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

London, 18 June 2007
Doc. Ref.: EMEA/211974/2007

# MINUTES OF THE SECOND MEETING OF THE EMEA HUMAN SCIENTIFIC COMMITTEES' WORKING PARTY WITH PATIENTS' AND CONSUMERS' ORGANISATIONS (PCWP)

**EMEA, 16 FEBRUARY 2007**
**CO-CHAIRPERSONS: ISABELLE MOULON (EMEA) - NIKOS DEDES (EATG)**

**PARTICIPANTS TO THE MEETING**

**Representatives of:** The European Consumers Organisation (BEUC), European AIDS Treatment Group (EATG), European Cancer Patient Coalition (ECPC), European Federation of Neurological Associations (EFNA), 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).

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. GENERAL ISSUES

### I.1 Welcome and Introduction

The Co-Chair welcomed the participants to the meeting.

### I.2 Election of the Co-chair

After presentation of the rules applying for the election procedures, the different candidates described their previous experience to the group. Following formal election, Nikos Dedes (EATG - European AIDS Treatment Group), was elected Co-chair of the Working Party.

### I.3 Adoption of Agenda

The agenda was adopted with minor changes.

### I.4 Minutes of Previous Meeting

The minutes of the 08th December PCWP meeting were adopted.

### I.5 Nomination of an Observer for the Health Care Professionals Working Group

Two representatives plus one alternate from the PCWP to attend as observers to the meetings of the Healthcare Professionals Working Group (HCPWG). After two rounds of votes, F. Houÿez (Eurordis), W. Wientjens (IDF) and H. Sundseth (ECPC) were elected.

W. Wientjens and H. Sundseth will alternate, so that two members attend every meeting of the HCPWG.

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## II. SUBGROUP SESSIONS – SPECIFIC TOPICS

Participants worked on two separate sub-groups. The topics of discussion were: "Risk Communication and Pharmacovigilance" and "Dissemination of Information".

### II.1 Risk Communication and Pharmacovigilance

After the nomination of the topic leader, the group discussed about different initiatives to be put in place in order to progress on this topic, as previously indicated in the *"Final Recommendations and Proposals for Action"* of the POWG.

### II.2 Dissemination of Information (Website and others Tools)

After the nomination of the topic leader, the group discussed the new draft proposal for a periodic email directed to patients' and consumers' organisations and the new site dedicated to patients, which is currently under construction within the EMEA website.

## III. REPORT FROM EC ON INFORMATION TO PATIENTS

Representatives from the European Commission reported back on the progress of the Pharmaceutical Forum, with particular focus on the Working Group on Information to Patients. A summary of the current achievements was given, acknowledging the relevance of the input provided by the PCWP.

The members were informed that the Commission will present to the European Parliament and the Council (following consultation with patients' and consumers' organisations, doctors' and pharmacists' organisations, Member States and other interested parties), a report on current practice of provision of information to patients as foreseen in article 88a of Directive 2001/83/EC. The document would endorse some of the work done by the POWG, following the *"Final Recommendations and Proposals for Action"*.

When the report is made available, it will be circulated within the PCWP. Discussion within the PCWP will be held and comments from the PCWP will be forwarded to the European Commission.

## IV. REPORT FROM SUBGROUPS

### IV.1 Subgroup on Risk Communication and Pharmacovigilance

The topic leader presented the main points agreed during the discussion.

It is proposed to present to the PCWP the experience from pharmacovigilance inspections of companies and with an update on the European Commission's response to the public consultation on their assessment of the pharmacovigilance system of the EU regulatory network.

Based on recent experiences presented to the group about direct patient reporting and patient surveys, input from patients' organisations will be considered with regard to their facilitating role and development of methodology.

It is recognised that pharmacovigilance is an area which will profit from preparation of educational modules for the interested parties.

With regard to risk management, it is proposed to perform a survey of practicality, acceptability and effectiveness of risk minimisation tools as well as to develop standard phrases and quantitative measures for risk communication.

Other considerations were given on transparency activities and interaction with third parties (healthcare professionals). It was proposed, for instance, that the content of periodic safety update assessment reports is explained to the group to promote the discussion on the information of interest to patients' organisations.

## IV.2 Subgroup on Dissemination of Information (Website and other Tools)

### EMEA First Monthly E-mail Directed to Patients' and Consumers' Organisations

Target audience, content, format and layout of the e-mail were discussed.

The topic leader reported of the points agreed. The addressees of the e-mail will be initially the patients' and consumers' organisations members of the PCWP; after this first step, the e-mail could be sent to other eligible organisations "on demand". Among others, the group proposed listing the products by therapeutic area, giving some details about their main indication and highlighting, in a dedicated section, the documents open for consultation.

### EMEA Website Section for Patients' and Consumers' Organisations

Target audience, level of the information contained, and accessibility for the navigation through the different sections were discussed. At the same time, the comments previously received by several organisations during the consultation phase were considered.

The general structure of the website for patients' organisations, as proposed in the draft, was considered useful and satisfactory. However, the wording in various sections should be improved in such a way that every page is "self standing" and every difficult term is paired with an explanation. Minimal use of acronyms is recommended. Deeper and clearer information is required for: the marketing authorisation procedure, the orphan designation, information on paediatrics and herbal medicinal products.

# V. NATIONAL AUTHORITY EXPERIENCE ON INTERACTION WITH PATIENTS' ORGANISATIONS

## V.1 The Dutch Experience

A Scientific Committee's representative gave a presentation on the Dutch experience on the reporting of Adverse Drug Reactions (ADR) by patients. He introduced "Lareb", the adverse drug reaction reporting centre in the Netherlands, and its ADR reporting system for patients and its very new initiative of intensive monitoring by patients. ADR reporting activity for patients started in 2003. To report, patients can get access to a special electronic form, different from the one used by health care professionals. Main characteristics of the flow of reports and their quality aspects were analysed. The results show that patient reporting of adverse drug reactions has high administrative quality; its medical quality, overall, is not inferior to other reports, therefore they seem to offer an added value that needs to be investigated.

# VI. UPDATE ON PREVIOUS ACTIVITIES

## VI.1 Insulin Naming

An update on the Invented Name Review Group (NRG) draft recommendations document on naming of insulins was given. The principles and recommendations for which common agreement has been reached were summarised.
A workshop in this topic is to be organised, very likely in June 2007. The Workshop will involve Industry; Patients' Organisations will be invited to participate if interested.

## VI.2 Published EPAR Summaries

An updated list of the new available European Public Assessment Report was circulated during the meeting.

### VI.3 Performance Indicators

The final version of the questionnaire incorporating all comments received was presented for final adoption by the group, and everybody agreed with the document. The group will be asked to fill in the questionnaire in September 2007. However, every patient/consumer expert/representative involved in EMEA activities, irrespective of their membership of the PCWP will do it after every activity performed which implies an interaction with the EMEA. Results will be presented to the Management Board at its December meeting.

### VI.4 PhWP NSAIDs Wording

After the suggestion proposed during last meeting of the PCWP, the Pharmacovigilance Working Party prepared a new simplified wording which was circulated, as a proposal, to PCWP members. The wording agreed by the PCWP will be introduced in the package leaflet of the concerned products.

## VII. PREPARATION OF FUTURE MEETINGS

### VII.1 Joint PCWP – HCP WG Meeting

Participants were reminded that the next meeting will be a joint one with the Healthcare Professionals Working Group. The draft agenda was presented and discussed.

### VII.2 Dates of 2008 Meetings

The dates of the next 2008 meetings were presented.

### Closure of the Meeting