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

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MINUTES OF THE FIRST MEETING OF THE EMEA SCIENTIFIC COMMITTEES' WORKING PARTY WITH PATIENTS' AND CONSUMERS' ORGANISATIONS (PCWP)
WITH ALL ELIGIBLE PATIENTS' AND CONSUMERS' ORGANISATIONS
EMEA, 6 JUNE 2008

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

MEETING PARTICIPANTS

Representatives of: Alzheimer Europe (AE), European AIDS Treatment Group (EATG), European Cancer Patient Coalition (ECPC), European Federation of Neurological Associations (EFNA), European Genetic Alliances' Network (EGAN), European Multiple Sclerosis Platform (EMSP), European Myeloma Platform (EMP), European Organisation for Rare Diseases (EURORDIS), European Parkinson's Disease Association (EPDA), European Public Health Alliance (EPHA), Health Action International (HAI), International Alliance of Patients' Organizations (IAPO), International Diabetes Federation (IDF), International Patient Organisation for Primary Immunodeficiencies (IPOPI), Myeloma Euronet (ME), Rett Syndrome Europe (RSE), Thalassaemia International Federation (TIF), The European Consumers Organisation (BEUC).

Committee on Herbal Medicinal Products (HMPC), Committee for Medicinal Products for Human Use (CHMP), European Medicines Agency (EMEA) Management Board & Secretariat.

I. MORNING PLENARY SESSION – GENERAL ISSUES

I.1 Welcome and introduction

The Executive Director of the Agency, together with the co-chairs, welcomed the participants to the meeting, congratulating them on progress made by patients' and consumers organisations at the EMEA. The Executive Director described the preparation of a new EMEA roadmap, which will have to address new challenges that lie ahead, including advanced therapies and demographic changes within the enlarged EU. He also mentioned some future activities where input from patients' and consumers' organisations will be considered, such as the redesign of the EMEA's website.

I.2 Tour de table

Since this meeting involved representatives from all organisations eligible to participate in the EMEA's activities, including newcomers who are not members of the PCWP, all participants were invited to introduce themselves. It was suggested that, given the increasing number of organisations working with the EMEA, the creation of a short summary with the main fields of expertise and activities of each organisation would help to improve the level of understanding about the work of the different members of the PCWP.

I.3 Adoption of the agenda

The agenda was adopted with minor changes.

I.4 Introduction to the EMEA

The EMEA secretariat gave a presentation on the general functioning of the EMEA and its activities. The meeting participants recognised the need to increase awareness of the EMEA amongst the members of their organisations and welcomed the initiative of being provided with some information leaflets that the EMEA has prepared. The EMEA will explore the possibility of having these leaflets translated for distribution among members of the PCWP.

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

II.1 The involvement of patients' and consumers' organisations at the EMEA: past experience and perspectives

The EMEA secretariat gave an overview of the current involvement of patients' and consumers' organisations within the Agency, explaining how the interaction with the EMEA has grown over the years. In addition, the speaker described how the EMEA, together with the PCWP, is currently working to widen the participation of patients and consumers within the Agency. Details about the current participation and membership of patients and consumers in the EMEA's Management Board and scientific committees were given (including the Committee for Orphan Medicinal Products, the Paediatric Committee in the near future, and in the forthcoming Committee for Advanced Therapies).

In order for representatives from eligible patients' and consumers' organisations to get clearer understanding of the activities of EMEA scientific committees, members made a proposal to participate in these committees meetings as observers for some periods. This could also apply to committees where patients and consumers are already represented. This proposal needs to be further discussed in the context of the forthcoming paper on further involvement of patients' and consumers' organisation in EMEA activities

II.2 The activities of the PCWP

Mr Nikos Dedes, co-chair of the PCWP, introduced the Working Party and outlined the progress made since its creation. He illustrated the steps that led to its creation in 2006, and described its current composition and scope, as well as the main areas in which the group is currently working.

II.3 Patients'/consumers' organisations and the EMEA code of conduct: confidentiality issues

The EMEA secretariat explained the two different ways in which patients and consumers can become involved in EMEA activities: either as representatives of their organisation; or as experts. These are described in the published EMEA document "Rules of involvement of members of patients' and/or consumers' organisations in committee-related activities" (http://www.emea.europa.eu/pdfs/human/pcwp/16166005en.pdf). During the presentation, particular emphasis was placed on the issue of confidentiality. EMEA staff reminded the participants that, according to its mandate, the PCWP cannot discuss topics of a confidential nature.

