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

London, 24 October 2007
Doc. Ref. EMEA/258866/2007

MINUTES OF THE FIRST 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, 01 JUNE 2007
CO-CHAIRPERSONS: ISABELLE MOULON (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 Patients' Forum (EPF), 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 Association for Clinical Pharmacology and Therapeutics (EACPT), European Association of Hospital Pharmacists (EAHP), European Association for the Study of Diabetes (EASD), European League Against Rheumatism (EULAR), European Society of Cardiology (ESC), European Union Geriatric Medicine Society (EUGMS), European Society for Medical Oncology (ESMO), European Union of General Practitioners (UEMO), Pharmaceutical Group of The European Union (PGEU).

Committee for Herbal Medicinal Products (HMPC), 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)), European Commission (EC), European Medicines Agency (EMEA) Management Board & Secretariat.

I. INTRODUCTION

I. Moulon and N. Dedes, Co-chairs of the meeting, welcomed the participants to the first joint meeting between the EMEA Patients' and Consumers' Working Party (PCWP) and Healthcare Professionals' Working Group (HCP WG).

I. Moulon highlighted that this joint meeting provided an excellent opportunity for patients', consumers' and healthcare professionals' organisations to exchange views and information between each other as well as with the European Commission and the EMEA. The main objective of this meeting was thus to discuss topics of joint interest between the groups.

The PCWP and HCP WG members adopted the latest minutes from their respective groups. These documents will be published on the EMEA website.

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II. EU REGULATION ON MEDICINAL PRODUCTS FOR PAEDIATRIC USE

The EMEA presented the new EU regulation on medicinal products for paediatric use. The presentation focused on the key aspects of the new regulation, including the establishment of a new EMEA scientific committee, the Paediatric Committee (PDCO).

The PDCO will hold its first meeting in July 2007 but representatives from patients', consumers' and healthcare professionals' organisations will be nominated at a later stage. These representatives will be appointed by the European Commission after consultation with the European Parliament. Candidates will be identified on the basis of a call for expression of interest. The EMEA will inform the PCWP and HCP WG as soon as this call has been published by the Commission.

Post meeting note: the call for expression of interest was launched on the Commission's website on 12 June 2007 with 31 August 2007 as the deadline for notifications.

The participants raised a number of specific questions relating to the new paediatric legislation, including paediatric investigation plans, pharmacovigilance and international cooperation. It was clarified that although the PDCO will build on existing organisational structures, the specific details of the Committee's working procedures are currently being developed and the relevant guidance documents will become available once the Committee starts its work.

Some concerns were raised during the discussion with regard to potential lack of compliance to the new legislation by pharmaceutical companies. It was clarified that the paediatric regulation could go further than ever before in this aspect; in order to promote compliance a mix of rewards and incentives, financial penalties, and the establishment of a 'name and shame' list of companies not meeting the new requirements could be expected.

It was stressed as important to ensure that ethical principles for children to be involved in clinical trials are agreed at the same time that research in children is being recommended. In this aspect, a recommendations document is being developed.

Participants also expressed views in relation to future public access to part of the information contained in the European Clinical Trials Database (EudraCT). Both groups asked to become involved in the future consultation on this topic.

III. PHARMACOVIGILANCE

The representative from the European Commission gave a presentation on the current status of the Commission's assessment of the Community pharmacovigilance system following the outcome of the public consultation. He reminded the participants about the background for the review, which is to improve the protection of public health by strengthening and rationalising EU pharmacovigilance.

Also, the presentation aimed at bringing the review to the attention of patients', consumers' and healthcare professionals' organisations and encourage their involvement in the next stages of the process, which is expected to lead to a legal proposal from the Commission in 2008. In this respect, the PCWP and HCP WG member organisations are considered as key stakeholders whose important views should be expressed.

The presentation clarified the background of the review as well of the outcome of the public consultation on an independent study of the EU pharmacovigilance system that was commissioned by the European Commission.

The Commission's response to the outcome of the public consultation will consist of two parts:

- Better implementation of the current system

- Proposals to change the current legal framework for pharmacovigilance in the EU

Various issues were subsequently discussed within the group. The participants pointed out the need to improve medical education in pharmacovigilance for healthcare professionals. However, competences in the area of education remain with the Member States and therefore the Commission's role in this relation will be limited.

No harmonisation exits among the different Members States on direct patient reporting of adverse reactions. Promotion and better informing patients and consumers of this possibility were encouraged by the group.

Risk management plans for centrally authorised products are individually implemented in the different Members States. It was acknowledged by all participants that even within the current framework some progress can be made in this aspect.

The Commission representative informed the group that a new EU legislation initiative on financial penalties will soon be adopted. This will provide a possibility to levy financial fines on companies that do not comply with regulation for centrally authorised products, also in the area of pharmacovigilance. The group requested a presentation on this regulation be held to the PCWP and HCP WG respectively once it has been adopted.

Post meeting note: the 'penalties regulation' (EC No 658/2007) was adopted by the Commission on 14 June 2007 and can be found here.

IV. REPORT ON INFORMATION TO PATIENTS

The EMEA presented the contents of the European Commission's draft report on the current practice with regard to provision of information on medicinal products to patients[1]. The report has been released for public consultation until 30 June 2007 and can be found here.

N. Dedes provided an update on the PCWP's comments to the EC report following discussion by the PCWP in a meeting held on 31 May 2007. These were shared with the representatives of the HCP WG member organisations. The objective is to send the PCWP's comments on the report to the European Commission before then end of the consultation period (30 June 2007).

Both the HCP WG and PCWP members were also encouraged to submit comments from their respective organisations directly to the European Commission.

V. RISK COMMUNICATION

A CHMP representative gave an overview of the main issues concerning communication of risk-benefit assessment. In addition, two presentations provided the view from patients/consumers and healthcare professionals respectively on communication of risk-benefit of medicines.

Everybody agreed on the need to improve benefit/risk communication to patients. The role of the Package Leaflet as a suitable vehicle to deliver this information was considered, which is in line with a previous proposal by the EMEA/CHMP working group with patients' and consumers' organisations in their recommendations and proposals for action.

In addition, there was a general discussion of the media's role in relation to risk communication. While the group agreed that the media is not an appropriate channel to communicate benefit-risk in a

[1] In accordance with Article 88a of Directive 2001/83/EC, as amended by Directive 2004/27/EC on the Community code relating to medicinal products for human use

systematic way it can still be useful on a case by case basis for specific issues such as education, communicating understandable interpretation of data etc., and this should be further assessed.

It was proposed that the EMEA, together with the PCWP and the HCP WG, would develop a paper further identifying the issues surrounding risk communication and which should include considerations on areas for improvement.

VI. CONCLUSIONS

The Chairs thanked the participants for this fruitful meeting. To further strengthen the coordination between the PCWP and HCP WG, the latter was invited to nominate 1 or 2 observers to the PCWP. This would complement the PCWP observers already nominated to the HCP WG.