19 April 2011
EMA/9241/2011
Patient Health Protection

Minutes of the twelfth European Medicines Agency (EMA) Human Scientific Committees' Working Party with Patients' and Consumers' Organisations (PCWP) meeting of 22-23 February 2011

Chairpersons:	Isabelle Moulon (EMA-Head of Medical Information) and Lise Murphy (Eurordis)
Present:	PCWP members: European AIDS Treatment Group (EATG), European Cancer Patient Coalition (ECPC), European Federation of Allergy and Airways Diseases Patients' Associations (EFA), European Federation of Neurological Associations (EFNA), European Heart Network (EHN), European Older People's Platform (AGE), European Organisation for Rare Diseases (Eurordis), European Patients' Forum (EPF), 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), The European Consumers' Organisation (BEUC). Representatives of Agency's scientific committees: Committee for Advanced Therapies (CAT), Committee for Medicinal Products for Human Use (CHMP), Committee on Herbal Medicinal Products (HMPC), Committee for Orphan Medicinal Products (COMP). Representative from the European Commission. Observers: Co-ordination Group for Mutual Recognition and Decentralised Procedures-Human (CMDh), EMA Management Board, European Organisation for Rare Diseases (EURORDIS), European Prostate Cancer Coalition (EUomo), Global Alliance for Mental Illness Advocacy Networks (GAMIAN-Europe), Healthcare Professionals' Working Group (HCP WG), IPA observers–EU enlargement.
Apologies:	European Multiple Sclerosis Platform (EMSP), Paediatric Committee (PDCO).

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Day 1

Introduction

The chairpersons welcomed the participants to the meeting, especially the newcomers and the observers.

Members were asked to declare any potential conflict of interest they may have in relation to any topic in the agenda.

- No issue was raised at this time.

The agenda was adopted with no additions.

1. Brainstorming on training strategy for patients and consumers

Isabelle Moulon introduced the session, explaining that the aim of the afternoon's discussion was to determine if, and what additional training facilities should/could be in place for patients' and consumers' organisations (PCOs) participating in EMA activities.

This followed with a brief presentation by the EMA which outlined the training options currently in place (see presentation).

Three groups were proposed for discussion in break-out sessions:

1. Training material for the website.
2. Increase visibility of patient involvement / dissemination of information.
3. In-house training.

It was also highlighted that any training for patients/consumers needs to be able to accommodate those patients who participate regularly as well as those who only take part on an occasional or one-off basis.

Some general comments/proposals included:

- Have a training school, held by a patient organisation, to expand participation;
- Nominate a welcome partner (PCO) for new members of the PCWP and make available a list of members 'start dates';
- Documents that have been reviewed by patients should be indicated as such (reviewed by PCO);
- Include a link to the relevant website sections when sending out the invitations.

The following issues were highlighted as priorities:

- More information/training on regulatory affairs and specific topics, namely to have basic level of information on procedures and also explain role of EMA vs MS;
- Ensure patients understand timelines for regulatory procedures;
- Increase network with National Competent Authorities (NCAs) with regard to patient involvement and also develop interaction between PCOs and NCAs;
- There will be the need for new training sessions on risk management and direct patient reporting.

Day 2

Introduction

The chairpersons welcomed the participants to the meeting and thanked all those who participated in a successful brainstorming session the day before.

Lise Murphy also encouraged all newcomers to visit the EMA website, especially the sections “About us” and “Patients and consumers”.

2. Product information

2.1. Package leaflet – update on the revision of the template

An EMA representative gave a presentation to highlight the changes which have been made to the package leaflet template subsequent to its recent revision (see presentation).

Following the presentation, it was acknowledged that this template incorporates several of the recommendations previously proposed by the PCOs.

There were several comments from the participants, including questions related to the linguistics of the leaflets and languages shared by different countries (e.g. Austria and Germany, Belgium and France). EMA clarified that based on mutual agreements amongst member states sharing the same language, only one language version is reviewed and subsequently published, with the exclusion of country specific elements. For example the package leaflet in the German language, which is reviewed only by the German authorities, will be the one marketed in Austria and Belgium without any national-specific linguistic adaptation.

There was also a query as to whether a warning could be given regarding interactions when taking illicit drugs to which the EMA responded that as these drugs are illicit it is not something which can be indicated on the package leaflet template. A further question related to the inclusion of a general warning on the concomitant intake of alcohol and medicines - the EMA advised that this was not a general practice unless there are specific warnings of this nature included within the summary of product characteristics (SmPC) of a particular medicine.

The EMA clarified that the Agency prepares the templates for the package leaflets in all languages; it is then the responsibility of the marketing authorisation applicants to translate the content of the leaflets, which are then checked by the member states (quality review of documents (QRD) group) before authorisation. Once authorised the product information cannot be changed by the applicant without a separate review procedure (e.g. following a variation or update).

2.2. Better packaging and labelling for better informed patients

A representative of BEUC gave a presentation on a qualitative study (4 focus groups) carried out to acquire data on the consumer perception on the package leaflets of 13 ‘over the counter’ medicines (see presentation).

