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Patient Health Protection

Minutes of the EMA Human Scientific Committees' Working Party with Patients' and Consumers' Organisations (PCWP) meeting of 07 May 2012

Role	Name
Chairpersons:	Isabelle Moulon (EMA) and Lise Murphy (Eurordis)
Present:	PCWP members: AGE Platform Europe (AGE), 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 Multiple Sclerosis Platform (EMSP), European Organisation for Rare Diseases (EURORDIS), European Patients' Forum (EPF), Health Action International (HAI), International Alliance of Patients' Organizations (IAPO), International Diabetes Federation European region (IDF Europe), 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 for Orphan Medicinal Products (COMP), Committee on Herbal Medicinal Products (HMPC), Paediatric Committee (PDCO) Representative from the European Commission (via teleconference) Observers: Co-ordination Group for Mutual Recognition & Decentralised Procedures – Human (CMD(h)), European Institute of Women's Health (EIWH), Myeloma Patients Europe (MPE), Fabry International Network (FIN), International Bureau of Epilepsy (IBE)
Apologies:	European Heart Network (EHN), European Public Health Alliance (EPHA), EMA Management Board, Healthcare Professionals' Working Group (HCP WG), Pharmacovigilance Working Party (PhVWP)

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Introduction

The chairpersons welcomed the participants to the meeting.

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

- No issues were raised.

The agenda was adopted with no additions.

1. Area of information to patients

1.1. Proposals on legislation for "information to patients – follow up on PCO questions

Stefano Soro and Barbara Mentre, from the European Commission (DG SANCO), joined the meeting via teleconference to respond to several questions previously conveyed by the PCWP in relation to the amended legislative proposals on "information to patients".

The Commission services responded to the key points as follows:

There is no specific legal definition of what is considered *information* and *advertising* within the proposals; the Commission services explained that they avoided including abstract definitions, which would not cover every possible eventuality. It is more efficient to identify what information is acceptable. Therefore Article 86 is modified and a new Title is introduced in order to provide clarity on what is and is not allowed. The new proposals aim to provide adequate guiding principles in terms of content, quality, availability fora and control mechanisms.

The proposals do not allow for promotional campaigns (apart from those related to vaccines). In this context it was reiterated that it is not acceptable to refer to a brand-name and that the new proposals specifically outline what information can be presented.

Although it is recognised that there are other information providers, in view of its legal basis the proposals focus in particular on the role of pharmaceutical industry.

The new legislation does not cover the provision of information on product therapeutic class as its scope is restricted to individual medicinal products. However, the Commission took note of the comment for future reference.

The current regulatory framework already acknowledges the need to regularly assess product information; in particular it foresees a report on the shortcomings of the statutory product information (i.e. package leaflet and SmPC), which may then help to define potential improvements. Therefore the amended proposals do not address this matter.

The proposals foresee that industry provides to the public all the necessary information related to clinical trials, taking into consideration commercially confidential information and principals of data protection.

The proposals address the provision of on-line information, acknowledging the capacity of such tools and channels to reach out to a wider public - however it also requires that suitable mechanisms should be in place to ensure that content complies with the legal requirements. It was also highlighted that websites should be linked to the national competent authority in the Member State and should include a post-box to allow users to provide feedback.

Concerning the impact that the implementation of the new legislation would add to the EMA, there has been a specific analysis carried out and reflected in the financial statement to ensure adequate workload estimation and resourcing.

The Commission services finalised by explaining that the European Parliament had its first reading of the proposals in November 2010 leading to the adoption of the Commission amended proposals in February 2012. The text is now under consideration by the Council, but that due to its complicated nature, it is likely that progress will be slow.

The session was finalised and it was mentioned that a future teleconference could be held when there are some new updates.

1.2. Information on medicines published by EMA

Juan Garcia (EMA) gave a presentation following some recent feedback obtained during a teleconference held with several PCOs in relation to some of the information which is made available for patients/consumers on the EMA website, in particular safety information (press releases and Q&A documents). It was felt that the implementation of the new Pharmacovigilance legislation would be a good opportunity to review existing practices and identify any areas for improvement.

The EMA asked if these documents respond to patients' information needs and are written in an appropriate language and in sufficient detail. It was also enquired if the documents are easily located within the website and whether they are published in a timely manner. This brainstorming referred only to information on medicines in the context of the EMA's role and responsibilities and did not include EPARs, SmPCs or package leaflets.

