22 June 2017
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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

15 March 2017 – 08:30hrs to 16:30hrs, meeting room 3E

Role	Name
Co-chairs:	Isabelle Moulon (EMA), Kaisa Immonen (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 Federation of Neurological Associations (EFNA); European Heart Network (EHN); European Institute of Women's Health (EIWH); European Multiple Sclerosis Platform (EMSP); European Organisation for Rare Diseases (EURORDIS); European Patients' Forum (EPF); 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); Myeloma Patients Europe (MPE); Patients Network for Medical Research and Health (EGAN) **HCPWP members**: European Academy of Neurology (EAN);European Academy of Paediatrics (EAP); European Association for Clinical Pharmacology and Therapeutics (EACPT); European Association for the Study of Diabetes (EASD); European Association of Hospital Pharmacists (EAHP); European Association of Urology (EAU); European Federation of Internal Medicines (EFIM); European Forum for Primary Care (EFPC); European Hematology Association (EHA); European Society for Medical Oncology (ESMO); European Society of Cardiology (ESC); European Society of Endocrinology (ESE); European Society of Radiology (ESR); European Union Geriatric Medicine Society (EUGMS); 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

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Role	Name
	Advanced Therapies (CAT); Committee on Herbal Medicinal Products (HMPC); Committee for Medicinal Products for Human Use (CHMP); Committee for Orphan Medicinal Products (COMP); Paediatric Committee (PDCO); Pharmacovigilance Risk Assessment Committee (PRAC) **Observers from eligible organisations**: European Network of Fibromyalgia Associations (ENFA); European Society of Oncology Pharmacy (ESOP); Global Alliance for Mental Illness Advocacy Networks (GAMIAN-Europe); International Bureau of Epilepsy (IBE); European Lung Foundation (ELF) **Observers from IPA**

Introduction

I. Moulon (EMA) welcomed all participants. She announced that this was her farewell meeting as co-chair of both PCWP and HCPWP, following many years of rewarding efforts. She praised the energy and determination of the working parties and the continued challenges they have given to EMA as an engine for moving step by step towards further engagement with patients and healthcare professionals and to open up more and more, becoming what she considers to be today a unique space for dialogue and transparency on the Agency's work. She was also pleased to inform that J. Garcia Burgos was nominated by the Executive Director to serve as the new EMA co-chair of the working parties from March onwards.

No conflicts of interests were declared in relation to the agenda items.

The agenda was adopted with two additional points to be covered under A.O.B.: Slovak presidency conference on shortages of human medicines in the EU and EMA communication perception survey.

1. Involvement in EMA activities

1.1. EMA preparedness on Brexit

N. Wathion (EMA) started by thanking I. Moulon for all the activities she has undertaken over the past 20 years in her different roles at the EMA and for the many successes with engaging patients and healthcare professionals in the Agency's activities.

He then gave an update on the EMA preparedness activities following the outcome of the UK referendum, which takes into account the 2-year timeline for finalising negotiations after the triggering of Article 50. He stated that EMA has no influence in the decision of moving to another member state as this will be a political decision; nevertheless the Agency has a responsibility to provide information to support an informed decision and as such has provided the European Commission with a list of prerequisites to ensure continuity of EMA operation.

Members expressed a number of concerns in relation to possible disturbance to the Agency's work and its public health mission. They voiced an expectation for EMA experts, including patients and healthcare professionals, to continue to have favourable conditions to attend meetings and that EMA will be able to retain its staff and minimise operational disruption.

The EMA will continue to update members on a regular basis at the PCWP/HCPWP meetings.

Post-meeting note: a webpage '[UK's withdrawal from EU]' has been added to the EMA website.

1.2. EMA interaction with patients, consumers, healthcare professionals and their organisations – Annual report 2016

N. Bere (EMA) and I. Silva (EMA) summarised the work carried out throughout 2016 by patients, consumers, healthcare professionals and their organisations that contribute to sustaining and consolidating interactions with EMA. They reported on key figures and highlighted some of the achievements for the year (see presentations). They noted that an overall increase of cases of interaction over the years continues to be registered; however these are dependent on the number and type of activities that take place throughout the reporting years.

