27 January 2016
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Stakeholders and Communication Division

Minutes of the EMA Human Scientific Committees' Working Party with Patients' and Consumers' Organisations (PCWP) meeting with all eligible organisations

26 November 2015, 09:15hrs to 17:00hrs – meeting room: 3E

Role	Name
Co-chairs:	Isabelle Moulon (EMA) and David Haerry (PCWP)
Present:	**PCWP members**: AGE Platform Europe (AGE); Alzheimer Europe (AE); European AIDS treatment Group (EATG); European Cancer Patient Coalition (ECPC); European Consumers' Organisation (BEUC); European Federation of Allergy and Airways Diseases Patients' Associations (EFA); European Institute of Women's Health (EIWH); 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 Europe); International Alliance of Patients' Organizations (IAPO); International Diabetes Federation European Region (IDF Europe); International Patient Organisation for Primary Immunodeficiencies (IPOPI); Patients Network for Medical Research and Health (EGAN) **Representatives from patient and consumer organisations**: European Foundation for the Care of Newborn Infants (EFCNI); European Gaucher Alliance (EGA); European Lung Foundation (ELF); European Network of Fibromyalgia Associations (ENFA); Global Alliance for Mental Illness Advocacy Networks (GAMIAN-Europe); International Bureau of Epilepsy (IBE); Myeloma Patients Europe (MPE); Pain Alliance Europe (PAE); SMA Europe (SMA E); Thalassaemia International Federation (TIF) **Representatives from the Agency's Scientific Committees**: Committee for Medicinal Products for Human Use (CHMP); Committee for Orphan Medicinal Products (COMP); Pharmacovigilance Risk Assessment Committee (PRAC) **External speakers:** European Lung Foundation (ELF); European Organisation for Rare Diseases (EURORDIS); European Patients' Academy on Therapeutic Innovation (EUPATI); Medical Products Agency (MPA), Sweden **Observers**: EMA Management Board; Healthcare Professionals' Working Party (HCPWP);

Role	Name
	Medical Products Agency (MPA), Sweden; The Dental and Pharmaceutical Benefits Agency (TLV), Sweden

Introduction

Isabelle Moulon (co-chair) welcomed the participants to the meeting. They were asked to declare any potential conflicts of interest in terms of the topics on the agenda and then relevant fire evacuation procedures were highlighted.

The agenda was adopted with two additional points to be covered under A.O.B. 1) Clinical data publication – web prototype testing and 2) Cross committee registries task force.

1. Patients and consumers involvement in EMA activities

1.1. Co-chair overview of 2015 for PCWP

David Haerry (co-chair) gave an overview of some key PCWP activities during 2015. He highlighted the introduction of the topic groups (more details below) which allow for more participation outside of the plenary meetings. He emphasised that it is an opportunity for organisations to become more involved and to put forward their suggestions and ideas within the respective topics which will then feed into the working party's activities.

David also spoke about the ongoing CHMP pilot project to involve patients in CHMP discussions; there have been three cases so far, however more examples are needed before a decision on the way forward can be made. The pilot will continue into 2016.

Finally David highlighted that the training day held the previous day, in which he participated, was an excellent training including a very rich and rewarding hands-on experience and it included many new engaged and professional participants from the different eligible organisations.

1.2. Overview of patient involvement at EMA during 2015

Nathalie Bere gave an overview of EMA's interaction with patients/consumers during 2015 (see presentation).

The analysis of patient involvement across the different activities within the Agency has again shown a consistently high level of collaboration between the EMA, patients, consumers and their organisations throughout 2015. Up to the end of November patients/consumers were involved on 687 occasions. There were some expected small fluctuations within the different activities year on year; however of note is the significant increase in the involvement within scientific advice /protocol assistance procedures.

Activities are categorised in three ways: 1) Activities in which patients/consumers are members, alternates or observers, 2) Activities involving individual patient/consumer experts and 3) Activities requiring organisation representatives. See the presentation for full figures and details.

After the presentation there followed several questions and comments from the members:

It was mentioned that there is perhaps no need to keep trying to find ways to evaluate patient input and rather consider it as a given.

There was a question regarding the ongoing pilot phase to involve patients in CHMP; specifically the criteria used as to when patients are invited and in what cases? – The EMA explained that the CHMP rapporteurs, together with EMA staff working on the dossier, discuss where there would be a benefit/need for input from patients. The PCWP CHMP member present highlighted that “we have scientific data but we need your personal experience and first-hand knowledge of the disease”.