The main feedback received during the teleconference was that the current information provided by the EMA is sufficient and of good quality but that improved targeting and increased accessibility would be welcomed. It was felt that both the press release and the Q&A documents are useful but that the key information contained there-in should be made more prominent. It was also highlighted that the search functionalities on the website could be improved, especially disease-specific information (see presentation for more detail).

After the presentation, some additional aspects were highlighted by the participants, such as the package leaflet being a very good tool, but that it takes 'too many clicks' to reach and that some of the important information is not always easy located – it could be made more prominent, bold, boxed etc.

One of the PCOs asked whether the information included within the press release and the DHPC is the same, to which the EMA responded that it tries to align the information and that the intention is to publish the DHPCs in the future.

It was also mentioned that the EMA could do more in terms of self-promotion and that it does not appear high in search engine results. The Agency responded that it is aware and is working on the search engine capacity. It was also suggested by a PCO that the PCOs themselves should ensure that a link to the EMA website is included on their (and their members) websites.

Some PCOs felt that information for patients and for healthcare professionals should not be the same; it was questioned whether the Q&A documents should be addressed to both patients and HCPs. It was also felt that some patients would like to have access to information for HCPs. The Agency explained that that they are currently considering these issues.

PCOs also enquired about possibilities for information being available via phone apps or e-publication formats? The Agency explained that these issues are also under consideration, e.g. whether to offer smart phone app or a mobile version website.

The PCOs finally requested information concerning who the EMA disseminates its information to, so the Agency proposed to give a presentation at the next meeting (joint PCWP/HCPWG) with details on how EMA information is distributed. The Agency would also appreciate receiving information from PCOs on how they disseminate EMA information and it was suggested to use a survey to gather this information, which could then also be presented and discussed at the next meeting.

2. Area of pharmacoepidemiology

Update on PROTECT (pharmacoepidemiological research on outcomes of therapeutics by a European Consortium):

2.1. Feedback from the external advisory board meeting / 2.2 WP5 – Potential patient involvement

David Haerry (EATG) provided some feedback from the recent PROTECT external advisory group meeting. PROTECT is a collaborative European project aiming to develop innovative methods in pharmacoepidemiology and pharmacovigilance. The EMA coordinates the project with a multi-national consortium of 29 public and private partners. There have been some significant advances made so far and both the FDA and Health Canada have expressed interested in the network.

David explained that work package 5 (WP5) within PROTECT concerns benefit/risk integration and representation. They envisage carrying out user-testing with patient representatives and they would like the help of the PCWP.

Georgy Genov (EMA) then followed with a presentation on WP5, explaining that the overall objective of this work package is to develop methods for use in the assessment of benefit-risk (see presentation). He emphasised that representing the benefit-risk of new medications is a challenge; weighing adverse effects/side effects against clinical benefits, taking into account changes over time and the differing perceptions on the relative importance of risks and benefits depending on experience/role in the disease.

He explained that they have reviewed current tools for measuring benefit-risk and carried out four initial case studies to analyse some of them. The next stage is to test in more complex situations, including the use of visual representation and they would like to involve patients / patient groups at this stage. The aim is to evaluate both treatment preferences and the model/analyses used to evaluate benefits and risks.

They hope to have some initial examples of different visual representations by autumn 2012 which would be presented to the PCWP for feedback.

It was explained that the best method to incorporate patient perspectives would benefit from further clarification and that this will be re-discussed at the next PCWP meeting, together with more specific details on the case-studies.

3. Conflicts of interest

3.1. Update of "policy on conflicts of interests" of experts and Committee Members

Noel Wathion (EMA) presented an update of the policy on conflicts of interests for experts and committee members (see presentation). Noel reminded that the objective of the policy is to ensure that members and experts have no interests in the pharmaceutical industry which could affect their impartiality, while securing the best scientific expertise. The policy has been in place since March 2004 with a major revision implemented in September 2011 and experts "declaration of interests" have been published since February 2012.

Following 6 months' analysis of the implementation of the revised policy, proposals for a further strengthening of the policy were presented and endorsed at the MB in March 2012. The amendments include a further clarification of some definitions, introduction of more consistency and robustness, checking the correctness of information provided and the development of a breach of trust procedure.

The updated policy and Breach Of Trust procedure are effective immediately and their implementation will be monitored with any remedial action taken if necessary. Finally, PCOS were reminded that DoIs have to be updated on an on-going basis (annual or when there is new information).

