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Post-authorisation Evaluation of Medicines for Human Use

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MINUTES OF THE EIGHTH MEETING OF THE EMEA HUMAN SCIENTIFIC COMMITTEES' WORKING PARTY WITH PATIENTS' AND CONSUMERS' ORGANISATIONS (PCWP) EMEA, 05 MARCH 2009

CO-CHAIRPERSONS: ISABELLE MOULON (EMEA) - NIKOS DEDES (EATG)

MEETING PARTICIPANTS

Representatives of: European AIDS Treatment Group (EATG), European Cancer Patient Coalition (ECPC), European Federation of Neurological Associations (EFNA), European Patients Forum (EPF), European Organisation for Rare Diseases (EURORDIS), European Public Health Alliance (EPHA), Health International Alliance of Patients' Organizations (IAPO), International Diabetes Federation (IDF), The European Consumers Organisation (BEUC).

Committee on Herbal Medicinal Products (HMPC), Committee for Medicinal Products for Human Use (CHMP), CHMP Pharmacovigilance Working Party (PhVWP), Committee for Orphan Medicinal Products (COMP), Co-ordination Group for Mutual Recognition and Decentralised Procedures–Human (CMD(h)), European Medicines Agency (EMEA) secretariat, Healthcare Professionals' Working Group (HCP WG), and Paediatric Committee (PDCO).

I. MORNING PLENARY SESSION – GENERAL ISSUES

I.1 Welcome and introduction

The co-chair welcomed the participants to the meeting.

I.2 Adoption of the agenda

The agenda of the meeting was adopted.

II. AREA OF INVOLVEMENT OF PATIENTS AND CONSUMERS IN EMEA ACTIVITIES

II.1 Results of the satisfaction questionnaire – 2008 report on patient involvement at the EMEA

Firstly the EMEA presented the analysis of the degree of satisfaction of patients and consumers involved in EMEA activities during 2008; the questions were related to the overall interaction between the EMEA and patients and consumers, how it has moved forward during 2008, as well as the impact of the interaction for the patients' and consumers' organisations.

A specific section of the questionnaire explored for the first time, after two years of operation, the degree of satisfaction from patients and consumers who have been involved in the review of EMEA documents.

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There were 11 questions in total; each response allowed for 5 grades of satisfaction and also included a section for open comments or suggestions. The analysis was based on 41 questionnaires received.

Overall there was a good level of satisfaction throughout, similar to 2007. However there were several areas for improvement which were identified, such as the need to improve the level of feedback on the review of documents, the need for more training and the need to involve more patients and consumers' organisations.

Secondly the EMEA presented some statistics related to the involvement of patients and consumers in EMEA activities during 2008; including which organisations were involved. Three methods of participation have been identified: experts, representatives of organisations and members (of committees/working parties/groups). An overview of the main activities carried out and the total number of individuals involved in each category as well as a comparative analysis with the figures from 2007 was presented. The results demonstrated an overall increase in the level of participation.

Some comments from the group included the fact that more intensive interaction would be possible if resources were available and that there are some major therapeutic areas not yet covered. In this respect, the EMEA confirmed that the aim is to increase the number of eligible organisations and to enlarge the PCWP to include areas not currently covered. In addition, some members indicated that perhaps it is up to PCOs to come forward in a proactive manner with new proposals for further involvement in EMEA activities.

It was concluded that 2008 has seen an overall increase in the number of patients and consumers involved in the EMEA activities compared to 2007.

The full report will be circulated to the PCWP by the end of March 2009 for comments and then presented to the EMEA Management Board in June 2009.

All the work achieved has set up the grounds towards a more systematic interaction and involvement of patients in the Agency work. A Reflection Paper with proposed actions in this respect is currently under development and will also be presented to the Management Board later this year. It will also be circulated beforehand to the members of the PCWP for their comments.