Another member asked whether the involvement of patients in CHMP would only be for initial approvals, or could it also be for renewals or updates, especially as there have only been a limited number so far – The EMA replied that the pilot is not only limited to initial marketing authorisation applications, and in fact there was recently a case where patients were involved during the assessment for a proposed variation for an existing medicine. Patients can be involved during any of the CHMP assessments.

One member enquired if only 64% of the package leaflets sent out were reviewed does this mean that the remaining leaflets are not reviewed at all? – The EMA explained that unfortunately this is the case as the review time is limited, there is usually not enough time to send a leaflet to someone else, if it has not been reviewed by the initial person. For this reason it was emphasised that it would be very helpful if those unable to do a review could advise EMA staff as soon as possible. In addition it is recommended to recruit more experts within the organisations who would be available to carry out the reviews on the different EMA documents. The EMA is very happy to provide appropriate training to any new experts proposed.

It was asked whether a large number of package leaflets concern medicines for which there is the therapeutic area is not covered by any eligible patient organisations and thus perhaps not covered by any eligible patients’ organisations? - The EMA explained that for these medicines they are sent to the general patient organisations for review.

Another member explained to the group that within their organisation they have created a task force specifically prepared to respond to requests for review – this way they have a ‘pool’ and can ask who is available at that particular time.

1.3. PCWP work plan / Eligibility requirements reminder

Nathalie Bere explained that the draft PCWP work plan for 2016 would be adopted by the committees and then published on the website. She highlighted that 2016 marks the 10 year anniversary of the PCWP and that there will be some celebrations as well as an anniversary book. The Members were asked if they had any questions or comments on the work plan (which had been included in the pre-mail pack).

There were no specific questions as such, although one member enquired about the new PCWP mandate next year. The EMA explained that the mandate renewal will take place in June, along with the election of the co-chairs, and that more information on the procedural aspects will be provided early next year.

Nathalie then gave a short presentation reminding all members of the new eligibility criteria which will come into force in January 2016.

Isabelle reminded everyone to be aware of the details of these new criteria so as not to lose eligibility.

1.4. Feedback from PCWP topic groups

The action plan within the revised framework of interaction between the EMA, patients, consumers and their organisations foresees the establishment of several topic groups related to ongoing areas of interest. Five such topic groups were set up during 2014 and each of the topic leaders gave an update of progress so far.

1. Acknowledge and promote visibility of patient input in the Agency's activities (topic group leaders: Isabel Proaño (EFA) and Isabelle Moulon (EMA).

This topic group was created to explore how to raise awareness and visibility of patients/consumers work at the EMA, how to best acknowledge their input in the context of the activities of scientific committees, working parties, scientific advisory groups and other expert groups and consequently to make recommendations to the PCWP.

The group has had several teleconferences and, together with the co-leaders, decided to prepare a survey to get a better understanding of the current status and generate new ideas; the survey was distributed to the 13 topic group members.

On the basis of the outcome of the responses to the questionnaire, the topic group agreed on some preliminary recommendations on how both the EMA and the organisations can improve acknowledgement, recognition and promotion of patient input into EMA activities.

A work plan will be developed including priorities for implementing the recommendations and will be circulated to all members for their input.

2. Measure impact of patient involvement in EMA activities (topic group leaders**:** Kaisa Immonen-Charalambous (EPF) and Nathalie Bere (EMA)

This group was created to look at the impact and value of patients input in the work of the EMA, as well as the effect on the patients themselves. The aims are to explore EMA's current practices for evaluating and documenting the impact/value of patient input, and discuss whether there is a need to improve or expand and if so, are there other methods which could potentially be feasible to incorporate.

The group had several teleconferences and prepared an overview of the current EMA methods for capturing patient value/impact. Through an initial literature search the group is also looking at other methodologies for capturing the benefit/value of patient input. There have been discussions on the definition of patient impact, how and for which activities can impact be measured. The group will prepare an overview with potential recommendations, if any, in the first quarter of 2016, also taking into account other initiatives in this area (e.g. CIRS).

3. Involvement of young people in EMA activities (topic group leaders: Rafal Swierzewski (ECPC) and Nathalie Bere (EMA)

This topic group was created to identify existing youth groups within the EMA eligible organisations; and to create, within the umbrella of the PCWP, a wider EU "young person's network", and to identify areas and methodologies for the involvement of young people in EMA / PDCO activities and to establish a framework for involving young people.

