European Medicines Agency

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MINUTES OF THE SECOND JOINT MEETING OF THE EMEA SCIENTIFIC COMMITTEES' WORKING PARTY WITH PATIENTS' AND CONSUMERS' ORGANISATIONS AND THE EMEA/CHMP WORKING GROUP WITH HEALTHCARE PROFESSIONALS' ORGANISATIONS

EMEA, 05 JUNE 2008
CO-CHAIRPERSONS: NOËL WATHION (EMEA) - NIKOS DEDES (EATG)

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

Representatives of Healthcare Professionals' Organisations: European Academy of Paediatrics (CESP-EAP), European Association for Clinical Pharmacology and Therapeutics (EACPT), European Association for the Study of Diabetes (EASD),European Federation of Nurses Associations (EFN), European Society of Cardiology (ESC), European Society for Medical Oncology (ESMO), Pharmaceutical Group of The European Union (PGEU).

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).

Chairman of the EudraPharm Telematics Implementation Group (TIG).

Observers from the national regulatory authorities in Croatia and the Former Yugoslav Republic of Macedonia, as well as from the Swiss Agency for Therapeutic Products.

I. INTRODUCTION

The second annual joint meeting between the PCWP and HCP WG was held at the EMEA on 5 June 2008.

Thomas Lönngren, the EMEA's Executive Director, welcomed the participants and reflected on some of the main challenges facing patients and healthcare professionals as well as regulators and pharmaceutical industry in the coming years. These include strains on resources for treatment due to demographic changes, a need for further stimulating research and development of new medicines as well as improving information to patients and ensuring transparency in the regulatory process.

Eric Abadie, Chair of the EMEA's Scientific Committee for Medicinal Products for Human Use, also welcomed the participants and highlighted the importance of continuous interaction between the EMEA's scientific committees and EMEA stakeholders.

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

II. UPDATE ON EU LEGISLATION

Financial penalties
Participants were given a presentation on the Commission Regulation on financial penalties[1].
The regulation enforces financial penalties at the level of the European Union for pharmaceutical manufacturers that do not comply with certain obligations related to a marketing authorisation. Currently, there has been no practical experience, and the participants will be further updated once such experience has been gained.

Advanced therapies
The new Commission Regulation on advanced therapy medicinal products[2] was also presented. This legislation has been created to make novel treatments safely available to patients as early as possible. It has provisions for gene therapy products, somatic cell therapy products and tissue engineered products. It will ensure the free movement of advanced therapy products within Europe, facilitate access to the EU market and foster the competitiveness of European companies in the field, while guaranteeing the highest level of health protection for patients The regulation entails the creation of an EMEA Scientific Committee on Advanced Therapies (CAT) by the end of 2008. This committee will see representatives from patients' organisations and clinicians' organisations appointed as full members.

III. BENEFIT – RISK COMMUNICATION

As part of the ongoing discussion on how to best communicate issues related to benefits and risks of medicines the EMEA has, together with a topic leader from PCWP and HCP WG respectively, coordinated a qualitative survey among patients', consumers' and healthcare professionals' organisations, as well as among representatives from regulatory authorities. A questionnaire was distributed in May 2008, seeking to explore the perceived definition(s) of the benefit-risk balance for a medicine, how it is communicated and what could be improved in order to better facilitate the communication.

The response rate to the survey was very good, and the responses provide very detailed views and suggestions to be analysed. The participants acknowledged that the ultimate goal of this initiative is to reflect on how to improve the information patients receive on the benefits and risks of a given medicine.

It was agreed that the results should be presented in a discussion paper prepared jointly by the EMEA and the topic leaders. Further discussion on outcome and follow-up will be held at next PCWP and HCP WG meeting respectively (30 September for the PCWP and 30 October for the HCP WG).

IV. EUDRAPHARM

During April and May 2008, all organisations represented in PCWP and HCP WG were invited to test a new draft version of the EudraPharm database[3], which features a multilingual interface and more data (including information on products that have been authorised by national regulatory authorities). The EMEA secretariat, together with the Chairperson of the EU Telematics Implementation Group, provided feedback on the input received during this user testing. A new version of EudraPharm will be released soon, and both the PCWP and HCP WG will be invited to provide comments and feedback.

[1] Commission regulation (EC) No 658/2007 of 14 June 2007 concerning financial penalties for infringement of certain obligations in connection with marketing authorisations granted under Regulation (EC) No 726/2004 of the European Parliament and of the Council
[2] Commission regulation (EC) No 1394/0007 of 13 November 2007 on advanced therapy medicinal products and amending Directive 2001/83/EC and Regulation (EC) No 726/2004
[3] EudraPharm is a database intended as a source of information on all medicinal products for human or veterinary use that have been authorised in the European Union (EU) and the European Economic Area (EEA).

V. CLINICAL TRIALS

Informed consent
On request from the European AIDS Treatment Group (EATG), there was a discussion on the informed consent for patients or healthy volunteers who participate in clinical trials. The participants heard a presentation on the objective and scope of informed consent. During the discussion participants highlighted current problems such as considerable differences in the way informed consent is applied depending on the various sponsors, investigators, and in which Member State the trial takes place. Also, it was highlighted that the informed consent forms seem to have become disproportionately large. This may reflect the amount and complexity of information provided in order to fulfil formal requirements, but can prevent participants in a given trial to fully understand the message conveyed.

Participants acknowledged that this is a complex area, but that a call for more regulation may not be the appropriate way forward. It was suggested to explore how to improve the ways in which guidance is implemented in Member States, so as to minimise discrepancies, and how collaboration between the various Ethics Committees can be strengthened.

The EATG will investigate the possibilities for a meeting or workshop outside the EMEA where issues related to clinical trials, including informed consent, could be addressed. The EATG's representatives will provide feedback to the PCWP and HCP WG on further progress with this issue.

EudraCT
The EMEA provided an update on the outcome of the EudraCT Paediatrics Group's consultation with interested parties regarding a public website with information on paediatric clinical trials from the EudraCT Database[4]. The meeting was held on 4 June 2008, and the purpose was to help the EMEA in gaining a clear understanding of the needs of patients, carers and healthcare professionals in the development of such a website. The PCWP and HCP WG will be invited to comment during the further development of the project.

VI. ANY OTHER BUSINESS

The representative from the Pharmaceutical Group of the European Union (PGEU) introduced a recently published study on pharmacists' initiatives on improving adherence to therapies in different EU countries 'Targeting Adherence'.

VII. CONCLUSIONS

The Chairpersons thanked the participants for a constructive meeting with fruitful discussions and highlighted the importance of continuing the tradition of annual joint meeting between the groups.

There was agreement that the project on risk-benefit communication will have high priority for the next meetings of the PCWP and the HCP WG respectively.

[4] EudraCT is a database containing information on all clinical trials commencing in the EU from 1 May 2004 onwards.