14 November 2011
EMA/545841/2011
Patient Health Protection

Minutes of the EMA Human Scientific Committees' Working Party with Patients' and Consumers' Organisations (PCWP) meeting of 13 September 2011

Role	Name
Chairpersons:	Isabelle Moulon (EMA-Head of Medical Information) and Lise Murphy (Eurordis)
Present:	PCWP members: AGE Platform Europe (AGE), European AIDS Treatment Group (EATG), European Federation of Allergy and Airways Diseases Patients' Associations (EFA), European Heart Network (EHN), European Multiple Sclerosis Platform (EMSP), 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 Patient Organisation for Primary Immunodeficiencies (IPOPI), European Consumers' Organisation (BEUC). Representatives of Agency's scientific committees: Committee for Medicinal Products for Human Use (CHMP), Committee on Herbal Medicinal Products (HMPC), Paediatric Committee (PDCO). Observers: Co-ordination Group for Mutual Recognition and Decentralised Procedures- Human (CMDh), Healthcare Professionals' Working Group (HCP WG), IPA Programme (EU enlargement), European Prostate Cancer Coalition (Europa Uomo), Rett Syndrome Europe (RSE).
Apologies:	Committee for Advanced Therapies (CAT), Committee for Orphan Medicinal Products (COMP), EMA management board, European Cancer Patient Coalition (ECPC), European Federation of Neurological Associations (EFNA), International Diabetes Federation (IDF), International Patient Organisation for Primary Immunodeficiencies (IPOPI), EMA Management Board, Healthcare Professionals' Working Group (HCP WG).

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Introduction

The chairpersons welcomed the participants to the meeting, including two observers from Croatia and Kosovo.

Members were asked to declare potential conflicts of interest in relation to any topic in the agenda.

- No issue was raised at this time.

The agenda was adopted with no additions.

1. Pharmacovigilance legislation

1.1. Direct Patient Reporting

An EMA representative gave a presentation highlighting how the new pharmacovigilance legislation will impact on direct patient reporting (see presentation). The legislation acknowledges that patients are well placed to report suspected adverse reactions and it thus requires appropriate methods be put in place to facilitate reporting. One such requirement is the development of standardised web-based reporting forms and it was emphasised that input from patients and consumers organisations (PCOs) is critical in the design of these forms.

The Agency has looked at some of the forms already in use within some member states and, based on the experience gained so far, is preparing a draft standardised form.

There followed several questions and comments from the floor, such as who would patients/consumers be reporting to? The EMA explained that the completed form would go directly to the national competent authority (NCA) who would then forward it to the EMA. It was also asked if the same form would be used within all EU countries? The EMA clarified that the core data will be harmonised, however as there are already several forms in use in several member states, some flexibility may be accepted in the format used. Another question pertained to translations, if and when they would be carried out? It is currently proposed that English translations be provided by the marketing authorisation holders, but this has not yet been fully defined (they currently provide a summary when requested).

There followed some discussion as to whether the same form should be used by patients/consumers and healthcare professionals, or if separate forms should apply. One PCO referred to the experience in the Netherlands of using one single form since 2005 which has been successful; however another participant felt that perhaps one single form would not be sufficiently 'patient-friendly'. It was highlighted that to obtain maximum information from patients/consumers, the form should be fully adapted for lay people. It was further mentioned from the floor that the use of language is very important, to avoid confusion between "adverse reaction", "side effects" and "interactions".

The EMA further explained that there is a possibility to include 'drop-down' lists of information to select, for ease of completion, which could be 'country-specific'. It was pointed out by PCOs that this may be problematic for patients when travelling in other countries, where perhaps this medicine is not available. The EMA explained that in all cases there will be a possibility to introduce free-text. The aim is to aggregate as much information as possible to facilitate assessment of the data received.

Several PCOs explained that they already have some experience on this topic and they proposed to send related information to the Agency for consideration. This initiative was fully welcomed.

The EMA advised that a draft form will be prepared during October and will be sent to all eligible organisations for input. The feedback will then be discussed at the next PCO meeting on 30 November 2011.

1.2. Access to Eudravigilance data - demonstration

An EMA representative presented an overview of the Eudravigilance Access Policy as well as giving a demonstration of the 'dashboard' which will be used by the public to access Eudravigilance data on adverse drug reactions (see presentation and dedicated webpage Eudravigilance).