The group had several teleconferences and contributed to the planning of an EMA 20th anniversary activity with the paediatric committee which took place on 7 October and included a young person (18 years) in a lunch panel discussion together with two youth group leaders and the chairs of both the PDCO and the PRAC. The event, attended by committee members and EMA staff, was a success and highlighted the need and benefit to involve young people in medicines development. This was a very useful event in paving the way forward for the Agency to establish a framework for involving young people in its work.

During their teleconferences the group also discussed how they could reach out within their organisations to try and locate patient youth groups within the EU. Discussions will continue in 2016 on areas of EMA's work where young people could be involved and setting up an appropriate framework to do so.

Rafal (co-lead) also highlighted that the aim is to include not only people living with a disease but also healthy young people who have a particular interest in health. Another member proposed that a short video of a young person explaining why they are involved would be useful to raise awareness and could be circulated using social media to reach out. It was also pointed out that it is important to understand young people's expectations for being involved.

4. Social media (joint with HCPWP) (topic group leaders: Donald Singer (EACPT), Ivana Silva and Maria Mavris (EMA)

This group was set up to map current practices in the digital world that are shaping clinical research and care and to raise awareness of how data and information related with real use of medicines is being collected and used for different purposes. Also how organisations can use their communication channels more widely to ensure easy, consistent and timely access to information on medicines and finally the group should identify topics and speakers for a PCWP/HCPWP workshop on social media to be organised in 2016.

Following some initial teleconferences it was suggested to carry out an scoping survey to gain a better understanding of social media usage among patient, consumer and healthcare professional organisations and how well EMA social media channels are known. The survey was distributed among all eligible patient/consumer and healthcare professional organisations, and the results will be discussed during a face to face meeting in December.

5. Training (topic group leaders: Richard West (Eurordis) and Maria Mavris (EMA)

This group was created to explore further training methods and tools for patients involved in EMA activities and to also look at synergies with other existing training initiatives. The group had several teleconferences and discussed creating an inventory of current initiatives that eligible organisations have created or participated in and explore possibilities to streamline provision of training (3 such initiatives were presented later in this meeting).

The group also discussed the content for the annual training day with all eligible organisations (25 November 2015) and agreed to launch a survey to gather information on the current EMA provision of training to patients and consumers involved in its activities followed by brainstorming on potential areas / ways to enhance EMA training tools / methodologies. The group will aim to prepare potential recommendations in the 2nd quarter of 2016.

1.5. Risk Management Plan (RMP) summaries - outcome of pilot phase

Juan Garcia (EMA) presented the outcome of the experience of a one-year pilot phase to prepare and publish risk management plan summaries (see presentation). The aim of publishing these summaries is to provide a new information resource and thus increase public access to relevant information on medicines, which complements other information on medicines such as the summary of product characteristics (SmPC), package leaflet, EPAR summary and product assessment report.

The pilot started in March 2014 and included all new medicines authorised since this time. Each summary is drafted by the EMA and incudes an overview of the disease & its epidemiology, a summary of the benefits and main safety concerns, important identified and potential risks as well as a summary of risk minimisation measures for each of the safety concerns and the planned post-authorisation development plan. The RMP is reviewed by the assessors within the relevant committee and the EMA staff and is then published at time of the medicine's authorisation.

To date 84 RMP summaries have been published and analysis has shown that there is interest in these documents and we can conclude that they are especially valuable to those requiring additional background to the package leaflet's safety information. Also as a live document, information will remain updated which would otherwise be fragmented or soon outdated.

The next steps will be to make some improvements to the current format and content and update the RMP summary template. Implementation will take place as of 2016, once new template is published.

Further research will be carried out to measure the uptake, acceptability and impact of RMP summaries by the different audiences.

Following the presentation there were some questions from the members, such as how the summaries will be updated when risk management plans are amended – Juan responded that every time there is an important change, the document will be updated, and there may well also be a safety communication, if felt necessary.

Another member asked whether the summaries will appear with 'google searches' – Juan explained that often the webpage of the EMA comes up and the RMP summary is within the EPAR page.

It was also asked whether patients would be reviewing the summaries, to which Juan responded that since patients will not be the main target audience of these documents, their review by patients will not be a priority and rather EMA will focus patient review on other lay-language documents such as EPAR summaries or safety communications.