Many participants praised the survey and its findings which provided informative and useful data.

A comment was made that the data may not be fully representative for all EU countries and different economic backgrounds, as the research was carried out with participants from only Portugal and of middle-class background. The response was that similar findings have already been found in other EU

qualitative and quantitative studies and that very low income groups were not specifically targeted because they usually lack general literacy skills not limited to health information.

The presenter did mention that when preparing the amended leaflets there was no consensus on a few of the characteristics tested.

2.3. Eligibility criteria

Following discussion at the previous PCWP meeting in November 2010 on the revision of the eligibility criteria (to ensure transparency on Agency procedures on the review of eligibility criteria and to generally update the document), the new draft was presented by the EMA. This draft included many of the comments previously received from PCOs.

After further discussion, several additional minor comments were made and will be included in the final draft document to be circulated in the post mail and which will then be presented to the Agency Management Board in June 2011 for endorsement.

2.4. Feedback on PCO involvement in scientific advisory group (SAG) meetings

An EMA representative provided an update on the ongoing pilot phase to include patient experts in SAG meetings which has been in effect from October 2010 and will continue for one year. There have been 8 requests for patient attendance at SAG meetings since start of the pilot phase with 6 patients attending. The therapeutic areas under discussion have included; hepatitis, HIV, multiple sclerosis, excessive sleepiness, anal cancer (HPV vaccine), breast cancer, malaria and skin/soft tissue infections.

Questionnaires are sent to both the patient who attends the meeting and the chair and rapporteur for their feedback which will be evaluated at the end of the pilot phase to produce a report and will determine the way forward. To date, feedback has generally been very positive from all respondents.

It was noted that there are some challenges involved in finding suitable patient representatives for all of the meetings/therapeutic areas, and the PCOs were encouraged to use their wider networks wherever possible.

A patient who had previously attended a SAG meeting gave a short presentation on his personal experience of attending such a meeting which he felt had been very insightful and informative.

2.5. List of medicines monitored through eudravigilance

The Agency will shortly be publishing a list of medicines monitored through the eudravigilance system, (referring to the frequency of their monitoring), as part of its initiative to increase transparency.

The meeting participants were asked for their views on an explanatory note which could potentially accompany the publication of the list, in order to provide additional information as to the background of the list and the products contained therein.

In response the participants felt that in order to avoid unnecessary confusion for the public, the text should be very clear and comprehensive.

3. Area of involvement of patients and consumers organisations (PCOs) in EMA activities

3.1. Performance indicators

An EMA representative gave an overview of the results from the performance indicator questionnaires which were sent out to over 100 patients and consumers who had participated in any EMA activities during 2010 (see presentation).

The overall feedback received has been predominantly 'very satisfactory' or 'satisfactory'.

From the analysis it is apparent that there are two different 'types' of patients being involved with the EMA; those involved regularly and those who only maybe participate on a one-off basis. This difference can make it difficult to compare the results for one group compared to the other group.

It was proposed to have a separate section for PCWP members, with specific questions related to their work at the Agency and a member suggested to have a 6-point scale response option, instead of the current 5-point scale, which would allow for a 'neutral' response.

The full analysis will be detailed within the "2010 annual report on the progress on the interaction with patients and consumers organisations".

3.2. Update on HCP WG and presentation of joint meeting agenda

The EMA representative responsible for the interaction with healthcare professionals (HCPs) gave an overview on the ongoing developments in the interaction with HCPs, especially with regards to the framework for interaction (see presentation).

It was highlighted that the work with the healthcare professionals working group is similar to that of the PCWP and that the aim is to strengthen the links between the PCWP and the HCP WG by identifying topics of common interest for join discussions within both forums.

The agenda for the next HCP WG meeting on 4 March 2011 was presented as well as the draft agenda for the next joint meeting between the PCWP and the HCPWG on 16-17 June 2011.

3.3. Presentation to HMA; "EMA model of working with patients and consumers"

Lise Murphy showed the draft presentation which she intends to give at the next Heads of Medicines Agencies (HMA) meeting on 29 April 2011. The aim is to highlight the way that PCOs are involved within the Agency activities and to present the PCWP, in order to promote similar activities within the national agencies.

The PCOs gave some feedback which will be included within an amended presentation to be circulated after the meeting.

3.4. Conflicts of interest form

The EMA presented the new declaration of interests form, following the revised policy on the conflicts of interest. The form will be live as of 1 May 2011.

There were several comments from PCOs, mainly relating to the question of funding and/or the patient organisations' involvement with pharmaceutical industry which were advised to be included within the form.

The EMA stressed that the function of this form is to declare information concerning any "personal" interests that a patient/consumer may have, which should not be confused with the interests of the patient/consumer organisation.

PCOs were invited to send any further comments in writing after the meeting.

4. A.O.B

The chairpersons thanked the participants for their contribution and participation in the meeting.

Close of meeting

Next meeting: 16-17 June 2011