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EMEA/CHMP WORKING GROUP WITH HEALTHCARE PROFESSIONALS' ORGANISATIONS

Friday, 17 November 2006

REPORT

Chairpersons: Noël Wathion – Giuseppe Nisticò

The first meeting of the EMEA/CHMP Working Group with Healthcare Professionals' Organisations (HCP WG) was held at the EMEA on 17 November 2006. The HCP WG has been established as part of the EMEA's objectives to strengthen the involvement of healthcare professionals (HCPs) in the work of the Agency.

The creation of this working group follows the workshop with HCPs organised by the EMEA on 28 March 2006. On this basis, the EMEA has established the HCP WG with the purpose to develop a framework and recommendations for long-term interaction between the Agency and HCPs.

Welcome and Introduction

The Chairpersons welcomed all participants and each of the representatives present from HCPs' organisations introduced themselves and their organisations (a list of attendees is annexed to this report).

N. Wathion, Head of Unit for EMEA Human Post-Authorisation, provided an introduction to the role of the EMEA. He briefly explained the EMEA's responsibilities for the evaluation of new medicinal products. The Agency's work is structured around a 'network model' consisting of the EMEA, national regulatory agencies and some 4,000 European experts. It was also mentioned that the EMEA is one of the decentralised agencies of the European Union, and that its role, vis-à-vis the European Commission is of an 'executive' rather than a 'policy-making' nature. In addition, N. Wathion reflected on the interaction between the EMEA and patients' and consumers' organisations, for which a formal framework has recently been established, and which will serve as inspiration for the further establishment of a similar framework for interaction between the EMEA and HCPs.

G. Nisticò, member of the Committee for Medicinal Products for Human Use (CHMP), emphasised the importance for the CHMP and the EMEA of the interaction with HCPs, and it is foreseen that the HCP WG can play a significant role in relation to a number of topics. Relations between the EMEA and HCPs' organisations should be interactive and continuous, and G. Nisticò strongly encouraged participants to engage in discussions and initiatives on the European level.

Group Composition & Public Declaration of Interests

An EMEA representative reported on the composition of the HCP WG. The working group composition consists of HCPs' organisations representing:

- Both specialised HCPs and general practitioners.
- Disease areas falling under the mandatory scope of the EMEA and/or other key treatment areas in Europe.

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

- A broad range of healthcare professionals on the European level (i.e. doctors, pharmacists, nurses etc.)

He informed the group that the HCP WG has been established to develop recommendations and proposals for action in relation to establishment of a framework for interaction between the EMEA, its scientific committees and HCPs. When this has been achieved, it is foreseen that the HCP WG will be replaced by a formal working party with HCPs organisations.

As regards potential conflicts of interest, participants had submitted a Declaration of Interests form to the EMEA prior to the meting. An EMEA representative informed that most participants had declared undertaking, or having previously undertaken, work for the pharmaceutical industry. In addition, participants were invited to expand on any particular interest they felt would be relevant to the agenda of the meeting. No further conflicts of interests were carried forward at this point in time.

Participants were reminded that only non-confidential issues will be discussed in this group.

Presentation of the EMEA/CHMP Working Group with Healthcare Professionals' Organisations

N. Wathion gave a presentation on the objectives of the working group and development of a framework of interaction. He provided participants with an overview of the context in which the strengthened interaction with stakeholders is taking place. The environment in which the EMEA is working has been subject to a number of major new initiatives during the last years, the main ones being the revised EU pharmaceutical legislation and the EMEA Road Map to 2010. The most important provisions of the legislation are the nomination of representatives from HCPs' and patients' organisations in the EMEA Management Board and the involvement of patients in the work of the Committee for Orphan Medicinal Products (COMP). An EMEA/CHMP Working Group with Patients Organisations (POWG) has been operational since May 2003 and was in December 2006 further formalised as a permanent working party under the EMEA human scientific committees as the Working Party with Patients' and Consumers' Organisations (PCWP).

The framework for interaction with the patients' and consumers' organisations has been developed in close and transparent contact between the POWG, the EMEA and its scientific committees. The framework defines the scope, objectives and working methodology for the interaction. N. Wathion proposed that based on the positive experiences from this process, a similar course of action would be initiated for the interaction with HCPs. It was stressed that such an exercise requires the active input and participation from the organisations involved in order to be successful. N. Wathion further reflected on the need for monitoring the work and impact of the HCP WG in the longer run by developing a set of relevant performance indicators.

In relation to the forthcoming work of the group, N. Wathion outlined the results of the workshop held in March 2006. As part of the conclusions, the following 3 areas of interaction had been agreed:

- Information on medicines
- Pharmacovigilance activities
- Involvement in EMEA Scientific Committees related activities

It was proposed that a subgroup would be established for each of the 3 areas. As to gain a better understanding of the issues comprised by each topic, presentations had been prepared by relevant EMEA staff members with a view to discuss in the group during the afternoon session.

To facilitate discussions in the HCP WG during this preparatory work, N. Wathion informed the participants that the current composition of the working group has deliberately been kept relatively small. However, it is foreseen that the group will be expanded to accommodate additional professions and/or disease areas.

Upon the participants' proposal, it was agreed that the EMEA would investigate the possibilities of nominating a member from a patients' organisation to the HCP WG. It was also acknowledged that the

HCP WG could potentially benefit from the work undertaken in relation to the interaction with patients' organisations. It was agreed to provide further information on the progress of this work at the next HCP WG meeting.

Mandate and rules of procedure

An EMEA representative presented the draft mandate and rules of procedures to the participants. The mandate has its legal base in Article 78 of Regulation (EC) No. 726/2004, which outlines the duty of the EMEA to develop contacts with different stakeholders.