1.6. Summaries of herbal monographs

Jill Kieffer gave a presentation on the new initiative to prepare and publish summaries of herbal monographs (see presentation). Most herbal medicines are authorised at national level in EU and the Herbal Committee (HMPC) was established to introduce a simplified registration procedure for traditional herbal medicines in EU Member States.

The HMPC prepares monographs (scientific opinions on herbal medicines), which comprise information on a herbal preparation (its therapeutic uses and a set of recommended safe conditions of use) that member states can then refer to when evaluating marketing applications for herbal medicines.

The format of the summary of a herbal monograph is similar to other documents for the general public, such as the EPAR summaries and summaries of orphan designation, etc, and the content is based on the adopted monograph and HMPC assessment report.

In the past, PCO representatives have highlighted the need for more information on herbal medicines adapted for the general public and expressed an interest in being involved in the preparation of this information. Involvement of patients and consumers in reviewing the herbal summaries is very much welcomed by the HMPC; it is expected that around 30 herbal summaries to be prepared per year and the timelines will be similar than those for reviewing PLs and EPAR summaries, i.e. 10 days.

After the presentation it was highlighted by one member that it is very important to provide information to the public about herbal products as they are often not aware of the potential interactions with other medicines, especially by classification of products. It was also asked whether it should be specific organisations to review the summaries, to which Jill emphasised that any of the members of the eligible organisations can participate in the review and which would be much appreciated. The idea would be to gather a pool of experts and then take it in turns to carry out each review, depending on workload. Another member highlighted that the interactions between herbal medicines and other medicines should be discussed between patients and their doctors and that this is something that could be discussed within the HCPWP (info on medicines and reporting of adverse drug reactions).

A call for expression of interest to participate in the review of herbal summaries will be sent out early in January.

1.7. Feedback from the Scientific Committees

- Daniel O'Connor, the representative from the Committee on Orphan Medicinal Products (COMP) gave an update to the group on recent COMP activities (see presentation).

The COMP is the committee at the EMA responsible for reviewing 'orphan-medicinal-product designations'. Sponsors of designated orphan medicines are eligible to benefit from certain incentives. Since the Orphan regulation came into force in 2000 to end 2014, there have been 2127 applications for designation and 1430 positive opinions. Orphan medicines often have to demonstrate a "significant benefit", i.e. that they provide a clinically relevant advantage or a major contribution to patient care.

There will be a workshop on significant benefit held on 7th December at EMA which will bring together industry, regulators, healthcare professionals, academia, patients, health-technology-assessment bodies with the aim to discuss and clarify with all stakeholders the concept of significant benefit, as well as the methodology and type of evidence required to support it.

The European Commission is currently revising its 2003 Communication on Orphan Medicinal Products - to be replaced by a Notice from the Commission. There is a period of consultation from 16 November 2015 to 15 February 2016: http://ec.europa.eu/health/human-use/orphan-medicines/developments/index_en.htm

- Concha Prieto, representative from the Committee for Medicinal Products for Human Use (CHMP), gave an update specifically regarding the ongoing CHMP pilot phase to involve patients in oral explanations during CHMP meetings. There have been 3 cases so far and Concha highlighted that we need to have more cases to be able to analyse the interaction and determine the best way forward in order to be able to gather patient input in the most useful way.

- Albert van der Zeidjen, the representative from the Pharmacovigilance Risk Assessment Committee (PRAC) gave an overview of their activities and highlighted that patients have been members of the committee since the committee started in 2012. He mentioned the recent referral procedure related to the hpv vaccine which received a lot of public interest and where many patients had been in contact with the PRAC representatives and the EMA. He emphasized the importance of having the support of the patients and healthcare professionals department in responding to such requests.

2. Training Topic Group: EU Patient-led training for patients

2.1. EUPATI

Jan Geissler, EUPATI Director, presented the European Patients' Academy: Overview & Status Quo (see presentation).

EUPATI is a Public Private Partnership within the Innovative Medicines Initiative Joint Undertaking and is a 5-year pan-European initiative launched in February 2012 comprising a multi-stakeholder consortium of patients' organisations, academia, NGOs and industry (33 organisations). It is coordinated by the European Patients' Forum, together with EGAN, EURORDIS and EATG.