II.2 Results from questionnaire on further involvement of patients and consumers in EMEA activities

Linked to the preparation of the above mentioned "Reflection Paper", the EMEA carried out a survey aimed to ascertain which areas/activities patients and consumers were more interested to participate as well as determining possible participation restrictions due to resource limitations. All eligible organisations were asked their views and the results were presented to the group.

It was evident that resource limitations do restrict most organisations from participating to the extent they would like to.

These results form the basis to explore the way forward for further involvement of PCOs and allow for the preparation of a priority list of activities on which EMEA should focus first, in order to progress in the interaction.

II.3 Patient involvement in EMEA communications

EURORDIS gave a presentation to the group reflecting on critical situations (e.g. safety communications) where EMEA needs to ensure that patients and consumers are systematically and timely informed by the EMEA. In addition, the need to involve them in the preparation of such communications was agreed. This issue will be addressed in the Reflection Paper (mentioned above). It is important that procedures are put in place to ensure that patients, consumers and healthcare professionals' organisations are involved whenever appropriate, even when there are considerable time constraints. The importance of having this kind of information from the regulatory authorities was also mentioned.

This topic will be included in the joint PCWP/HCPWP meeting in June where a proposal will be discussed and in the meantime members are requested to send any suggestions in advance (a wish-list).

II.4 Overview of patient/consumer experts

The current list of EMEA patient/consumer experts detailing their fields of expertise is to be updated. It will be circulated and members are requested to ensure that the information contained therein is correct, to confirm the areas in which they are pleased to collaborate and to nominate any additional expert to join the list as currently the number of experts available is limited.

II.5 Consideration on a template for facilitating PCWP consultation by other groups (i.e. CMD(h), PhVWP)

A template to facilitate the consultation of the PCWP by third parties, specifically on the wording of package leaflets, has been developed. An updated version of the template was proposed, taking into account previous comments. The PCWP adopted the template which will be sent to the CMD(h) and the PhWP for final comments and agreement before being put into use.

It was requested that in order to ensure feedback, the patients/consumers consulted should copy the PCWP systematically– this will be added to the template.

III. AREA OF PRODUCT INFORMATION

III.1 Pharmacovigilance and direct patients' reporting – experience from a consumers' organisation

A representative from Altroconsumo (BEUC) presented to the group the results of a project on direct patient reporting in relation to the use of Protopic and Elidel, which they conducted in collaboration with the Italian authorities. The group felt that this was a very good study with interesting results and reflected on the important role patients and consumers can play in the pharmacovigilance system.

A second presentation was given by a representative from AIFA (Italian Medicines Agency) and which stressed that the Altroconsumo was a good example of cooperation between a Regulatory Authority and consumers' associations and also concluded that patient reporting is an important field to explore.

EURORDIS / HAI have also looked at pilot projects on direct patient reporting and HAI is currently preparing a report on this topic.

PhVWP will keep the PCWP updated on any progress on this area, especially in view of the new legislative proposal in Pharmacovigilance. In this regard, it was suggested that EMEA could explore the possibility to have a specific meeting on direct patient reporting within the framework of the new legislative proposal.

IV. AREA OF PHARMACOVIGILANCE

IV.1 Public PhVWP meeting report

An EMEA representative from the PhVWP secretariat presented a proposal for public reports of the PhVWP meetings which would be similar to the CHMP Monthly Report and would increase transparency.

Feedback from the group was requested however it was agreed to wait until the PCWP observers have already been present at the PhVWP meetings.

A future update will be given.

IV.2 Patient involvement in PhVWP

The proposal for the PCWP to be observers at the PhVWP will be presented for endorsement by the EMEA Management Board in March 09. The pilot phase of 3-months will start in April 09; the observers nominated will be able to participate and present their views but will not take part in any conclusions/decisions made. Once the pilot phase has been completed the two representatives will prepare a report which will analyse the experience and serve to evaluate the pros and cons of this participation and will also define the roles and expected contribution. This report will be forwarded to the Management Board and the Head of Medicines Agencies in October/November 2009 respectively, and will pertain to a strategy for further participation of patients and consumers in the EMEA.