The year was marked by the 10th anniversary of the PCWP, the beginning of the new mandates for both working parties (covering the period 2016-2019), elections for each working party co-chairs and the approval of a new structure for the work plans for the working parties to encompass a longer term vision that takes into consideration the EU medicines agencies network strategy to 2020 and the EMA multiannual work plan.

Other highlights of the year included the endorsement by the EMA's Management Board of a revised framework of interaction with healthcare professionals, the establishment of an expert group with general practitioners/ family physicians as well as the creation of a pool of individual patient experts to ensure participation throughout the lifecycle of medicines and the conclusion of the pilot to include patients in plenary meetings of the CHMP.

The findings of the satisfaction survey that EMA undertakes every two years with patients and healthcare professionals involved in EMA activities were also presented (see presentation).

A detailed annual report, including the findings of the satisfaction survey, is expected to be published in June.

Members welcomed the work undertaken over the year with some participants expressing their view that there was still room for improvement in relation to further detailing on the impact of the input provided by patients and healthcare professionals in EMA activities. I. Moulon clarified that 'impact analysis' in this field is complex. However, wherever possible, the annual report provides detail on how the involvement of patients and healthcare professionals has contributed to a particular EMA activity.

Members called for a continued effort to improve activities beyond face-to-face meetings and that interactions between members of the working parties outside meetings should be encouraged as much as possible.

Some participants were also interested to learn more about the annual EMA training day and follow up activities; a follow up on this topic will be provided at an upcoming meeting.

Post-meeting note: the 2016 Annual Report of EMA interactions with patients, consumers, healthcare professionals and their organisations was published on the EMA website.

1.3. Topic Groups update

I. Silva (EMA) updated members on topic group-related activities (see presentation). She outlined the key milestones and outcomes of the topic groups started in 2015. Most of these have concluded their activities and a consolidated report, including all the recommendations adopted by PCWP and HCPWP during that period is expected to be published as a complement to the EMA 2016 report on the interaction with patients, consumers, healthcare professionals and their organisations.

One ongoing topic group is that for the involvement of young people in Agency activities, where guidelines are currently being approved by EMA management to enable the involvement of young

people in EMA activities. Another ongoing topic group will see its scope enlarged in 2017 from social media to digital media and health, in order to also encompass developments in mHealth and real-world evidence.

The experience gained since 2015 shows that the topic groups have been a very helpful way to engage with all EMA eligible organisations in the margin of the working parties meetings in order to exchange and discuss on issues of common interest. Nevertheless, it is acknowledged that these are resource intensive for all involved and may not be suitable for all types of topics. When considering the establishment of novel topic groups it is recommended to first explore synergies with other existing structures/ activities within EMA to avoid work duplication. The uptake of new topic groups should be accompanied by well-defined tasks with outcomes to be achieved within an agreed period of time and where commitment from both the organisations and EMA is feasible.

Early in the year, a number of topics were proposed by working party members. These will be further discussed during the June meeting in the wider context of planning the working parties' activities for the period 2018-19.

Post-meeting note: the consolidated report on the activities of topic groups established in 2015 was published on the EMA website.

1.4. Recommendations on:

- ***Social Media***

The recommendations from the PCWP/HCPWP topic group on social media were adopted.

- ***Risk Minimisation Measures***

The recommendations from the HCPWP topic group on risk minimisation measures were adopted.

1.5. CHMP Pilot project outcome & other methodologies

N. Bere (EMA) presented the outcome of the pilot project to involve patients in CHMP oral explanations (see presentation). The project to involve patients in discussions on the benefits and risks of medicines is in line with the work programme of the CHMP, which recommends a further integration of patients' views in the assessment of benefits and risks of medicines. It also reflects the Agency's continued emphasis on stakeholder involvement. During the pilot, which ran from September 2014 to December 2016, patients participated in discussions at the CHMP and gave their views on the benefits and risks of six medicines.

The outcome of the pilot is that patients should continue to be invited to oral explanations when their input could be valuable to the assessment of a medicine. This could be the case, for example, when the committee is considering whether to recommend the authorisation of a new medicine or the maintenance, suspension or revocation of an existing authorisation, or a restriction of indication of an authorised medicine.