Some participants inquired to what extent the working group will be able to influence the broader EU agenda, e.g. on the level of the European Commission. G. Nisticò encouraged the group to find its motivation on the European level and to take interest in the European harmonisation processes. At the same time, it was clarified that the working group is not a political group and will need to work and act within the boundaries of the EMEA's mandate and responsibilities. Although nothing hinders the group in addressing the Commission through e.g. proposals for action, it will still be up to the individual HCPs' organisations to maintain their contacts on the political level.

On request from the participants, the future composition of the group was outlined in more detail. The size of working group should eventually not exceed 20-30 members. Participation of organisations representing other key treatment areas, e.g. hepatology, gastro-enterology and geriatric medicine, will also be considered.

The draft mandate and rules of procedures were endorsed and subsequently adopted by the CHMP in December 2006. The final document can be found here.

Criteria to be fulfilled by HCP Organisations involved in EMEA Activities

As was also done in the context of interaction with patients' organisations, the EMEA finds it important that a set of clear and transparent criteria for involvement in the EMEA's activities be developed and agreed upon by the working group. To initiate a discussion on this topic, an EMEA representative presented the criteria developed by the POWG with regard to interaction with patients' and consumers' organisations.

There are a total of seven criteria applicable to patients' and consumers' organisations involved in the Agency's tasks. They are published on the EMEA website and include requirements for the organisations to be established at EU level, communication/dialogue with members and transparency on objectives, activities and funding.

Although some adjustments may be needed, the majority of HCP representatives indicated that their organisations would support that the same criteria be applied to them. All representatives were invited to consult their organisation on the appropriateness of the criteria, which will be further discussed at the next meeting of the working group. In addition, it was agreed that participants come forward with proposals for a suitable definition of a HCP organisation before the next HCP WG meeting.

Working procedures of the HCP WG

An EMEA representative presented the suggested working procedures for the group. A meeting frequency of 3-4 meetings per year is anticipated by the EMEA. 3 meetings have been scheduled for 2007, with the possibility of increasing to 4 meetings in 2008. One meeting per year will be held jointly with the PCWP.

It was agreed to establish subgroups for each of the identified areas for action, i.e. information on medicines, pharmacovigilance activities and involvement in EMEA Scientific Committees related activities. Consequently, the HCP WG identified and appointed members of these subgroups. 'Topic leaders' were appointed from among the HCP representatives present.

It is foreseen that these subgroups will meet during the morning session of the scheduled HCP WG meetings. However, due to the annual joint meeting with the PCWP only 2-3 subgroup meetings can be conducted per year. This will require the active contribution of topic leaders and subgroup members in between meetings as to achieve the progress that would be expected.

Presentations on areas identified for further interaction

During the afternoon session time had been allocated for a more in-depth discussion on each of the identified areas for action. To provide further information, and to facilitate the discussion, EMEA staff members gave a number of presentations to the group. The HCP WG members were encouraged to convey their views in relation to each of the topics raised.

Information on medicines
An EMEA representative presented a brief overview of the available EMEA information documents, such as the European public assessment reports (EPARs), the summaries of these, the packet leaflet (PL), the summary of product characteristics (SPC) and other sources available on the EMEA website.

The HCP WG was asked to reflect on how to better inform HCPs and how to improve the quality of the information provided. It was agreed that more information and discussion would be requested in relation to the SPC and PL. In addition, further discussion is anticipated with regard to the HCPs' expectations to the SPC, e.g. in relation to contents, structure, off-label use etc.

Pharmacovigilance activities
An EMEA representative gave an overview of the ongoing pharmacovigilance activities at the EMEA with particular focus on risk communication and risk management plans.

The HCP WG discussed a number of issues related to pharmacovigilance, which will be further investigated in the relevant subgroup. One of the main points raised at the meeting concerns reporting of adverse drug reactions, in particular the practical aspects of reporting for different groups of HCPs, the available IT tools and appropriate training. There was also a proposal to discuss the need for complementing existing pharmacovigilance activities with epidemiological studies, using e.g. cohort design.

Involvement in EMEA Scientific Committees related activities
An EMEA representative gave an overview of the structure, composition and core tasks of the EMEA human scientific committees and the associated working parties. The presentation aimed at putting the foreseen interaction of the HCP WG into perspective with the general structure of the EMEA.

The HCP representatives generally welcomed the EMEA's efforts to further improve and structure the relationship with the Agency's stakeholders. The involvement of HCPs in Committees related activities will be further discussed at future HCP WG meetings. However, there was consensus among the HCP representatives that a more active participation in scientific debates, e.g. conferences, symposiums etc, by the EMEA would be welcome.

In addition to these areas of discussion, the participants were invited to express other fields of interest. Clinical research was highlighted as an important topic for HCPs, especially with regard to the difficulties in implementing the clinical trials Directive. Advanced therapies (e.g. stem cell therapy) were also mentioned as a topic of interest. These points will be taken up for further discussions at forthcoming HCP WG meetings.

Conclusions

The Chairpersons reflected on the outcome of the meeting, thanking all the participants for their active participation and fruitful discussions. They acknowledged that many aspects of the EMEA and its activities are very complex. The EMEA will provide the HCP WG with additional information on the Agency and appoint an EMEA coordinator to each of the subgroups.

The next step in relation to further consolidate the tasks of the HCP WG will be to develop a report on 'Recommendations and Proposals for Action', which will help define the future focus points of the group. The 3 identified subgroups will play a key role in compiling the contents of the document as it is crucial to take into account the HCPs expectations to the future interaction with the EMEA.