Following a call for expression of interest sent to all eligible organisations (with priority being given to organisations who are members of the PCWP) the EMEA received 5 valid candidates. The EMEA has decided that a representative from IAPO and a representative from EATG will participate in the pilot phase of this exercise.

V. AREA OF TRANSPARENCY AND DISSEMINATION

V.1 EMEA Transparency Policy

In January 2009 a Workshop on Transparency was held at the EMEA. Representatives of patients' organisations attended and the co-chair of the PCWP reported back to the group from his participation on this Workshop.

Secondly, an EMEA representative from Regulatory Affairs gave a presentation outlining an overview of the draft EMEA transparency policy and its key principles.

It was explained that the rationale for this policy stems from an increased demand from society for more openness, the need for a more robust and consistent approach towards transparency in EMEA activities. The EMEA objectives for this policy are to apply a more proactive approach towards transparency in its daily operation, to increase the understanding of its activities, to strengthen interaction with EMEA Stakeholders and NCAs and finally to promote good administrative and regulatory practices.

The Workshop on transparency allowed for a first discussion with Stakeholders on experience on current transparency measures and expectations on the development of the EMEA transparency. The feedback received will contribute to the ongoing development of the EMEA Transparency Policy which is expected to be sent out for external consultation mid of June 2009 until end of September 2009.

The third presentation was given by an EMEA representative and covered aspects of commercially confidential information (CCI). Basically the exception to refuse access to documents refers to "Commercial interests of a natural or legal person, including intellectual property". Some examples of what can be considered commercially confidential information were presented. It was concluded that the aim of this public consultation is to trigger discussion on whether it is possible to agree on a shared notion of CCI between the EMEA and its stakeholders for which a positive outcome would increase the accountability of the medicines network and improve the efficiency of the system by minimising the need of third party consultation.

In relation to this, the group referred to the new proposal of pharmaceutical legislation which is in the pipeline and which will incur much debate over the next couple of years with regard to information to patients.

The group expressed their appreciation that the EMEA is looking at aspects of CCI and that it is important that the Agency improves in this regard.

The PCWP will be informed on further developments in this area.

V.2 EMEA website restructuring update

An EMEA representative gave an overview of the current public facing online project. The project initially started back in September 2008 and is essentially aimed at restructuring and re-launching the EMEA website. The focus is on helping improve the usability, especially for patients, consumers and healthcare professionals, while maintaining vital information for Regulators and Industry. Following consultation with external stakeholders a prototype has now been developed and is ready for testing.

In order to test the prototype the EMEA is looking for three volunteers from the PCWP to take part in one-to-one, hour long user testing in London carried out by an external web communications company.

V.3 Proposed revision of the EMEA experts' nomination form

As per previous requests received from some experts, an update to the EMEA expert's nomination was proposed to the PCWP in previous meetings. Following receipt of comments, a revised version will be circulated shortly.

V.4 Monthly email: update of current version

The monthly newsletter called "Human Medicines Highlights" is addressed to patients, consumers and healthcare professionals' organisations' and is intended to provide a monthly update on key information on human medicines produced and published by the EMEA. It is now available on the EMEA website and is available for subscription, either as an email or as a link to the webpage. (http://www.emea.europa.eu/whatsnew/newsletters/highlights/index.htm).

V.5 Creation of a short summary with the main fields of expertise and activities of each organisation

A proposed template will be circulated for comments by 13 March 2009.

VI. A.O.B

VI.1 Translation of the leaflet for patients and consumers

The versions of the EMEA leaflet on patients and consumers in English, French, German, Spanish and Italian are available on the EMEA website. All other official EU languages are available upon request. (http://www.emea.europa.eu/Patients/introduction.htm).

VI.2 Nomination of PCWP representatives to other groups

A participant asked for further transparency when informing the group about procedures for the selection of PCWP representatives to other groups (i.e. to inform of all individual responses to calls for interest and of the rationale for the decision). The request was noted.

Close of the meeting