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Stakeholders and Communication Division

Minutes of the EMA Human Scientific Committees' Working Parties with Patients' and Consumers' Organisations (PCWP) and Healthcare Professionals' Organisations (HCPWP) joint meeting

9 March 2016 – 08:45hrs to 16:00hrs, meeting room 3E

Role	Name
Co-chairs:	Isabelle Moulon (EMA), David Haerry (PCWP) and Gonzalo Calvo (HCPWP)
Present:	**PCWP members**: AGE Platform Europe (AGE); Alzheimer Europe (AE); European AIDS treatment Group (EATG); European Consumers' Organisation (BEUC); European Federation of Allergy and Airways Diseases Patients' Associations (EFA); European Federation of Neurological Associations (EFNA); European Heart Network (EHN); European Multiple Sclerosis Platform (EMSP); European Organisation for Rare Diseases (EURORDIS); European Patients' Forum (EPF); European Prostate Cancer Coalition (EUomo); European Public Health Alliance (EPHA); Health Action International - Europe (HAI); International Alliance of Patients' Organizations (IAPO); International Diabetes Federation European Region (IDF Europe); International Patient Organisation for Primary Immunodeficiencies (IPOPI); **HCPWP members**: European Aids Clinical Society (EACS); European Association for Clinical Pharmacology and Therapeutics (EACPT); European Association of Hospital Pharmacists (EAHP); European Association for the Study of Diabetes (EASD); European Association of Urology (EAU); European Federation of Internal Medicines (EFIM); European Society for Medical Oncology (ESMO); Pharmaceutical Group of the European Union (PGEU); Standing Committee of European Doctors (CPME); The European Specialists Nurses Organisations (ESNO); United European Gastroenterology (UEG); **Representatives from the Agency's Scientific Committees**: Committee for Advanced Therapies (CAT); Committee on Herbal Medicinal Products (HMPC); Committee for Medicinal Products for Human Use (CHMP); Committee for Orphan Medicinal Products (COMP); Pharmacovigilance Risk Assessment Committee (PRAC) **Observers**: EMA Management Board; Patients' and Consumers' Working Party (PCWP); Healthcare Professionals' Working Party (HCPWP); European Forum for

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Role	Name
	Primary Care (EFPC); European Haemophilia Consortium (EHC); European Network of Fibromyalgia Associations (ENFA); European Society of Oncology Pharmacy (ESOP); Global Alliance for Mental Illness Advocacy Networks (GAMIAN-Europe); Healthcare Without Harm Europe (HCWH Europe); Myeloma Patients Europe (MPE); Pain Alliance Europe (PAE); Spanish Agency of Medicines and Medical Devices (AEMPS)

Introduction

Isabelle Moulon (co-chair) welcomed all participants to the meeting. They were asked to declare any potential conflicts of interests in terms of the topics on the agenda. None of the attendants had declarations to address. Fire evacuation procedures were highlighted. New attendees from member organisations and observers were introduced by I. Moulon.

The agenda was adopted with two contributions to A.O.B; the Zika virus and combination medicines.

1. Involvement in EMA activities

1.1. EMA interaction with patients, consumers, healthcare professionals and their organisation – Annual report 2015

N. Bere (EMA) presented an overview of the interactions of patients' and consumers' and their organisations' with the Agency during 2015 (see presentation). After presenting preliminary results during the meeting with all eligible organisations in November 2015, the final figures were shared.

An increase in the number of interactions has once again been observed, in particular in activities where patients act as representatives of their organisations. Nevertheless it is important to keep in mind that it is not just about the numbers, but that focus should be on identifying appropriate and mutually beneficial opportunities for involvement. One such area is scientific advice (protocol assistance) procedures that increased substantially in 2015. Other activities remained constant or had slightly less involvement, which can be attributed to natural fluctuations between years.

In addition, 2015 stood out as a year where the revised framework of interaction was implemented, the CHMP pilot included 2 more cases, topic groups were introduced, benefit-risk preference studies were conducted and will be expanded in 2016 and training and webpages for patients were updated. For 2016 the Agency looks forward to a continued fruitful collaboration.