C. Prieto (CHMP) added that the committee is working towards identifying as early as possible those medicines under evaluation for which an oral explanation with patient involvement would add value to informing the CHMP benefit/risk discussion.

Following the positive outcome of the pilot, the committee also discussed and agreed on the use of additional methods to provide opportunities for more regular involvement, such as inviting patients to

participate in CHMP discussions by teleconference, or by the use of written consultations, which would allow for input outside CHMP meetings and could provide feedback from a larger number of patients.

H. Sundseth (EIWH) and F. Houyez (EURORDIS) also provided their perspectives as the PCWP mentors for the patients participating in the CHMP oral explanations. They reflected on whether there was a need to maintain mentors for patients that had already participated in other EMA procedures and the importance of using a broad toolkit to support training for EMA-naïve patients.

Post-meeting note: the outcome report on pilot to involve patients in benefit/risk discussions at CHMP meetings was published on the EMA website.

1.6. Work-plans 2018/19

I. Silva (EMA) briefly recapped the new structure of work plans to be applied for 2016-2019, which is organised around the themes and objectives of the EMA multiannual programme to 2020. In order to promote a two-year planning covering both 2018 and 2019, it was suggested that the drafting process for the work plans should take into account PCWP/HCPWP work, i.e. workshops, information sessions and topic group recommendations, and consider a horizon scanning with members to identify one or two themes to concentrate upon during each year. In addition, it could be considered to pre-identify topics to be addressed by working parties' members during face-to-face meetings.

Members welcomed the two-year planning process with some participants strengthening the importance of allowing sufficient time for organisations to discuss and identify topics of interest which would align their own priorities with those of EMA. Topics around access to medicines, including interaction with HTA bodies, shortages and general availability of medicines, and repurposing of medicines were proposed as some to be covered in the planning.

Considering the many common areas of work, and following a similar approach as that used for the annual report, it was suggested to develop a single work plan covering both PCWP and HCPWP. A first draft should be circulated for comments prior to the PCWP/HCPWP meeting in June.

2. Antimicrobial Resistance

I. Moulon (EMA) explained that antimicrobial resistance was one of EMA's priorities. This was therefore reflected in the PCWP/HCPWP work plan for 2017, which included organising a dedicated information session in September. The session will be jointly prepared between EMA and European Centre for Disease Prevention and Control (ECDC). The European Antibiotic Awareness Day (EAAD) will be one of the topics covered during the session. As preparatory work for EAAD 2017 is already underway, ECDC was invited to introduce the concept behind the campaign and provide a more detailed insight of how interested PCWP/HCWP members could get involved, in advance of the September session.

2.1. European Antibiotic Awareness Day (EAAD)

D. Monnet (ECDC) gave a presentation on the European Antibiotic Awareness Day (EAAD) (see presentation). This is a European health initiative across Europe taking place annually on the 18th of November to raise awareness and promote prudent use of antibiotics. The campaign builds on successful national campaigns to raise awareness about the threat to human health of antibiotic resistance and communicate about prudent antibiotic use. EAAD was launched in 2008 with support from the European Commission, European Parliament, EU Member States and non-governmental health stakeholders across the EU. Since then, ECDC has been focusing on the following targets – general public, and in particular parents of young children (2008), primary care practitioners (2009),

hospital prescribers (2010) and self-medication with antibiotics (2014). In 2017 the campaign will re-focus on hospitals with a new toolkit for healthcare professionals in hospitals and other healthcare settings that will soon be launched (Post-meeting note: the toolkit was launched for use by EU Member States on 15 May).

Dr Monnet explained the several ways organisations wanting to contribute to EAAD in 2017 could become engaged. These include, among others, shooting a video pledge, promoting EAAD to national member organisations, promoting participation in global Twitter activities, re-tweeting and sharing messages posted by ECDC on Facebook before EAAD, adding a banner on the organisation's website and communicating on EAAD via the organisation's newsletter.

A number of organisations expressed an interest to become involved and were encouraged to liaise directly with ECDC.