The Eudravigilance access policy (adopted by the EMA management board end of 2010) foresees the publication of collated adverse reaction data related to spontaneous reports for authorised medicines. The objective is to proactively disclose information which meets public needs, whilst maintaining personal data protection.

Even though everyone has access the same data fields, there are two levels of access; the signal detection and data analysis tools in the Data Warehouse and Analysis System are not currently available to the general public.

The timelines for giving access to data on centrally authorised products to the general public is the end of 2011 and data on all other medicinal products (i.e. non centralised) will be towards the end of 2012.

The dashboard will have a user-friendly dynamic interface, able to combine multiple reports, with simple visualisation and navigation. The draft dashboard has been presented to the EudraVigilance Users Group for their input, specifically concerning user-friendliness, layout, level of detail, navigation, and relevance of information.

The EMA representative showed some of the feedback received and informed that the draft will be improved upon and expanded.

It was asked why the general public would not have access to the signal detection and analysis tools in the data warehouse. The EMA explained that the tools are very complex to use and require specialized training.

A PCO highlighted the fact that no information will be available on the actual number of medicinal products prescribed or sold. Therefore the frequency of the suspected adverse reactions can not be put into context and the data could be difficult to interpret. The Agency responded that it currently does not have access to sales or prescription data in structured format. An overview of the sales and prescription data is available to the Agency in the form of Periodic Safety Update Reports for centrally authorised products, but these data cannot be easily extracted for statistical purposes on a website. The Agency confirmed that a correlation between the number of reported adverse reactions and actual consumption data would be of added value in the future.

Finally it was clarified that the data only relates to adverse events of authorised products and not those associated with clinical trials.

The revised draft dashboard will be presented at the next meeting with all eligible organisations on 30 November 2011.

1.3. Report from follow-up meeting with Thalidomide Patients and Victims organisations

An EMA representative gave a presentation on the recent follow-up meeting with Thalidomide patients and victims' organisations (see presentation). These organisations were involved in the evaluation of

the initial thalidomide marketing authorisation, specifically concerning the risk management plan (RMP) and package leaflet (see Q&A: Thalidomide Celgene).

Following authorisation, the Agency agreed to provide the organisations with regular updates, namely through the assessment reports of periodic safety update reports (PSURs) and also to hold follow-up meetings to present post-authorisation safety aspects.

A follow-up meeting was held on 5 September 2011 and included representatives from patients and victims of thalidomide, as well as members from the assessment team, representatives of national competent authorities and the EMA. The meeting covered the implementation of the risk management plan and the Pregnancy Prevention Programme (PPP) to date, as well as the PSURs, revisions to the marketing authorisation and reports of events of interest, and the practical experience of some member states.

It was highlighted that since the product launch in the EU there have been no reported cases of pregnancy of a patient, indicating a successful implementation of the PPP.

The agenda and minutes of the meeting are published on the EMA website.

2. Research

2.1. "Looking at alternative models for research and development of medicines in Europe"

Health Action International gave a presentation on potential models of research and development to improve access to medicines (see presentation).

Following the presentation there were several comments from the floor; it was discussed that the cost of development varies considerably - medicines that 'fail' also have to be taken into account and that in fact research and development are two separate issues.

The current system of patent of medicines was discussed; and although it was felt not to be ideal, it was acknowledged that there is currently no other model which would be preferable. Reference was made to a report recently released by the WHO on "Priority Medicines for Europe and the World" which recommends ways in which pharmaceutical research and innovation can best address health needs and emerging threats in Europe and the world.

2.2. European Network of Paediatric Research at the European Medicines Agency (Enpr-EMA)

An EMA representative, together with a PDCO member representing patients, gave presentations introducing the Enpr-EMA network. The development of this network is mandated by the paediatric legislation which requires the EMA, with the Paediatric Committee, to develop a network of existing national and European networks, investigators and centres with specific expertise in the performance of studies in the paediatric population. The aim of the network is to foster high quality ethical research on medicinal products to be used in children, through efficient inter-network and stakeholder collaborations. (see presentation and dedicated webpage: Enpr-EMA).

Networks are recognised by quality of paediatric research and a minimum set of recognition criteria has to be fulfilled in order to qualify as member of Enpr-EMA. One of these criteria is the involvement of patients, parents or PCOs in either, the protocol design, information package and/or the prioritisation of needs for clinical trials in children. A workshop was held in March 2011 to introduce the network to stakeholders and which patient representatives attended.