The key objectives of EUPATI are to empower patients with education in key areas of medicines R&D by educating and training them with objective, credible, correct and up-to-date information on key elements such as discovery of medicines, Non-Clinical Testing and Pharmaceutical Development, exploratory and confirmatory Clinical Development, Clinical Trials, Regulatory Affairs, Medicinal Product Safety, Pharmacovigilance and Pharmaco - epidemiology and HTA principles and practices.

The education is targeted at different levels and has so far been translated into French, German, Spanish, Polish, Italian and Russian. All EUPATI material is under “Creative Commons License” and so can be copied, distributed, edited, remixed, and built upon, on a non-commercial basis. The learning includes Online self-learning, Face-to-face events and a Patient involvement forum.

The 1st EUPATI’s Patient Experts Training Course kicked off on 6 Oct 2014 with more than 200 Applications for 2 courses with around 50 trainees each, including patient advocates from 30 countries and 28 disease areas enrolled. These first course students will be graduating in December 2015.

Following Jan’s presentation one of the course participants in the meeting gave some very positive feedback from her experience in participating in the EUPATI course.

Another meeting participant asked whether there would be a possibility for a ‘speaker’ from EUPATI to go to patient organisations to provide short trainings – Jan explained that all of the material (presentations and course content) are freely available for use by patient organisations. EUPATI also has national platforms that could also provide assistance in this context.

2.2. EURORDIS Summer School

Virginie Hivert from EURORDIS gave an overview of the long-running ‘Summer School’ patient training program which they have been organising each year since 2008 (see presentation).

EURORDIS designed this training program specifically to help build capacity for patients to engage along the product development life cycle. The program consists of an annual 4 day face-to face meeting which includes plenary/formal lectures, small groups sessions, round table discussions and practical exercises (‘mock’ COMP & SAWP, review of product information, etc.), coupled with online training (quizzes, video recordings, webinars).

The content covers evidence-based medicine, clinical research, clinical trial methodology, ethics, statistics, regulatory principles & processes in the EU, the EMA, HTA appraisal, pharmacovigilance, etc as well as highlighting opportunities for patient involvement. The content is continuously adapted and updated to ensure it is in line with current regulation and processes.

So far more than 250 patient representatives have been trained, from 33 different countries, representing more than 75 diseases and since 2015 some academics have also joined on the course. This new version is called ExPRESS for Expert Patients and Researchers EURORDIS Summer School.

2.3. European Patient Ambassador Programme (EPAP)

Kerstin Morrison, from the European Patient Forum (ELF) gave an overview of their patient ambassador programme (EPAP) (see presentation).

EPAP started three years ago when ELF, together with the National Institute for Health Research (NIHR) Collaborations for Leadership in Applied Health Research and Care (CLAHRCs), and patient representatives, developed the programme to improve patient involvement in their own treatment and care, as well as in research, health policies and conferences. An advisory board, consisting of healthcare professionals and patients, was set up to ensure the design and information was correct and appropriate. After the inception of EPAP a Patient Advisory Group was formed to drive the progress of the programme.

The programme is not only for those affected by a lung condition, but for anyone affected by a chronic condition. The programme aims to provide people with knowledge on how to find more information about their condition, understand how decisions about healthcare are made, recognize key terms, be more confident in exploring their ideas and identifying the best ways to achieve their aims, have the knowledge to interact with professionals, politicians and the media, and be ready to take part in activities such as input into guidelines, research projects, speaking at conferences, and explain their concerns to policy makers and the media.

The programme is currently available in English and Dutch but with further translations planned (hopefully Italian in spring followed by 2 per year). It is based online, within its own website, in the form of an interactive, modular system which is flexible so that people can choose their interests and can stop and start when convenient. The programme is about 10 hours in total and a certificate is issued at the end of each completed module.

Anyone who has completed the programme then becomes a patient ambassador and has access to the EPAP LinkedIn forum. ELF posts opportunities for patients to get involved as well as articles of interest on patient involvement across Europe. So far 450 people have registered on the program (it is not clear how many have finished the full program).

After the presentation one of the members suggested that perhaps other patient organisations could contribute to the translations of the modules into the different languages to which Kerstin responded that it would be a great help.

The co-chair Isabelle highlighted that these are both great examples of capacity building programs for patients and if any other patient organisations have, or know of, similar programs it would be good to present them at future PCWP (and HCPWP) meetings.

3. Patient involvement in national agencies

3.1. Survey to national competent authorities

Maria Mavris presented an overview of a survey that was developed by the EMA, in collaboration with the PCWP and the member states 'Working Group of Communication Professionals', which was circulated to all EU medicines agencies in February/March 2015 (see presentation).