I. Silva (EMA) presented an overview of healthcare professionals' and their organisations' interactions with the Agency during 2015 (see presentation). Overall, and as a result of the continued implementation of the framework of interaction, 2015 showed an increased level of healthcare professionals' involvement in EMA core activities, with additional opportunities for interaction generated by the introduction of topic groups and participation in a number of surveys. Throughout the year efforts were made to maintain the Network of European healthcare professional organisations (HCPOs) and support the eligible organisations to meet the revised Agency's standards on transparency. Furthermore, 2015 was also a year of brainstorming with healthcare professionals/learned societies on the EMA's collaboration with Academia.

For upcoming years it is important to find the right balance between clinical practice and academic interests and maintain mutually beneficial interactions. As a result it was identified that the framework

of interaction with healthcare professionals will need to be revised. In addition it was suggested that internal strategies for involvement will become more long-term focussed.

Further details related to these presentations will be provided in the Annual report on EMA's interaction with patients, consumers, healthcare professionals and their organisations. This report will be published later in the year.

One of the PCWP members took the opportunity to address the benefits of having joint meetings with patients' and healthcare professionals' organisations. This was supported by other participants who shared positive experiences of their collaboration and insights it provides. Another participant commented that currently for some consultations the contribution made by stakeholders is not very obvious and it was suggested to look into ways to make these contributions more visible and be more emphasised.

1.2. PCWP and HCPWP 2016-2019 mandates and elections of co-chairs

N. Bere (EMA) presented the renewal of the mandate for the PCWP and HCPWP member organisations. All organisations who would like to (re-) apply for membership need to fulfil the revised eligibility criteria adopted in 2014. EMA decides on membership of the working parties based on the organisations appropriateness to the subjects covered within the scope of the working party's mandate. There is a maximum of 20 member organisations per working party.

June 2016 marks the end of the current 3 year mandate for both PCWP and HCPWP and the new mandate will be for 2016-2019. For the HCPWP it is the first renewal and the Agency will thus aim for continuity within the working party. For the PCWP it is the fourth renewal and members who want to renew or apply will be asked to provide a motivation letter including their involvement so far with the working party and EMA and their anticipated commitment to the working parties work for the upcoming three years. The renewal procedure will be organised during April/ May 2016 and the Executive Director's Decision will be finalised by 31 May 2016.

N. Bere also described the upcoming election of the co-chairs of the working parties. For each working party, the two co-chairs are elected for a period of 3 years, which can be renewed. One of the co-chairs is nominated by the EMA and the other co-chair is elected amongst PCWP or HCPWP members and alternates. During the presentation the responsibilities of Chairpersons were explained (see presentation). The elections are planned to take place during the PCWP and HCPWP meeting in September 2016.

When questioned about the workload and time associated with co-chairing, D. Haerry, current PCWP co-chair, mentioned he did not experience it as more time consuming compared to being a member and that it is mainly a different kind of work with a different perspective towards the meeting. G. Calvo, HCPWP co-chair, mentioned the main work is carried out by the secretariat and in his experience it is more about personal commitment and activity and encouraging people to be engaged.

1.3. Topic Groups: interim reports and discussion on overlaps and synergies between topics

I. Silva (EMA) provided an interim report of the activity of 8 the topic groups established in June 2015. A consolidated high level summary on the progress so far as well as possible synergies identified between topic groups was presented (see presentation).

The co-leaders of the topic groups present expressed their appreciation for everyone's involvement and looked forward to more collaboration between topic groups. One suggestion was to include a topic

group on older people, which was noted and will be further discussed when the current topic groups are re-assessed in September.

1.4. Topic Groups: questions for reflection

Some topic groups identified questions or issues they wanted to discuss with the working parties for additional feedback.

Topic group: acknowledge and promote visibility of patient input in the Agency's activities

I. Moulon, co-chair of this topic group, mentioned that one of their recommendations was to create a certificate of participation/ attendance for patients. Isabelle asked the members why such a certificate is needed, for what activities and when they should be given. Healthcare professionals mentioned that in their case such a certificate was required to justify their absences to employers. Patients' representatives mentioned that such a certificate would mainly serve as an acknowledgement and could be something to be included in their CV. In general, members agreed it would be sufficient to request for such a certificate on a need basis rather than receiving one for each activity.