3. Biosimilars

3.1. Action-plan on Biosimilars

A. Hidalgo-Simon (EMA) emphasised that evidence acquired over ten years of clinical experience shows that biosimilars approved through EMA can be used as safely and effectively in all their approved indications as other biological medicines. Nevertheless, it is important to ensure experience gained is shared as widely as possible. Equally important is to ensure feedback on the use of biosimilars to be continuously collected and appropriately taken into account. Therefore communication and engagement with stakeholders are key pillars in EMA's action-plan on biosimilars and the next two agenda items illustrate such commitment.

3.2. Biosimilars Working Party (BMWP) meeting with interested parties

C. Vleminckx (EMA) presented a proposal to organise a dedicated session with patients' and healthcare professionals' representatives during the September BMWP meeting, at the margin of the PCWP/HCPWP meeting. The aim is to discuss with stakeholders topics of mutual interest with a view to share experiences and identify areas for future collaboration and focus.

There was a very positive reaction from members. To further prepare for the meeting, members were asked to express interest and identify topics to be addressed in writing.

3.3. Communication plan on Biosimilars

R. Gonzalez-Quevedo (EMA) presented on the planned activities, as a joint effort from the European Commission (EC) and EMA, to explain the EU biosimilar concept to different audiences. Overall, the intention is to foster:

- Understanding of what biosimilars are and how they are developed and approved;
- Confidence in the use of biosimilars, as for all medicines approved by EC via EMA in the EU;
- Trust in the robustness of the regulatory system for approval of biosimilar medicines in the EU;
- Consistency in public health messages on biosimilars across the EU.

The first deliverable is a guide for healthcare professionals (HCPs), developed with contributions from scientific experts from the EU Member States and from EU healthcare professional organisations. The guide will be launched at the EC workshop on 5 May 2017.

I. Silva (EMA) complemented the presentation with a proposal for joining efforts to coordinate communication around the guide. Members welcomed the initiative to prepare such a guide and agreed with the proposal for coordinating communication at the time of the guide's launching.

Post-meeting note: the information guide for healthcare professionals was published.

3.4. EC stakeholders workshop

H. Juhász (EC/ DG GROW) outlined the work developed by the EC since 2010 to define the necessary conditions for an informed uptake and adequate patient access to biosimilars (see presentation). She also provided details on the EC's multi-stakeholder workshop on biosimilar medicinal products, scheduled for 5 May 2017, in Brussels.

DG GROW would welcome wide participation of PCWP/HCPWP members. Members were encouraged to contact directly DG GROW for expressing their interest.

4. Conditional Marketing Authorisation

4.1. 10 year report

This agenda item was postponed to the June meeting due to time constraints.

5. EU initiatives on HTA

5.1. EMA activities related to synergies between regulators and HTA bodies

M. Berntgen (EMA) provided an overview of EMA's activities related to synergies between regulators and health technology assessment (HTA) bodies (see presentation). He indicated the reference points for exploring synergies. These include, on a more strategic level, the HTA network reflection paper on "synergies between regulatory and HTA issues on pharmaceuticals", issued on 10 November 2016. On the scientific and technical cooperation levels, the EUnetHTA Joint Action 3 and the EMA/EUnetHTA collaboration (in place since 2010) provide the basis for concrete interaction.

The objective of the EMA-EUnetHTA collaboration is to identify and undertake specific steps to improve the efficiency of the processes and conditions for patients' timely access to an effective medicine. The area of scientific advice/early dialogue involving regulators and HTAs is the one that is currently most developed since it started in 2010. Initial data for 2017 counted already 21 requests for parallel EMA/HTA scientific advice. For all discussion meetings the involvement of patients is facilitated. Other examples of areas for ongoing or expected collaboration include the PRIME (PRIority-MEdicines) scheme, the exchange at time of market entry and post-licensing data generation.

A discussion followed where members emphasised the importance of including patient engagement as a domain for synergies between regulators and HTA bodies. In this context, members requested EMA to explore a possible meeting with relevant EUNetHTA working package leaders at the margins of a PCWP/HCPWP meeting.

6. Committee feedback

6.1. Committee for Medicinal Products for Human Use (CHMP)

F. Ventura (CHMP) highlighted CHMP opinions and provided some statistics on scientific advice/protocol assistance as well as on PRIME eligibility covering the period October 2016-February 2017 (see presentation).

