28 February 2017
EMA/801985/2016
Stakeholders and Communication Division

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

30 November 2016 – 08:20hrs to 16:45hrs, meeting room 3E

Role	Name
Co-chairs:	Isabelle Moulon (EMA) and 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 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 Patient Organisation for Primary Immunodeficiencies (IPOPI); Myeloma Patients Europe (MPE); Patients Network for Medical Research and Health (EGAN) **Representatives from patient and consumer organisations**: European Haemophilia Consortium (EHC); European Liver Patients Association (ELPA); European Lung Foundation (ELF); European Network of Fibromyalgia Associations (ENFA); International Bureau of Epilepsy (IBE); Thalassaemia International Federation (TIF); United Parent Projects Muscular Dystrophy (UPPMD) **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) **European Commission:** DG Sante **Observers**: EMA Management Board; Healthcare Professionals' Working Party (HCPWP); Medicines and Healthcare Products Regulatory Agency (MHRA)

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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 no additions.

1. Election of PCWP co-chair

1.1. PCWP co-chair election proceedings

The election proceedings started once the quorum of 18 members was confirmed. There were 19 voting members in the room, including EMA who abstains to avoid conflict of interest.

N. Bere (EMA) presented the election procedure (see presentation).

All potential candidates had been requested to send their expressions of interest, together with a letter of motivation prior to the meeting and four candidatures were received: V. Cursaru, from the Myeloma Patients Europe (MPE), K. Apostolidis, from European Cancer Patient Coalition (ECPC), K. Immonen from the European Patients' Forum (EPF), and F. Houyez, from European Organisation for Rare Diseases (EURORDIS).

The election took place by secret ballot.

Kaisa Immonen was elected as the new PCWP co-chair with a majority of 14 out of 18 votes.

2. Next steps for public engagement

2.1. Looking towards 2020

Melanie Carr (Head of Stakeholder and Engagement) presented an overview of the Agency's overall engagement strategy; looking towards 2020 (see presentation). Some highlights include the EMA Stakeholder Relation Management Framework setting out the fundamental principles of all stakeholder interaction adopted in June 2016 and also the EU Medicines Agencies Network Strategy to 2020, which is a joint EMA and Member State high-level vision to 2020, outlining the joint key strategic priorities for the coming years and which is complemented by specific multi-annual work plans.

Melanie also presented the vision for the European Medicines Web Portal which aims to make available free, reliable, unbiased online information on medicines for patients, consumers, carers, healthcare professionals and academia across the EU on all authorised medicines in Europe.

2.2. PCWP topic groups

An update was given on all the PCWP topic groups which were established in 2015 (see presentation).

Maria Mavris started by highlighting the recommendations and actions stemming from the group on training; these included a revision of the EMA Training Day, an updated questionnaire for training feedback, revamped webpages/information and the introduction of EMABasics (voice over presentations on specific topics). These recommendations were endorsed in March 2016 and this group will close to be re-assessed in one year time.

Nathalie Bere then provided an update on the group looking at the impact/value of patient input within EMA activities; this group reviewed the current EMA methods for capturing patient value/impact and looked for potential additional/alternative methods. The overall recommendations suggested that the *impact* of patient involvement in EMA activities should be viewed from a holistic viewpoint (not individuals' impact) and be considered as 'added value' rather than 'impact'. It was also concluded following a review of the literature that there are no other suitable methods available to evaluate the value of input (for use within EMA), however a revision of the questionnaire on feedback on involvement within scientific advice procedures was revised and its potential usefulness within other activities (e.g. SAG meetings) will be analysed. The recommendations (as detailed within the outcome report) were for endorsement (included in pre and post-mail). The group will also close and be re-assessed in one year's time.