Patients and consumers were reminded about how to fill in the "Public Declaration of Interests and Confidentiality Undertaking of EMEA Scientific Committees Members and Experts" form and also the "Nomination form for European Experts". Some patients expressed their concerns over the appropriateness of the nomination form currently in use, since it does not include any specific fields that are addressed to patients acting as EMEA experts (http://www.emea.europa.eu/pdfs/general/direct/conflicts/Annex1-NominationForm.pdf). It was decided that modification of the existing form should be considered, in order to adapt it better to the needs of patients and consumers involved in EMEA activities.

III. AREA OF PRODUCT INFORMATION

III.1 Participation of patients' and consumers' organisations (PCOs) in the review of product information: report following one year of activity

The EMEA secretariat presented the preliminary results following one year of the involvement of experts from PCOs in the review of Package Leaflets at the time of renewal of the marketing authorisations and of European Public Assessment Report (EPAR) summaries for newly authorised medicines. The experience has shown very high compliance from patients' and consumers' organisations, and the comments received have contributed to an increase in the quality of these documents. The EMEA reminded PCOs to involve all of the currently nominated experts as far as possible so that the workload is shared equally. EMEA also indicated the therapeutic areas where patient expertise is currently lacking in order to call for the nomination of additional experts.

III.2 Package Leaflets and the linguistic review process for new applications for marketing authorisation

The EMEA secretariat described how the Product Information, especially the Package Leaflet, is created and how the Quality Review of Documents (QRD) group performs its linguistic review before a medicine receives a marketing authorisation.

III.3 Review of Package Leaflets: extension of the current procedure

Building on the positive experience previously presented, a proposal for involving patients and consumers as experts in the review of Package Leaflets during the evaluation of initial marketing authorisation applications was presented by the EMEA. Following endorsement by the PCWP, the proposal will be presented to the CHMP before implementation starts in September 2008. A public announcement will be also made on the EMEA's website.

IV. AFTERNOON PLENARY SESSION – PHARMACOVIGILANCE

IV.1 Reporting of adverse drug reactions by patients: the experience of a consumers' organisation

A presentation was given by a consumers' organisation on a project developed by them in collaboration with the Belgian Medicines Agency, in which consumers are able to report possible adverse drug reactions that they experience, via a website. The pros and cons of the exercise were debated. The valuable contribution of PCOs in promoting reporting by patients was highlighted, but the importance of doing so in close partnership with regulatory authorities was underlined.

IV.2 Proposal for involvement and participation of patients' and consumers' representatives in the meetings of the CHMP's Pharmacovigilance Working Party (PhVWP)

The PhVWP and the PCWP agreed on a "briefing note" laying down the principles for interaction and participation of patients' and consumers' representatives in the PhVWP. It was agreed that to elaborate a formal proposal there is the need of a pilot phase where patients and consumers participate as observers in 2 to 3 consecutive meetings of the PhVWP. This proposal will form part of a more general strategy to involve patients and consumers more at the EMEA. The briefing note will be presented to the CHMP, for endorsement before implementation in the 1st quarter of 2009.

V. AOB

V.1 Report from 2nd EMEA meeting with Research Centres and Interested Parties on ENCePP

A representative of the PCWP participated in the 2nd meeting of EU research centres and interested parties on the European Network of Centres for Pharmacoepidemiology and Pharmacovigilance (ENCePP) and reported back on the outcome of the meeting (the official report of the meeting will be published on the EMEA website in due course and members of the PCWP will be informed). The members of the EMEA secretariat who are responsible for the project led the discussion and introduced the Innovative Medicines Initiative (IMI). The IMI is a unique public-private partnership (PPP) between the pharmaceutical industry, represented by the European Federation of Pharmaceutical Industries and Associations (EFPIA), and the European Commission.

The EMEA representatives described how, in response to a specific call of the IMI aimed at strengthening the monitoring of benefit/risk of medicines marketed in the EU, the agency is working to establish a public consortium that could include PCOs.

Members of the PCWP were invited to express their interest to work together with the EMEA in the public IMI consortium.

Close of the meeting