should also be taken into account in pharmacovigilance assessment and decision making. However, such a proposal would need to be explored taking into account the views of the national competent authorities and the European Commission. Possibilities for surveillance of therapeutic strategies rather than individual drugs could also be explored.

The *HCP WG drafting group on 'Involvement in EMEA Scientific Committee Related Activities'* first discussed the appropriate definition of 'healthcare professionals' organisations'. It was agreed to follow the EMEA's suggestion, defining such organisations as *"not-for-profit organisations that have a main focus on patient care, and where healthcare professionals represent a majority of members in governing bodies."*

The group agreed that a set of rules for involvement in EMEA scientific committee related activities – similar to the existing rules applying to patients' and consumers' organisations – should be established, and confirmed the interest to expand the scope of the HCP WG to all EMEA scientific committees. The EMEA works on the basis of a network of European experts, many of which are healthcare professionals. They are generally made available to the Agency by the national competent authorities of the EU Member States. These experts are involved in the Agency's activities (e.g. scientific assessments, membership of the EMEA's scientific committees or working parties, etc). It was highlighted that the HCP WG could constitute an additional excellent source of advice on the required expertise for the Agency's daily work. The difference of individual healthcare professionals participating in EMEA activities as an expert or as a representative of his/her organisation was clarified.

The group further discussed issues related to the involvement of healthcare professionals in the preparation of EMEA guidelines as well as their involvement in product related issues within the EMEA scientific committees. With regard to the involvement in guideline preparation it was noted that experience has already been gained and a procedure established. However, the group encouraged the EMEA to pro-actively disseminate draft guidelines for consultation with healthcare professionals' organisations.

Additional considerations referred to the involvement of healthcare professionals in other EMEA activities such as activities in relation to innovation and participation in EMEA workshops, conferences etc.

Following these discussions, a first draft set of recommendations for the future work in each of the areas covered by the drafting groups will be presented for discussion at the HCP WG meeting scheduled for October 2007.

Other issues

The HCP WG had since the last HCP WG meeting been invited to submit comments on the draft 'Note for Guidance on establishing definitions for genomic biomarkers' to the EMEA with a view to facilitate contributions to the International Conference on Harmonisation (ICH) on this guideline. A number of very constructive comments had been received from members of the HCP WG. The EMEA thanked the participants for their contributions and provided feedback on the forthcoming assessment of the comments received during consultation and subsequent revision of the draft guideline.

A joint meeting between the HCP WG and the EMEA Scientific Committees' Working Party with Patients' and Consumers' Organisations (PCWP) is scheduled for 1 June 2007. The draft agenda for this meeting was presented to the HCP WG. The meeting will provide a platform for exchange and discussion between patients and consumers' organisations and the healthcare professionals' organisations. The main topics to be discussed will focus on the different aspects of involvement in EMEA activities, risk communication and the new EU paediatric legislation.

The draft meeting dates for HCP WG in 2008 were circulated to the group and will be published on the EMEA website once agreed.

Conclusions

The Chairpersons reflected on the positive outcome of the meeting, thanking all the participants for their active contribution and fruitful discussions.

The next meeting of the HCP WG is scheduled for October 2007, where it will be a priority to further discuss a first draft set of HCP WG recommendations and proposals for action with a view to produce a consolidated document defining the future work of the group.