The next topic group, presented by Nathalie Bere was related to the involvement of young people in EMA activities; the group has prepared "Rules of Procedure" (guidance) to establish methods for involving/consulting young people within EMA activities associated to the development of paediatric medicines. This guidance is currently being discussed at EMA management level. The group also created a list of youth groups within the EU via the eligible patient/consumer organisations which it hopes to further extend. The work of the group is in collaboration with Enpr-EMA and the PDCO. The group will feed back as it progresses.

Ivana Silva then presented an overview of the work of the topic group on social media; the group first carried out a scoping survey among EMA eligible organisations to understand social media usage and how well EMA social media channels are known. It also provided input to the PCWP/HCPWP workshop on Social Media in September 2016. Recommendations for the group are in preparation and the work will continue with wider focus on digital media and health; and in fact the group will be renamed Digital media and health and its respective terms of reference/composition to be updated accordingly.

Isabelle Moulon presented the work of the group tasked with exploring how to raise awareness and visibility of patients/consumers input in the context of the activities of scientific committees, working parties, scientific advisory groups and other expert groups. The group focused on how to improve acknowledgement and promotion of patient input into EMA activities by EMA and also by the organisations. The recommendations from the group were presented at the meeting in November 2015, and Isabelle now gave an overview of the implementation plan (see presentation).

After the presentations, EMA then suggested several new topic groups: Personalised medicines (preparations for workshop in 2017), antimicrobial resistance - AMR (preparations for info-session in 2017), Health literacy and Biosimilar medicines.

This followed with some participants also suggesting new topic groups such as: qualification process, pharmacovigilance, synergies between EMA and HTA, women and gender health, older people, compassionate use programs, biomarkers, PROs / real world data, reporting adverse reactions, repurposing of medicines.

The EMA requested that all members who suggested new topic groups to provide an outline of the topic including objectives, aims and actions, by 15 January 2017.

A list of new topic groups will be circulated once finalised for members to express interest to join specific groups.

2.3. Public hearings

Nathalie Bere (EMA) gave an update on the introduction of public hearings at the EMA. The legal basis for holding public hearings is linked to the Pharmacovigilance Risk Assessment Committee (PRAC) legislation and as such it can convene a public hearing the context of certain safety referral procedures (Article 20, Article 31 or 107i).

The "Rules of procedure on the organisation and conduct of public hearings at the Pharmacovigilance Risk Assessment Committee" are published on the EMA website in all EU languages.

When a hearing is convened, the public will be invited to participate and express its views, guided by a pre-defined set of questions; Participation will be as observers or speakers.

In order to be ready for the public hearings, which are a new activity for the Agency, held a 'dry run' in July to prepare for possible scenarios and fine-tune the process. The overall conclusions and feedback confirmed that processes put in place generally worked well; and subsequently guidance for both the public and for the PRAC members/EMA staff has been prepared. The EMA/PRAC is now ready to hold public hearings whenever there will be a suitable occasion.

2.4. Presentation of anniversary collection

Maria Mavris gave an overview of the variety of materials that have been prepared to celebrate the 10th anniversary of the PCWP.

The working party had a dedicated meeting on 14 June 2016 to start the celebrations. This meeting reflected on how the involvement of patients in EMA activities has evolved since the creation of the Agency and discussed future priorities and challenges.

For more information, read the report on the 10th anniversary celebration and the presentation where the original PCWP members describe the highlights and challenges of the past 10 years.

In addition, two anniversary publications were also prepared; in the first the working party members reflect on how, starting from a blank page, EMA and patients and consumers were able to design their own vision for working together. The second highlights how PCWP quickly recognised the importance of working with the healthcare professionals and a framework of collaboration with academia is also underway: 1) When patients and consumers join forces and 2) When healthcare professionals came to the (working) party.

2.5. Patient interaction with consumers

Francesca Cattarin (BEUC) gave a presentation on how patients and consumers have evolved working together over the past 10 years within the PCWP (see presentation). She highlighted that even though patients and consumers may have underlying different approaches and experience, at the end of the day they both represent the interests of all European citizens within health policy and regulatory decisions. Additionally over the years they have also both been able to directly interact together, with the Agency and also within other groups, to gather information and exchange views, follow trainings, include the voice of patients and consumers at EMA, provide input on general issues and real life experiences which has ultimately increased legitimacy for EMA input and outputs.

