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

London, 13 December 2006
Doc. Ref.: EMEA/66146/2007

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

**EMEA, 08 December 2006**
**Co-Chairpersons: Isabelle Moulon; other co-chair to be elected**

## Participants to the Meeting

**Representatives of:** Alzheimer Europe (AE), The 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 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 this first meeting of the PCWP. The PCWP replaces the previous EMEA CHMP Patients' Organisation Working Group (POWG). The PCWP has been established to provide recommendations to the EMEA and its Human Scientific Committees on all matters of interest to patients in relation to medicinal products. New participants were introduced to the group.

### I.2 Adoption of Agenda

The agenda was adopted.

### I.3 Minutes of Previous Meeting

The minutes of the previous POWG meeting were adopted. These minutes will be circulated for information to the EMEA Human Scientific Committees and CMD(h).

### I.4 Creation of the Group and Nomination of the Co-chair

The organisations represented in the PCWP are general consumers' and patients' organisations, and organisations with specific interest in the mandatory scope of the centralised procedure. All organisations fulfil the criteria adopted by the EMEA Management Board to be involved in the EMEA activities (*http://www.emea.europa.eu/pdfs/human/pcwp/1461004en.pdf*) and appropriately cover the subjects within the scope of the working party, as stated in the PCWP mandate.
Isabelle Moulon has been nominated Co-Chairperson by the EMEA. A letter asking for candidatures for the second Co-Chairperson will be sent to each PCWP Member. Election will take place at the next meeting.
The group was informed about the first meeting of the EMEA/CHMP Health-Care Professionals' Organisations Working Group (HCP WG), held on 17 November 2006. The minutes of this meeting will be circulated to the PCWP Members. A representative of the PCWP could attend as observer to future HCP WG meetings.

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

## I.5 Working Procedures

It was agreed to work in subgroups for drafting recommendations from the group. Three main subgroups were identified:

1. Pharmacovigilance & Risk Communication
2. Dissemination of Information (Website and other Tools)
3. Commission Report to the European Parliament and the Council on Information to Patients.

All subgroups will report back to the plenary session, where general discussion will be held.
A meeting report will be prepared for each meeting and it will be published on the EMEA website.

## I.6 Performance Indicators: Degree of Satisfaction from Patients and Consumers Involved in EMEA Activities

EMEA Secretariat presented a draft questionnaire that was approved by the group. It will be used for assessing their degree of satisfaction as of 2007. The results will be regularly reported to the EMEA Management Board.

## I.7 Pharmaceutical Forum

The Pharmaceutical Forum takes forward the main issues outstanding from the G10 Medicines process: in particular Information to Patients, Relative Effectiveness and Pricing/Reimbursement. Three technical Working Groups, supported by a Steering Committee, have been established on each of these three subjects.

The Co-Chair reported on the last meeting of the “Information to Patients” Working Group. The aim of the working group is to advise the Commission on ways to improve the quality of information on authorised medicines and related health issues available to European patients.

The Forum’s Working Group on Information to Patients has developed the following three work streams:

a) Quality of Information: to develop a model package of information on diseases (using diabetes as a first example); it establishes quality criteria for information to patients and considers areas for more harmonised action on information on medicines at an EU level.

b) Statutory Information: where the EMEA CHMP/POWG “Recommendation and proposal for action” were considered by the Working Group.

c) Accessibility of Information: to improve patient access to good quality health information in healthcare environments.

## I.8 NSAID (Non-steroidal anti-inflammatory drugs): Draft New Wording for Package Leaflet

Following CHMP recommendations on positive benefit-risk balance for non-selective NSAIDs, the CHMP Pharmacovigilance Working Party (PhVWP) has considered additional warning for Package Leaflets (PLs) of prescription-only NSAIDs and also for NSAIDs available "over the counter" (i.e. without prescription - "OTC"). The PCWP has been consulted on this proposal. The group acknowledged that communication to patients on this topic is necessary, but required some improvement in terms of clarity and comprehensibility.

*Post-meeting note:*
*Following the above discussion the PhVWP fully endorsed the suggestions received by the group and prepared a new simplified wording, which was circulated, as a proposal, to PCWP members. The new wording was welcome by the group and then taken into account as a final wording.*

## II. PHARMACOVIGILANCE

### II.1 Risk Communication

The EMEA secretariat proposed a mailing scheme to disseminate documents published by the EMEA in a way that could meet patients' and consumers' organisations' specific needs.
A first mailing will be performed after the January 2007 CHMP meeting. The mailing scheme will be further developed together with the PCWP subgroup on dissemination of information.

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

### III.1 Partnership between the 'Agence française de sécurité sanitaire des produits de santé (Afssaps)' and Patients' Organisations: a progressive change in France

A presentation was shown, describing the involvement of patients in different activities of the French Agency (Afssaps).
The presentation was welcomed by the group who asked for additional presentations from other national experiences.

## IV. PRODUCT INFORMATION TRANSPARENCY AND DISSEMINATION

### IV.1 EMEA Website section for Patients' and Consumers' Organisations

A new specific site within the EMEA website, dedicated to patients and consumers is currently under development. The EMEA Secretariat presented the draft to the group, explaining the backbone of the subsections and briefly summarising its contents. Further comments for improvement will be considered during meetings.

### IV.2 Creation of the Experts List for the Review of the Package Leaflets and the EPAR (European Public Assessment Report) Summaries

The EMEA will send the letters requesting nomination of experts for the involvement of patients in the review of Package Leaflet and EPAR summaries. A training session for this new activity will be held on the 15th of February 2006.

### IV.3 EudraPharm

The group was informed of the 06th December launch of EudraPharm for public access. The database includes the summary of product characteristics, package leaflets and the labelling of medicinal products. It currently gives access only to information on Centrally Authorised Products and only in English, but information in the other official EU languages will be available at a later phase.

### IV.4 Published EPAR (European Public Assessment Report) Summaries

EMEA Secretariat provided the group with an updated list of the 140 published EPAR summaries.
EPAR summaries are published in the emea website on the following page (*http://www.emea.europa.eu/htms/human/epar/eparintro.htm*).

## V. A.O.B

### V.1 Organisations Eligible to Participate in EMEA Activities

A list with all organisations eligible to participate in EMEA activities, following evaluation of their request, is available on the website (*http://www.emea.europa.eu/pdfs/human/pcwp/41635606en.pdf*). The list will be regularly updated as new organisations are successfully evaluated.

### V.2 Draft European Commission Guideline on the Readability of the Label and Package Leaflet of Medicinal Products for Human Use

EMEA Secretariat presented a draft guideline on this topic. The compiled comments previously received from PCOs were summarised. They have been sent to the EC for consideration.

### V.3 International Conference of Harmonisation (ICH) Draft Definition for Genomic Biomarkers, Pharmacogenomics, Pharmacogenetics, Genomic Data and Sample Coding Categories

The document was presented to the group, introducing its contents. Comments from the PCOs will be provided.

### Conclusion and Closure of the Meeting

Attendees were thanked for their participation and contribution to the work of the group.