Following the presentation it was also mentioned that the European Parliament has been asked to create legislation whereby industry would be obliged to publish details of its interactions with different stakeholders. A PCO advised that in the USA there is the 'Sunshine Act' which obliges industry to publish information on who it gives funds to.

3.2. Outcome from "working group on funding for patient/consumer organisations"

Juan Garcia (EMA) gave a presentation highlighting feedback from the above-mentioned working group (see presentation). Juan clarified that the aim of the discussions was to improve the way to handle potential conflicts of interest of patient/consumer organisations (not individuals) in relation to funding received from pharmaceutical industry.

Patients can be involved in the Agency in the following capacities; as committee members (incl. EMA management board), as individual patient experts (e.g. participation in SAGs, scientific advice working party, review of documents, etc) or as representatives of their organisations (e.g. Committee consultation, participation in EMA conferences and workshops, PCWP members, etc).

Committee members and individual experts are governed by the EMA policy on conflict of interests (see above 3.1), however the participation of representatives of an organisation is currently ruled by the EMA eligibility criteria (used to select organisations for involvement) but which do not explicitly determine how information on funding is used to handle potential conflict of interest**.**

Following discussions with the working group a draft document was prepared. The key outcome was that the eligibility criteria remain a useful tool for the EMA to select appropriate patients´ and consumers´ organisations for interaction, and although they provide information on the funding sources of the organisations, they do not deal with potential conflicts of interest in relation to sources of funding. It was therefore felt that additional measures should be put in place.

Different options in terms of additional measures were discussed, including the possibility to apply a threshold (maximum percentage of industry funding), but this was not considered optimal since its application in practice would not take into account the different types of organisations and the different

EMA activities. A preferred option was to have a set of parameters to evaluate funding related information for each organisation.

The proposed parameters were:

- Diversity of funding (full funding by a single pharmaceutical company not accepted).
- Organisations´ accounts audited annually.
- Code of conduct/policy in place regulating relations with pharmaceutical companies.
- Consideration on the therapeutic area of interest of the organisation (e.g. difference between an organisation representing a rare disease *vs* a general umbrella organisation).
- Transparency of the organisation; whether funding information is published on their website.

In addition the group agreed that any procedures put in place should allow for a distinction depending on the nature of the EMA activity, for example participating in a general conference or workshop is not the same as being involved in benefit-risk evaluations.

Therefore every organisation would be evaluated (annually) according to the defined methodology, and if accepted, would be able to participate in EMA general activities. If an activity relates to benefit-risk / decision making, an additional evaluation prior to the involvement would be required, which would also take into consideration the specific product/activity under discussion.

After the presentation there following some discussion; one issue was whether or not to make a distinction between core and project funding. Overall it was felt that it is perhaps difficult to distinguish between the different types (e.g. what is 'core' funding) but that both should be declared for transparency, with a proposal to use the distinction restricted vs unrestricted funding. It was also mentioned that all sources of income should be mentioned; not only from industry.

It was agreed that the draft document will be amended and recirculated for adoption.

4. Pharmacovigilance legislation

4.1. Access to Eudravigilance data – demonstration

Steven Le Meur presented an update of the Eudravigilance Access Policy implementation to date and gave a live demonstration of the web reporting which will be used by the public to access data on adverse drug reactions (see presentation).

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.

The website was tested by PCWP members for usability, especially concerning user-friendliness, layout, level of detail, navigation, and relevance of information.

Steven demonstrated the different kinds of information that can be obtained and explained that the website will be live as of 31 May.

Following the demonstration several of the PCOs congratulated the EMA on a good website! There was a suggestion to include a list of 'most reported reactions' and it was also mentioned that there would be different search results depending on different but similar headings, e.g. weight gain vs obesity.

The EMA responded that they would like the PCOs to use the website and provide further feedback, such as these suggestions, which can be used for the development of future enhancements of the website.

The agency will send the link to the website to all PCOs once it is live.

4.2. Update on implementation of pharmacovigilance legislation

Several members of the EMA gave a brief overview of where we are in terms of the implementation of the new legislation. Much work has gone on behind the scenes in preparation of the implementation in July 2012, especially the establishment of the new pharmacovigilance risk assessment committee (PRAC). However there are some elements (e.g. public hearings) which are still under development.

Work is also continuing on preparation of 'good vigilance practice'. In particular modules on communication and on public participation will be circulated to all PCOs for comments when available.