Yves Brandt (EMSP) also supported Francesca's presentation with some words from Christoph Thalheim as this topic had been prepared by both organisations.

2.6. Next steps for patient/consumer engagement

Nathalie Bere (EMA) highlighted some of the key ongoing and future activities (see presentation), such as increasing the network of individual patients interested to work with the Agency via the new individual expert database and its outreach. She also mentioned the recent work to establish a framework for the Agency to also consult with young people (under 18 years of age) whenever appropriate regarding medicines for paediatric use. The initiative of 'Members Voice' will continue in order to give further opportunities for organisations to share their initiatives within the PCWP meetings. Practices are in place to hold public hearings whereby the public can give their input to certain PRAC safety procedures and the Agency looks forward to holding its first public hearing in 2017. There will also be some future discussion regarding the PCWP structure as well as streamlining the review of eligibility of organisations. Finally Nathalie mentioned the ongoing work looking at alternative methodologies to consult patients; the finalisation of the CHMP pilot project to involve patients in CHMP discussions and also research into elicitation of patient preferences via online questionnaires.

3. EU-wide initiatives / developments

3.1. HTA cooperation at EU level

Flora Giorgio from the European Commission presented an overview of the current EU initiatives regarding cooperation with Health Technology Bodies (HTAs) (see presentation).

She explained that EU cooperation on HTA through projects/joint actions has been essential for developing a collaborative spirit among HTA bodies and for the elaboration of common tools and methodologies. So far there have been two Joint Actions within EUnetHTA, and a third Joint Action is running until 2020 (see www.eunethta.eu for more details). To complement the scientific and technical cooperation of the Joint Actions, an HTA Network was set up in 2013 to work on strategic and policy aspects. This Network provides guidance to HTA cooperation at EU level, as it involves representatives of health ministries or authorities responsible for HTA.

To build on the achievement so far and to ensure a sustainable cooperation beyond the existing Joint Action the European Commission has published an Inception Impact Assessment, which sets out the challenges and opportunities of continuing cooperation on sustainable beyond 2020 when the current Joint Action ends. An open public stakeholder consultation is ongoing (http://ec.europa.eu/yourvoice/consultations) to gather detailed views and opinions relating to the future of the EU cooperation on HTA. The results of this public consultation will feed into the impact assessment process which the Commission services are currently preparing on strengthening EU cooperation on HTA. In particular the consultation aims to explore how a continued and sustainable EU cooperation could support the Member States in their HTA activities, taking into consideration the views of all key stakeholders.

The EC also proposes to set up a stakeholder Pool associated to the HTA Network to contribute to policy developments on HTA. The call for expression of interest to identify relevant stakeholders will be launched 4Q 2016. Stakeholders will be also asked to participate as experts in the joint production (e.g REA, ED, Full HTA, methodology developments etc.) within the Joint Action EUnetHTA.

After the presentation there were several questions from the floor; such as whether there would eventually be a central EU HTA? Flora responded that they don't yet know what will be the outcome and all different options will be carefully considered and assessed. The inception paper is a good summary to share.

Another participant also asked how the EMA was involved. Flora explained that on HTA work regarding pharmaceuticals the EMA is involved in all levels; for example at strategic level in the development of the HTA Network reflection paper on "synergies between HTA and regulatory issues" which identifies a set of areas in which cooperation between Regulators and HTA bodies is important. The EMA is also involved at a technical level in the work of the Joint Action EUnetHTA, for example in performing Parallel Early dialogues, or in commenting on guidelines developed by the HTA bodies.

3.2. ADR website enhancements & users guidance

Francois Domergue presented some new Eudravigilance website enhancements including a user guide (see presentation).

