European Medicines Agency
Post-authorisation Evaluation of Medicines for Human Use

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MINUTES OF THE THIRD JOINT MEETING OF THE EMEA SCIENTIFIC COMMITTEES' WORKING PARTY WITH PATIENTS' AND CONSUMERS' ORGANISATIONS (PCWP) AND THE EMEA/CHMP WORKING GROUP WITH HEALTHCARE PROFESSIONALS' ORGANISATIONS (HCP WG)

EMEA, 09 JUNE 2009

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

MEETING PARTICIPANTS

Representatives of Patients' and Consumers' Organisations: European Consumers Organisation (BEUC), European AIDS Treatment Group (EATG), European Cancer Patient Coalition (ECPC), European Public Health Alliance (EPHA), European Organisation for Rare Diseases (EURORDIS), International Alliance of Patients' Organisations (IAPO), International Diabetes Federation (IDF) and International Patient Organisation for Primary Immunodeficiencies (IPOPI).

Representatives of Healthcare Professionals' Organisations: European Association for Clinical Pharmacology and Therapeutics (EACPT), European Association of Hospital Pharmacists (EAHP), European Federation of Nurses Associations (EFN), European Society for Medical Oncology (ESMO), European Society of Cardiology (ESC), European Union Geriatric Medicine Society (EUGMS), European Association for the Study of Diabetes (EASD), Pharmaceutical Group of The European Union (PGEU), Standing Committee of European Doctors (CPME) and United European Gastroenterology Federation (UEGF).

Representatives from EMEA Scientific Committees and National Regulatory Agencies: Representatives and observers from the Committee for Medicinal Products for Human Use (CHMP), Committee for Orphan Medicinal Products (COMP), Co-ordination Group for Mutual Recognition and Decentralised Procedures–Human (CMD(h)), Committee for Herbal Medicinal Products (HMPC), and Committee for Advanced Therapies (CAT).

Observers: from the national regulatory authorities in Croatia and Turkey.

I. INTRODUCTION

The third annual joint meeting between the PCWP and the HCP WG was held at the EMEA on 9 June 2009.

Thomas Lönngren, the EMEA's Executive Director, and Noël Wathion, Head of Human Post-authorisation Unit, welcomed the participants and wished them a fruitful meeting. The Executive Director presented some of the main priorities of the EMEA that will be included in the Agency's roadmap to 2015 currently under preparation. He highlighted the importance of improving the safety monitoring of medicines in the European Union, and the need to foster transparency, communication and provision of information on medicines. Isabelle Moulon, Head of Medical Information Sector and co-chair of the meeting, informed participants that the European Commission will present the new Pharmaceutical package at a dedicated meeting in September 2009.

II. UPDATE ON THE EMEA TRANSPARENCY POLICY PROJECT

The EMEA presented the Agency's Transparency Policy which main objectives are: to apply a more proactive approach towards transparency in the daily operations of the EMEA, to further strengthen interactions with EMEA stakeholders, and to enhance and promote a closer interaction with National Competent Authorities (NCAs).

The results of the first workshop on Transparency, held on 22 January 2009, were presented. Information was provided about the working methodology of the Agency, and on the next steps towards improved transparency in the way the Agency operates. A draft proposal on the EMEA Transparency Policy will be published for consultation following its endorsement by the EMEA Management Board on 11 June 2009. In order to finalise this policy, a second workshop will take place on 19 October 2009, and PCWP/HCP WG members will be invited to participate.

It was asked if transparency measures will apply to specific activities such as scientific advice and benefit-risk assessment. The EMEA secretariat explained that there is an ongoing process (e.g. revision of the EPAR template) aimed at enhancing the level of openness by providing information that is better adapted and targeted to the expectations and needs of the public.

It was agreed to further discuss the adequacy to provide the information presented on the EMEA website in all EU official languages.

III. BASIS FOR THE REIMBURSEMENT OF EXPENSES FOR DELEGATES AND EXPERTS ATTENDING MEETINGS AT THE EMEA

The EMEA provided information concerning the new rules and procedures for the reimbursement of expenses for delegates and experts attending meetings at the EMEA, especially with regard to delegates with specific requirements. It was pointed out that patients' suggestions had been taken into account in the preparation of these rules.

IV. PROVISION OF INFORMATION

IV.1 Preparing information for the public on medicines at the EMEA

EMEA communication tools

The EMEA presented its tools for communicating information on medicines to the general public and the media. These tools are mainly EPARs, Press Releases, and Questions and Answers documents. A detailed explanation was given on how these documents are prepared, and it was explained how they differ according to their target audiences and purposes. These documents are published on the EMEA website when there is a need to inform about positive/negative opinions on marketing authorisations, safety issues, withdrawals of applications, etc.

Participants agreed that these tools are very useful for the provision of information on medicines.

Dear Healthcare Professional Communications (DHPCs)

The EMEA gave an overview of DHPCs (also known as "Dear Doctor letters"); marketing authorisation holders (MAHs) use these letters to provide individual healthcare professionals with up-to-date information on medicines, in compliance with the European legislation. Situations in which DHPCs have to be elaborated and disseminated, such as the suspension of a marketing authorisation or a change to the benefit-risk balance, were described, putting special emphasis on the several phases of the development of these documents, and the various ways of dissemination in some European countries.

It was agreed that a proposal for the publication of DHPCs on the EMEA website would be presented and discussed at a future meeting.