6.2. Committee for Orphan Medicinal Products (COMP)

D. O'Connor (COMP) described how sponsors who obtain orphan designation benefit from protocol assistance, market exclusivity and fee reductions and provided an update on the status of orphan designations at end of 2016 (see presentation). He also referred to the report of the EMA workshop on patient registries, published in February 2017. Finally he outlined key areas emerging from the COMP workshop on the review of applications for orphan designation and how the COMP 2017 work plan will be addressing the development of strategies to implement recommendations stemming from this workshop when assessing orphan designation applications.

6.3. Committee for Advanced Therapies (CAT)

K. Breen (CAT) provided some statistics on CAT procedures and PRIME eligibility for ATMPs (see presentation). He also highlighted other CAT activities planned for the year, such as the revision of the guideline on quality, non-clinical and clinical aspects of medicinal products containing genetically modified cells, a reflection on the Benefit-Risk assessment of ATMPs, and a CAT discussion on the use of registry data for the approval and post-marketing follow-up of ATMPs (with cross-committee Patient Registry Initiative).

6.4. Committee on Herbal Medicinal Products (HMPC)

S. Bager (HMPC) reported on the start of patient involvement in committee meetings and the positive feedback received.

6.5. Pharmacovigilance Risk Assessment Committee (PRAC)

A. van der Zeijden (PRAC) drew attention to the ongoing safety referral on retinoid medicines to evaluate measures currently in place for pregnancy prevention and for minimising the possible risk of neuropsychiatric disorders. In the context of this review, PRAC adopted a list of questions for a targeted meeting with patients and healthcare professionals (HCP) in January 2017. The meeting was then organised on 3 March 2017, with patients' organisations and healthcare professionals who work in the area of psoriasis, acne and women's health. The participants expressed their views as regards a PRAC list of questions on how to improve awareness, understanding and compliance with retinoids' pregnancy prevention programme. The outcome of the meeting will be reported back to the PRAC in May 2017 to feed into the review and contribute to the PRAC recommendation later in 2017.

He also highlighted that in early March, a new review of valproate use in pregnancy and women of childbearing age was started. PRAC will consider if risks of these medicines require further restrictions of use, will examine the available evidence and will consult with relevant stakeholder groups. This will include holding a public hearing.

6.6. Paediatric Committee (PDCO)

J. Taminiau (PDCO) reported on a discussion to build up a pool of experts available for issues related to Paediatric Investigation Plans (PIP's) and how Enpr-EMA and the HCPWP could support the process, particularly for extremely rare treatment issues in rare conditions or adult diseases extremely rare in children. He also shared some reflections on the possible evolution of paediatric disease databases and suggested this could be a potential topic of common interest for PCWP and HCPWP.

7. Members voice: sharing practices

7.1. Twitter use training

K. Plass (EAU) presented on EAU's training for their members on Twitter use (see presentation).

8. A.O.B

8.1. Conference on medicines shortages

F. Houyez (Eurordis) reported on the conference "Shortages of Human Medicines in the European Union", organised by the Slovak Presidency of the Council in November 2016 (see presentation). It was agreed to allocate appropriate time for discussing the topic of shortages (and availability of medicines more generally) at the PCWP/HCPWP meetings in June.

Members interested to discuss a revision of the Common Position on Shortages, patients, consumers and healthcare professionals are encouraged to contact directly Mr Houyez.

8.2. EMA Communication Perception Survey

E. Scanlan (EMA) presented the second edition of this survey (see presentation). The survey aims to:

- Obtain representative, quantitative, qualitative and credible feedback about EMA's communication activities from its partners and stakeholders in the EU and elsewhere,
- Identify communication challenges and opportunities that can feed into the development of EMA's future communication strategies and annual work plans, and
- Build on the baselines established by the 2015 survey and compare results from 2015 and 2017 to measure trend and impact of EMA's communication strategies.

Members will be contacted during the second half of April, upon the survey's launch.

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

Close of meeting

Next PCWP/HCPWP meeting: 27-28 June 2017