Eudravigilance is the system for managing and analysing information on suspected adverse reactions to medicines which have been authorised in the European Economic Area (EEA). The EMA operates the system on behalf of the EU medicines regulatory network (see website: http://www.adrreports.eu).

This portal allows users to view the total number of individual suspected side effect reports submitted to EudraVigilance for each centrally authorised medicine and these can be filtered by age group, sex, type of suspected side effect and outcome. Since October 2014, reports for common drug substances used in nationally authorised medicines are also available.

As of November 2017, the ADRreports.eu portal contains 3 additional tabs providing enhanced functionality relative to the current implementation. These enhancements will allow the general public to view the number of cases received over time, the number of cases received in a particular geography and to download data using various criteria (age, sex, time, geography) in an excel file for further analysis.

Francois demonstrated the use of the portal via several use cases to demonstrate the different options.

Comments received during the consultation on elearning with PCWP members have been implemented. The training module EV-M6 – "ADRreports.eu portal" will be published by the end of 2016 via the EudraVigilance training page and further enhanced functionalities will be released in November 2017. He reminded all members to use the existing adrreports.eu portal for any suspected adverse reaction data queries.

3.3. Biomarkers in clinical drug development and use – patient awareness and role

Marisa Papaluca gave an overview of biomarkers; what they are, how they are used in medicines development and in clinical use and what is the future for biomarkers (see presentation).

Marisa's take home messages were that biomarkers can be measured with modern technologies (e.g. genomics, digital tools) and are useful to better develop medicines and personalise care by adding precision to the clinical judgment about which medicines an individual may either benefit from or should avoid. Biomarkers are measurements that may be requested by the regulatory authorities or proposed by sponsors for medicines in clinical development and use and in fact data generated by biomarkers goes well beyond the medicines themselves, i.e. personalised, participatory, preventive, predictive and patient centred health care.

Patient groups can participate and contribute to the discussions on Biomarkers, for example in shaping the informed consent principles; a key document with statements on the reason for taking samples/ measurements, the planned and future use of the samples and data, the measures in place for data

privacy protection, the description of interactions and the communication on both expected and unexpected findings.

Marisa also recommended to all to keep any interpreted results with them for the future (https://www.pharmgkb.org/) and to know in which biobank/database any “sample” is stored and for how long.

4. Patient/consumer activities

4.1. Feedback from the Scientific Committees

H. Enzmann (CHMP) gave an update of the work of the committee, including the CHMP pilot phase to involve patients in some of the CHMP oral explanations, which will finalise at the end of 2016 with an outcome report published early 2017.

D. O'Connor (COMP) provided feedback on the latest activities within the COMP in addition to its core work of reviewing designations for 'orphan-medicinal-products'.

The Committee is finalising its work plan for 2017, implementing changes following a new Commission Notice including principles and practices for determining significant benefit, defining orphan conditions and prevalence criteria.

COMP has an interest in the challenges of developing medicines in small populations and an initiative for patient registries was launched in September 2015, including a cross-committee task force. There was a patient registries workshop held on 28 October 2016 for which a video recording and meeting report will be made available: http://www.ema.europa.eu/ema/index.jsp?curl=pages/news_and_events/events/2016/08/event_detail_001315.jsp&mid=WC0b01ac058004d5c3.

K. Breen (CAT) outlined the activities of the Committee for Advanced Therapies and their work-plan as well as its involvement in the PRIME programme (see presentation).

S. Bager (HMPC) highlighted that patients/consumers are now regularly reviewing the herbal summaries prior to their publication (since March) and that involvement of patients in the HMPC activities will be further extended and the pool of interested patient/consumer experts have been invited to observe at least one HMPC meeting during 2017 so that they can be more familiar with the work of the Committee.

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

Close of meeting

Next PCWP meeting: 14 March 2017: PCWP/HCPWP Workshop on personalised medicines
15 March 2017: PCWP/HCPWP Joint meeting