The presenters made several suggestions concerning further involvement of PCOs in this activity; such as providing links between the PCOs and Enpr-EMA (discussed in the March 2011 Workshop). PCOs were invited to nominate one representative to act as the contact point and to participate in the coordinating group for Enpr-EMA.

In the following presentation the patient representative member of PDCO also highlighted other possibilities for collaboration between Enpr-EMA and PCWP such as patient involvement in clinical trials; raising awareness, ethics committees, helping to identify research priorities, etc) (see presentation).

The EMA representative proposed to send a summary on Enpr-EMA and its activities to the PCWP members after the meeting.

One PCWP member volunteered to be the contact point / member of the coordinating group.

Post-meeting note: Jose Drabwell from IPOPI has been nominated as the PCWP representative for Enpr-EMA.

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

3.1. Interaction PCWP / HCPWG

Isabelle Moulon proposed to strengthen the interaction between the PCWP and the healthcare professionals working group (HCPWG) by increasing the number of joint meetings. Many topics on the agendas are of mutual interest and would benefit from joint discussions between the two groups. It was therefore proposed, as a pilot, to hold two joint meetings in 2012, including the possibility for the groups to meet separately for one half day either before or after the main meetings.

The meeting participants supported this initiative and it was acknowledged it would improve communication between the groups. It was mentioned that there would however still be a need to meet as individual groups as well. It was agreed to begin the pilot as of 2012 and the EMA will forward the meeting dates.

3.2. Feedback from Lise Murphy's presentation at HMA meeting April 2011

Lise Murphy provided an overview of her presentation given to the Heads of medicines Agencies (NCAs) on the EMA model of involving patients/consumers (see presentation). Lise explained that the feedback she received at the meeting indicated that there are varying levels of PCO involvement within the different agencies.

The Agency explained that a current survey is being carried out by the NCAs to define their current activities with PCOs. It was suggested to prepare a similar survey for the PCOs to complete which could then be discussed at the meeting in November, together with the results of the NCAs survey.

3.3. Training for PCOs

- **Mentorship**
  Lise Murphy explained that the mentorship system is now in place and that several patient representatives have already met and have found the experience to be a positive one. It was reiterated that the mentorship is open to anyone, not only new members (see presentation).

- **Material on the web**

An EMA representative gave an overview of a new feature on the EMA website; a "frequently asked questions document" (see presentation). EMA responds to many enquiries from various stakeholders and a document has been prepared including the most common questions received and their responses. It is hoped that this can be a first point of information for enquirers to obtain a quick answer, updated on a regular basis. Additionally it can be a useful source of information on EMA activities in general.

An EMA representative also gave an update on the training plan for PCOs following the 'brainstorming' with PCOs in 2010. The communications team are currently working on options to increase the range of media (video, audio, flash presentations, etc.) which describe the Agency's core business and processes. They are also developing a user-friendly glossary for the website and will introduce related "mouse-overs". Work is similarly ongoing to enhance the "search engine optimisation" to improve search results. Finally, the Agency is looking at "in page feedback forms" to gather information directly from online users concerning satisfaction levels on specific pages.

Following the presentation, a PCWP member suggested including a short question which would pop up when a browser is closed – e.g. "did you find what you were looking for?" which could provide vital information on where users are having problems? The agency advised that they would look into the feasibility of this.

- **Training strategy/Priorities for 2012/November training session**
  The group proposed that the training for PCOs needs to be more structured, so next year, PCWP and EMA will prepare a training strategy using feedback and experience already gained. This strategy will be part of the planned revision of the framework of interaction.

- **Role of patients in the scientific committees**
  The EMA provided a summary of the document which has been drafted on this issue (see presentation). It was highlighted that it has taken some time to prepare, as several discussions were necessary to incorporate the views and experience of members of committees, chairs and the EMA into the document. Once adopted by all the committees it will become part of the planned revision of the framework of interaction.

  Comments from the floor included a request to specify that where it mentions 'patients' this also means 'patient representative'. It was proposed to include a footnote to make this clearer. It was also requested to include a reference to the new Pharmacovigilance committee (PRAC) which will commence in 2012.

3.4. Presentation on patient/consumer interaction at EMA – Annual Report for 2010

The annual report on the interaction with patients and consumers during 2010 was presented (see presentation). 2010 has again seen an important increase in patient/consumer participation in a wider range of activities. The report is for adoption at the Management Board meeting in October and then will be made available on the EMA website.

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

Close of meeting

Next meeting: PCWP meeting with all eligible organisations – 30 November 2011