The aim of the survey was to gather information on how the different agencies work with patients and patient organisations, on the kinds of activities and the requirements in place for such interactions.

The following countries completed the survey: Czech Republic, Denmark, Finland, Germany, Greece, Hungary, Ireland, Liechtenstein, Lithuania, Portugal, Romania, Slovakia, Spain, The Netherlands and UK.

Overall the results showed that although different agencies were at varying stages in terms of their level of interaction with patients, almost all Agencies felt involving patients was beneficial to their work and that more mutual trust, training on understanding of regulations, resources and experience are needed to further build on the current interactions.

The results were shared with the working group of communication professionals in June 2015.

After the presentation several members shared their views and experience of their involvement at national level and highlighted that this is a progressive journey and that headway has been made and patients are becoming more and more involved in their local agencies.

One member also reminded the group that a template letter of introduction prepared by PCWP members is available for use by patient organisations to approach national agencies.

3.2. Swedish Medicines Agency proposals for patient engagement

Lina Ring from the Swedish Medicines Agency gave a presentation on their plans to move forward with patient engagement (see presentation).

Lena explained that in 2009 they had created a patients' council which mainly focused on the dissemination of information however this was not so well attended, due to the fact that the time taken to attend meetings purely for the purpose to receive information did not represent much added value.

They recently carried out an internal survey to ask the different departments within the Agency their view on the usefulness of patient involvement and the response was a unanimous agreement that it is valuable.

Although the Swedish Agency does interact with patients they do not currently have an advisory board or a working party of patients that works across the agency for a more structured involvement and this is something that Lena will suggest in her report after her visit as observer to this PCWP meeting. The aim is to focus more on a partnership and not only on dissemination of information.

4. A.O.B

4.1. Clinical Data Publication

Frances Nuttall addressed the group and asked for volunteers for “user testing of the Clinical Data Publication Website Prototype”.

In October 2014, the Agency published its policy on publication of clinical data: European Medicines Agency policy on publication of clinical data for medicinal products for human use.

Under this policy which entered into force on 1 January 2015, the Agency will proactively publish the clinical reports submitted as part of marketing-authorisation applications. The adoption of the policy followed extensive consultations by EMA with patients, healthcare professionals, academia, industry and other European entities.

A targeted user survey was carried out in June 2015 and now the focus is on the design of website, together with a design company who will create a click through prototype of the main web pages.

The User testing is scheduled to take place over 2 days in February 2016 at the EMA offices (travel/accommodation will be covered) and the EMA is looking for 5 Patients and 5 healthcare professionals to take part.

Participants were asked to register their interest to take part in the user testing by 18 November.

4.2. Cross committee registries task force

Christoph Thalheim from EMSP gave an update on the Cross-Committee Task Force on Patient Registries.

The task force was set up in 2014 to develop and support the EMA initiative on patient registries; it includes representatives from EMA committees and working parties, the European Commission and national competent authorities. The main objective is to facilitate the use of existing patient registries and the establishment and utility of new registries if none are available, in order to collect and analyse high quality data informing regulatory decisions.

There are two components: a strategy on registries (based on PARENT guidelines) and a pilot phase to test whether this strategy better supports MAAs/MAHs to meet regulators' (and potentially other stakeholders') needs for data and information. Currently there are four proposed medicines being discussed for the pilot to be done by the Task Force (lentiglobin, ravicti, immunocore and strimvelis).

"PARENT" (PAtient REgistries iNiTiative) is a joint EU and Member States response to poor cross-border availability of health data for public health and research. PARENT brings added value by providing Member States with recommendations and tools for implementation of interoperable and cross-border enabled patient registries.

The two main "ready-for use" outcomes of this Joint Action are the so-called "Register of Registries" and the "Methodological Guidelines and Recommendations for Efficient and Rational Governance of Patient Registries" See the website for more details: http://patientregistries.eu/general-info.

Christoph would also like to see a drug from the MS field to be included in the pilot phase, as the existing European Network of MS Registries (EUReMS) would provide an excellent opportunity for the development of a model of regular cooperation between such (disease specific) networks of registries, MAAs/MAHs and the EMA, with valuable learnings to be expected beyond the Multiple Sclerosis specifics.

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

Close of meeting

Next PCWP meeting: 9 March 2016