One of the participants suggested visibility could be improved by creating an 'acknowledgment' slide, prepared by EMA, to be included by organisations in their presentations, which would recognise the organisation as an EMA stakeholder. The co-chair responded that this could be included as an additional recommendation of the topic group.

Presentations during congresses and making training regarding EMA activities CME accredited were also suggested as possible additional actions to improve recognition of patients' and healthcare professionals' involvement in EMA.

Topic group: training

R. West (EURORDIS), co-chair of the topic group, highlighted one of their main recommendations, which had been to expand the EMA's annual training day, which had been done for the training in November 2015 and was successfully received, based on feedback received. It was proposed to close the topic group at this point and re-evaluate in one year.

Topic group: social media

D. Singer (EACPT), the topic group's co-chair, mentioned the progress the topic group is making regarding the SWOT analysis. This analysis aims to gather a better understanding on individual's and organisations' perception of social media and, if used, what the strengths, weaknesses, opportunities and threats are and to share case studies. Currently the analysis is first being performed within the topic group, which will then be optimised and sent to all organisations. This analysis should help the topic group to identify next steps and recommendations.

Topic group: Risk minimisation measures and assessment of their effectiveness

J. Wilkinson (PGEU), co-chair of the topic group, pointed to a set of case studies addressing concrete risk minimisation measures that were identified and developed by the group. He announced these would serve as the basis for a targeted survey amongst interested healthcare professional organisations to support the identification of criteria to improve healthcare professionals' early involvement in PRAC risk minimisation activities. The aim is to present the group's findings in September 2016.

2. Pharmacovigilance

2.1. PRAC strategy on measuring the impact of Pharmacovigilance activities

The strategy was presented during the joint meeting in September 2015 and has since been adopted by PRAC with further adjustments. The presentation elaborated on the PRAC strategy including an analysis of patient reporting in EudraVigilance.

T. Goedecke (EMA) presented the strategy of measuring impact of pharmacovigilance activities. The approach of measuring impact is health-focused and science-based at the level of the national agencies and the EMA. The work is conducted in collaboration with academia and the pharmaceutical industry. The key objectives are to inform the review of the benefits and risks of individual medicines that have been the subject of major risk minimisation efforts (effectiveness of risk minimisation) and to determine which activities have been successful and which have not, and therefore identifies enablers and barriers for generating positive impacts which would contribute to the development of proactive pharmacovigilance in the EU. There are four building blocks for the strategy: pharmacovigilance processes, stakeholder engagement, health outcomes (studies) and methodological aspects. Every building block has activities, namely routine data collection, stakeholder engagement, conduct of collaborative impact studies and development of methods for measuring impact of pharmacovigilance activities. The stakeholder engagement mentioned, which will mainly focus on trust measurements, will be done through surveys, though the timing and content is not defined yet and PCWP and HCPWP will become involved in the discussion.

M. Banovac (EMA) presented preliminary results of the analysis of EudraVigilance data. The analysis was done to complement previous research and further profile the patient reporting three years after the implementation of the pharmacovigilance legislation. These results could be compared with those of three years before. When comparing the difference between the patients' and healthcare professionals' reports, the analyses are done in a descriptive way. First results seem to show an increase in reporting after the implementation of the legislation, which was expected. Nevertheless, there is room for growth in patient reporting. There appear to be differences in issues reported by patients and healthcare professionals, such as patients reporting relatively more drug ineffectiveness compared to healthcare professionals. In the end the identified gaps found during the analyses should inform the provision of information and training to patients, support better collaboration with patient associations, support better communication campaigns on the awareness of reporting suspected ADRs and inform improved approaches to the analysis of reports for future safety signal detection and evaluation. The final results are expected to be published in the upcoming months.