The risk management plan summaries will be discussed at the workshop on 8 May and a further update presented at the joint meeting in September.

Ana Sempere (EMA) gave an overview on the planned measures in relation to the impact of the new pharmacovigilance legislation on the product information (see presentation). A black symbol and an explanatory sentence will be introduced in the SmPC and PL of medicines subject to additional monitoring, as well as a standardised text to encourage adverse reactions reporting for all medicines.

The Quality Review of Documents (QRD) group, together with the EMA, prepared initial draft proposals on which PCOs were consulted. Discussions and consultations are on-going and the final proposal will be given to the PRAC.

5. Area of research

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

Irmgaard Eichler presented an overview of the Enpr-EMA network to date. This network consists 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).

The networks are recognised by the quality of their paediatric research with six recognition criteria and quality standards for self-assessment (to become member of Enpr-EMA a set of minimum recognition criteria has to be fulfilled). One of the criteria relates to public involvement; involvement of patients, parents or their organisations in the protocol design, the creation of the protocol information package, and/or in the prioritisation of needs for clinical trials in children. There are currently 34 networks which are published on the EMA website: www.enprema.europa.eu

The annual Enpr-EMA workshop was held in March 2012 to which Jose Drabwell (IPOPI), the representing PCWP member on the coordinating group of Enpr-EMA, attended and gave a presentation.

Following the presentation there was some discussion with the participants concerning the involvement of young children in clinical trials - it was explained that a questionnaire will soon be circulated to the networks to ascertain exactly how they involve minors in the clinical trials. Additionally the paediatric

committee will be involving the networks and will convene small groups to discuss specific therapeutic areas whereby an interested eligible organisation could also potentially be invited.

Further updates will be given as and when available.

6. Involvement of patients and consumers organisations in NCA activities

6.1. Results of "PCO involvement in NCAs" survey

Nathalie Bere (EMA) gave a presentation highlighting the results of a survey related to the involvement of patient/consumer organisations with their National Competent Authorities (NCAs). The aim was to obtain some general feedback from organisations on any involvement with the national medicines agencies. The survey ran from 14 October to 25 November 2011 and 91 responses were received from over 75 organisations in 24 EU countries (see presentation for full results).

The responses within each country were notably inconsistent, i.e. some PCOs stated they had no interaction with their NCAs, whilst others, within the same country had regular involvement. There could be several explanations for this variability; the initiative on the part of the PCO, resource limitations, the size of the organisation, or perhaps the disease area.

Some organisations reported a successful interaction with their NCAs and were of the impression that their input had an impact; however other organisations (mainly those not involved) reported a lack of experience and willingness from the NCAs towards collaboration with PCOs and the need for improved understanding of the potential value of PCO contributions to the NCAs work.

With regards to the future, it seems many PCOs would very much welcome the opportunity to meet with the NCAs, to discuss possibilities for interaction and to highlight potential benefits that patient contribution can bring. For those that already interact, they would hope to regularise and enhance their involvement.

After the presentation there followed some discussion and it was proposed that the results of the survey be shared with the NCAs.

Jose Drabwell proposed to prepare a draft 'template' letter which could be used by patient/consumer organisations to introduce themselves to the national agencies.

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It was highlighted that the 'overview document' is very useful in highlighting all of the different activities that patients/consumers are involved in at the Agency. PCos asked if they could circulated it to other members within the organisations, to which the EMA responded positively with encouragement, and confirmed it would include a sentence beneath information related to SAG meetings to emphasise that SAG information/discussions remain confidential to the person attending. The opportunity was also taken to recap that a patient attending a SAG meeting does so as an individual expert, not representing any patient organisation.

An email is sent out to all eligible organisations prior to meetings (PCWP, joint, all eligible) asking for expression of interest to attend the meeting should there be any available spaces. Lise, the co-chair, encouraged the organisations to join the meetings whenever possible.

Lise Murphy also requested for additional mentors willing to help the newer organisations. An email with further information will be sent after the meeting.

Francois Houyez from Eurordis gave a brief overview of the 'code du travail' francais (French work law) which includes provisions for patient representatives who are invited to participate in any work activities with their national agencies (see presentation for further details). Francois suggested that this be brought up with the Commission and it was also suggested that the PCWP members look if there are any similar provisions within their own member states.

Close of meeting

Next meeting: Joint PCWP/HCPWG meeting – 24/25 September 2012