IV.2 Involvement of patients and consumers in preparation and dissemination of EMEA communications

EURORDIS gave a presentation on the involvement of patients and consumers in the preparation and dissemination of EMEA communications in critical situations, such as an unexpected adverse reaction, contamination or batch recalls following quality defects, supply shortage, etc. It was suggested that eligible organisations could appoint a contact person that could be consulted on the preparation of EMEA documents in these situations. He/she could also be invited to participate in explanatory meetings. It was mentioned by the EMEA that this issue would be covered in the reflection paper on the progress of the interaction between the EMEA and PCOs, currently under preparation, which would be presented to the Management Board by the end of 2009. The participants in the meeting were invited to send their comments on this paper, which would be further discussed at the next PCWP meeting in September 2009.

V. CLINICAL TRIALS

V.1 Report from the ad hoc Working Group on clinical trials in third countries

The EMEA secretariat gave a report on the work of the newly created ad hoc Working Group on Clinical Trials in Third Countries, which aims to clarify the practical application of ethical standards for clinical trials, in countries outside of the EU, in the context of EMEA activities, and to identify the practical steps to be undertaken during the provision of guidance and advice in the drug development and marketing authorisation phases. The working group will also discuss the issue of international cooperation in the regulation of clinical trials. The PCWP and HCP WG are represented in this working group and actively contribute to its activities.

The EMEA advised that reflection papers on these topics would be released for public consultation by the end of 2009, and a workshop would be organised in 2010.

V.2 EudraCT public information

The EMEA presented the legal requirements that apply to the release of public information on clinical trials, both protocol- and results-related. Rules for publication of adult and paediatric trials' data would be combined in order that a single set of information would be made available. This will include trials for products without a marketing authorisation and those conducted in third countries which are part of a Paediatric Investigation Plan.

As part of the development of the EudraCT public interface, the EMEA will draft a glossary to facilitate the understanding of the data presented on the website. Patients', consumers' and healthcare professionals' organisations were invited to contribute to this initiative with any material related to clinical trials terminology.

V.3 EudraCT website design

The EMEA announced the dissemination of a web-based survey on EudraCT. The aim of this survey is to better understand what type of information people look for and how this information has to be presented. Some participants kindly contributed to this initiative by completing the survey during the meeting.

VI. UPDATE ON WEBSITE RECONSTRUCTION

The EMEA secretariat provided an update on its website reconstruction, which would include substantial innovations and improvements, such as information tailored for specific audiences, a multilingual interface, etc. The prototype of the new website, which would be launched in December

2009, was shown. Improved access to information, in particular for centrally authorised medicines, was demonstrated with practical examples.

Participants acknowledged the Agency's efforts and the fact that their proposals had been taken into consideration during the reconstruction process. They asked questions on the specific types of search functions and the possibility to obtain information in different formats. The EMEA answered that although some technical obstacles persist the access to all public information would be further improved in the coming years.

VII. UPDATE ON THE PHARMACOVIGILANCE WORKING PARTY IMPLEMENTATION OF THE PILOT PHASE

A PCWP member presented an overview of the draft report from the pilot phase of patients' and consumers´ participation in the PhVWP. He considered that overall it was a positive experience and the patient's contribution was appreciated and encouraged by the PhVWP. The two members of the PCWP that participate in this pilot phase as observers, recommended one permanent observer and one alternate, as well as disease specific experts, when necessary.

These initial recommendations were discussed and will be presented to the PhVWP. Once the PCWP and the PhVWP have agreed, the recommendations and the report on the outcome of the pilot phase will be presented to the EMEA Management Board and the Heads of Medicines Agencies (HMA) in October and November 2009, respectively.

During the discussion, it was mentioned that the interaction between the PhVWP and healthcare professionals should be further discussed at a future HCP WG meeting, taking into account the recommendations developed by the HCP WG with regard to interaction with EMEA's scientific committees and related working parties.

VIII. RECOMMENDATIONS AND USERS' VIEWS ON PACKAGE LEAFLET

BEUC presented the results from a survey carried out in 8 European countries on the use of the package leaflet (PL) by patients. This survey demonstrated that many aspects of the PL should be improved, especially in terms of readability, design and layout, and complexity of content. Some of the suggestions made in light of these results included the need for a more straightforward language, in a larger print, and with more pictures and pictograms.

Participants agreed on the conclusions of this study, and discussed on how to present the PL information in a more patient-friendly way.

The EMEA informed that a new PL template in a more friendly language would be published for consultation in the near future, and that further recommendations on user consultation will be prepared on the basis of the experience gathered.

IX. EMEA INITIATIVES TO STRENGTHEN THE ASSESSMENT AND COMMUNICATION OF BENEFITS AND RISKS OF MEDICINES

Due to the lack of time, the presentation of the EMEA initiatives to strengthen the assessment and communication of benefits and risks of medicines was postponed to the next meeting.

X. A.O.B

X.1 Proposals for public meeting reports for the PhVWP

The EMEA secretariat presented a proposal for publishing the PhVWP monthly report. These reports will follow the concept of the CHMP monthly report. These proposals fall within the framework of the Agency's Transparency Policy.

After the publication of the first meeting reports, a discussion on the outcome will be held by the PCWP and the HCP WG.

CONCLUSIONS

The chairpersons thanked the participants for their contribution and participation to the meeting, and stressed the importance on holding an annual meeting with both groups.

Close of the meeting