There is a call for expressions of interest for PCWP and HCPWP members to collaborate with EMA on the strategies. Furthermore, a 1.5 day workshop on impact will be planned at the end of 2016, proposed dates are 5 and 6 December. By the end of March there should be a call for expression for this workshop.

The point was raised whether feedback is provided to the patients when they report an adverse drug reaction (ADR). In response, members shared experiences from their countries. In Sweden they thought it is important to acknowledge and provide some evaluation on the ADR. In the Netherlands feedback is always given with a thank you email and when more information is required, the patient who reported will be asked for further input. In Croatia both healthcare professionals and patients receive feedback however under certain circumstances, responses are grouped and updates are sent quarterly.

2.2. Access to EudraVigilance data to Patients and Health Care professionals: discussion on communicating the revised access

F. Domergue (EMA) gave a presentation on the implementation of the revised EudraVigilance Access Policy (see presentation). The aim of the presentation was to provide the PCWP/ HCPWP with an overview of the Pharmacovigilance Programme and in particular the EudraVigilance (EV) auditable requirements project and to update them on the implementation of the revised EV Access Policy, in particular the new functionalities that will be made available in the ADR website.

The objectives of the EV policy are to provide openness to citizens, facilitate the monitoring of the safety of medicines, support signal detection and evaluation, allowing the use of adverse reaction data for research purpose. With the revised policy it will become possible to proactively or reactively disclose individual case safety reports (ICSR). Prior to the presentation, mock-ups of the proposed line listing and ISCR form was shared with the PCWP and HCPWP and feedback was welcomed.

One of the participants asked how abuse of the system could be avoided to ensure a side effect truly takes place. EMA responded that there has to be trust in the system, and that is why patient reporting is introduced. At the Agency no negative effects have been experienced so far and patient reports are very detailed so the risk of faking is considered low.

2.3. User testing of clinical data publication website prototype

F. Nuttall (EMA) addressed the group regarding the “user testing of the Clinical Data Publication Website Prototype”. Following on her request during the November meeting of all eligible patients’ organisations there was many feedback received and their input is currently being processed. Another test-session will be organised for between mid-June and mid- July. Dates are to be confirmed and volunteers are once again requested.

3. EMA dedicated webpages for patients and healthcare professionals

3.1. Updated EMA dedicated webpages for patients and healthcare professionals

M. Mavris (EMA) presented the updated webpages for both patients/consumers and healthcare professionals. As part of the Training topic group of the PCWP, it was decided that the EMA webpages for these stakeholders were to be updated, simplified and harmonised. The pages and content have been made more user friendly with easier identification of key information as well as relevant links to other pages or documents. The respective Working Party pages and meeting dates have been linked to in these pages as well as traditionally via the committee pages. An important emphasis was made on the pages providing training and support for patients and resources for healthcare professionals. Supportive short (5-6 minute) videos entitled EMABasics that describe the main activities of EMA such as the centralised procedure, Pharmacovigilance as well as the roles of patients and healthcare professionals have been initiated and are available via the website for public use.

4. Committee feedback

4.1. Feedback from scientific committees

H. Enzmann provided feedback on behalf of the Committee for Medicinal Products for Human Use (CHMP). The CHMP is increasingly receiving patients input within their meetings, in addition to the input already provided in Scientific Advisory Groups.

D. O'Connor provided an update on behalf of the Committee for Orphan Medicinal Products (COMP). The work plan of the committee was highlighted, including involvement of patients, publication of an article and (possible) updates on guidelines (see presentation). In the context of orphan designation, the systematic involvement of patients' representatives in COMP discussions on significant benefit based on major contribution to patient's care will continue to be an area of focus.

S. Bager provided an update on behalf of the Committee on Herbal Medicinal Products (HMPC). The HMPC is a committee with no specific product evaluations, but creates guidelines and monographs for herbal medicines which are often available over the counter and used as self-medication. A pool of 6 consumers has now been established who will review ERSPs, which are the herbal equivalent of the EPAR, and will be invited to the committee meeting to discuss how patients and consumers could be involved further within the committee's activities.

K. Breen provided the update on behalf of the Committee for Advanced Therapies (CAT). He introduced the work of the CAT (see presentation). It is expected that applications for advanced therapy medicinal products (ATMPs) will grow in upcoming years based on the scientific advice requested at the Agency. There is a lot of overlap between those applying for ATMP and orphan designation, resulting in 2 of the 6 approved ATMPs taken off the marked because of high costs and too small market. The CAT work plan for 2016 was presented.

5. Update on EU and global initiatives

5.1. Update on revision of ICH GCP guideline

F. Sweeney (EMA) presented the ICH E6 addendum on Good Clinical Practice guideline, a collaboration between the EU, USA, Japan, Canada and Switzerland (see presentation). The Good Clinical Practice (GCP) guideline is a system regarding practicalities and ethical aspects of performing clinical trials implemented in 1996. The addendum is needed as since GCP has been implemented there has been an increase in globalisation, study complexity and technological capabilities; modernisation is thus desired. In addition, ICH E6 has been misinterpreted in the past and clarification was desirable via an addendum. The addendum should, besides modernize, facilitate innovative approaches to clinical trials. The open consultation closed February 2016 and received input from 52 organisations/ individuals from the EU. The next steps are to evaluate the feedback and update the addendum accordingly. The addendum is expected to be put in place in 2017.

6. Members voice: sharing practices

6.1. EATG training programme

S. Konov presented on behalf of the European AIDS Treatment Group (EATG) on their training projects (see presentation). Their main programme is STEP-UP, a year-long voluntary programme focussing on participants from both Western and Eastern Europe to share their experiences. Besides English,

Russian is chosen as an additional language in which the training is provided. EATG provides funding for their trainees so they can (preferably) create their own cross-cultural/ cross-border projects during and after the training. Some of these projects resulted in publishing abstracts in conferences.

6.2. PGEU launches The European Pharmacists' Professional Forum (EPPF)

J. Wilkinson presented the launch of the European Pharmacists' Professional Forum (EPPF) on behalf of the Pharmaceutical Group of the European Union (PGEU) (see presentation). EPPF will be a working group of PGEU with an aim to engage their members better. They already changed the number of internal meetings, the structure of their agenda and included regulatory affairs in their structure.

6.3. The Hospital Pharmacist common training framework project

J. Peppard presented the European Association of Hospital Pharmacists' (EAHP) strategy on good and safe usage of medicines (see presentation). The strategy is the follow-up of EAHP's vision for hospital pharmacists to improve access and safety for patients. The strategy is based on hospital pharmacist's best practices and contains a 5-step implementation plan: increase awareness, define achievements to be made, educational tools, developing a long-term strategy and self-assessment.

6.4. UEGW 2016 Congress

M. Delvaux presented on behalf of the United European Gastroenterology (UEG) on their continued work to include an EMA perspective in their annual congress (see presentation), through identifying what EMA contributions could be in the field of new regulations and new medicines and how these could be of interest to the different types of people attending their congresses.

7. A.O.B

7.1. Zika Virus

J. Drabwell mentioned to the members the position statement written by IPOPI on the Zika virus. The statement is aimed at patients with primary-immunodeficiencies as it is important for them to be aware of it, but everyone who desires to gain more background knowledge on the Zika virus is welcome to read it.

7.2. Combination medicines

D. Haerry highlighted the concerns EATG faces with combination medicines. It seems the market is being taken over by this type of medicines. Although they have obvious advantages, EATG has concerns that there are several disadvantageous situations as it might not be the best option of combinations for certain patients. Furthermore, with combination medicines patients will have less flexibility, are not able to easily switch to a treatment with fewer side effects or change the dose of a certain medicine. New promising results of clinical trials are additionally harder to test as doses and components are fixed.

He mentioned combination medicines are a public health concern that goes beyond HIA/AIDS and that EATG would like to know if other members of the working parties would consider working together on this topic. Both members of the PCWP and HCPWP supported the initiative. I. Moulon suggested pursuing a similar approach as for 'shortages' to first prepare a statement paper to be shared with all eligible organisations.

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

Close of meeting

Next PCWP meeting: 14 June 2016

Next HCPWP meeting: 15 June 2016