30 September 2016
EMA/419205/2016
Stakeholders and Communication Division

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

14 June 2016, 09:00hrs to 13:00hrs – 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 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 Europe); 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) **Representatives from the Agency's Scientific Committees**: 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; Healthcare Professionals' Working Party (HCPWP)

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; no attendants had any declarations to address.

Two members requested to include short topics under AOB (see below).

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Fire evacuation procedures were highlighted.

New attendees from member organisations and observers were introduced.

1. PCWP activities

1.1. New PCWP mandate

As this was the first meeting within the new 2016-2019 mandate, N. Bere (EMA) presented the overall composition of the PCWP, a summary of the type of activities members will be involved in, as well as showing relevant information located on the EMA website. She also outlined the process for the election of the PCWP co-chair and the nomination of the PCWP observer to the Healthcare Professionals Working Party (HCPWP) (see presentation).

Members were invited to submit co-chair candidatures to the PCWP secretariat by 20 September latest, including background, experience and motivation.

Members were also invited to submit interest for the HCPWP observer position to the PCWP secretariat by 30 June.

1.2. PCWP members 'Tour de table'

I. Moulon (EMA) called for a tour de table to allow all members of the working party to introduce themselves and the organisations or committees they represent within the PCWP. EMA staff supporting and contributing to the work of the PCWP also introduced themselves.

1.3. PCWP anniversary

M. Mavris (EMA) gave an overview of the planned events to celebrate the 10th anniversary of the PCWP (See presentation). These comprised a dedicated PCWP anniversary session in the afternoon (2pm-5pm) of the same day, which is a look back on the last 10 years as well as a look forward to the direction and future of the working party. In addition, a collection is to be published end 2016, which will include quotes from the original members and perspectives from the co-chair of the PCWP and co-chair of the healthcare professionals' working party (HCPWP). This collection will be shared during a lunchtime talk to be held during the 30 November meeting with all eligible organisations.

2. EMA initiatives to support and accelerate early access insert heading

2.1. Update on PRIME initiative

Jordi Llinares Garcia (EMA) provided an update on the Agency's latest initiative; PRIME (see presentation).

The EMA developed PRIME in line with the European Commission's priorities and the common strategy to 2020 for the European medicines regulatory network. The goal is to foster research on and development of medicines for patients whose diseases cannot be treated or who need better treatment options to help them live healthier lives.

For medicines to be eligible for PRIME they must address an unmet medical need and the initial data must show the potential to address this need and bring a major therapeutic advantage to patients.

Building on the existing regulatory framework, including the provision of scientific advice and the accelerated assessment procedure, PRIME will provide early and enhanced support to optimise the development of eligible medicines, speed up their evaluation and contribute to timely patients' access.

For more information see the dedicated webpage.

2.2. Update on adaptive pathways

Francesca Cerreta (EMA) gave an update on the 'Adaptive Pathways' initiative, in particular, lessons learnt since the end of the pilot phase (see presentation).

In March 2014 EMA launched a pilot project to explore the adaptive pathways approach, a scientific concept of medicines development and data generation intended for medicines that address patients' unmet medical needs.

Adaptive pathways seeks to balance timely access for patients who are likely to benefit most from the medicine with the need to provide adequate evolving information on the benefits and risks of the medicine itself.

Adaptive pathways is not a new route of approval for medicines. It makes use of existing approval tools, in particular conditional marketing authorisation, which has been in operation in the European Union (EU) since 2006. It also builds on the experience gained with strengthened post-marketing monitoring tools introduced by the 2012 pharmacovigilance legislation (e.g., post-authorisation studies and patient registries).

The adaptive pathways concept is not meant to be applicable to all medicines, but only to medicines that are likely to offer help for a patient population with an unmet medical need, and where the criteria for adaptive pathways apply.

As for any medicine, a marketing authorisation will only be granted if the balance of benefits and risks for a defined patient population is found to be positive; the same principles and legal tools apply as for any other new medicine.

A report on the initial pilot project is published on the EMA website: here.

3. Access to documents

3.1. Proactive publication of clinical study reports; redaction of commercially confidential information

Anne-Sophie Henry-Eude (EMA) provided a general overview of transparency and access to documents policy at the Agency and more specifically clinical data publication via Policy 70 (see presentation).

Policy 70, which is currently being established, is the latest transparency initiative at the EMA whereby clinical study reports that are assessed as part of a Marketing Authorisation Application will be published (see Guidance: http://www.ema.europa.eu/docs/en_GB/document_library/Regulatory_and_procedural guideline/2016/03/WC500202621.pdf).

The target date for first publication is second half of October 2016 and in preparation the Agency would like the feedback from the PCWP to better understand not only what is considered 'commercially confidential information' (CCI) in clinical reports, but also what patients consider as essential within such reports.

In this regard a short questionnaire has been prepared which members were kindly requested to complete (included in post-mail pack) to gather information on what patients are looking for when reading clinical reports and what kind of information they feel should or should not be redacted.

The participants then commented that they felt most information should not be redacted – The EMA clarified that they take 'no redaction' as baseline and companies have to provide justification if they would like information to be redacted.

It was also asked what has been the feedback from companies so far? - The EMA explained that in fact the "access to documents" Service has been running for 3 years now and today much less information is redacted. The EMA team dealing with the requests for information has much more experience and there is much less resistance from companies.

4. Committees feedback

4.1. Feedback from scientific committee members

Daniel O'Connor, the COMP representative gave the members an overview of the committee's work (committee responsible for reviewing 'orphan-medicinal-product designation) (see presentation).

Steffen Bager, the HMPC representative (Committee responsible for preparing opinions on herbal medicines) highlighted that the EU legislation does not currently include patients as members in this committee however last month the committee adopted guidelines on options to engage and involve patients within its work whenever it could be of benefit. In this regard one or two observers interested in the work of the HMPC work will be invited to observe in upcoming meetings in preparation. The guidance is published on the EMA website.

Harald Enzmann, the CHMP representative (responsible for preparing opinions on questions concerning medicines), gave an overview of the ongoing CHMP pilot to involve patients within certain CHMP discussions. He explained that the experience so far has been very positive and that towards the end of the year the pilot will be assessed and proposals for the way forward will be discussed.

5. EUPATI guidance documents

On behalf of EUPATI, David Haerry (EATG) provided information on Guidance that has been prepared to aid a structured interaction at national and EU level between Patient representatives and Industry, Regulatory Agencies, HTA, Ethics Committees (see presentation).

The guidance is currently open for public consultation and members were invited to provide feedback (see website: www.patientsacademy.eu/consultation). Suggested changes should be sent to giorgio.barbareschi@eatg.org.

6. A.O.B

Francois Houÿez (Eurordis & co-chair of the EUnetHTA Stakeholders' Forum) provided an overview of the European Commission (EC) call for collaboration to create a health technology assessment (HTA) working group. Two important initiatives will soon expand membership in the domain of HTA. One is the HTA Network, composed of Member States and the EC. Its legal mandate derives from the European Directive on Patients' Rights to Cross-border Care 2011/24/EU (Article 15, Cooperation on HTA). The network supervises the strategic and political aspects of the European cooperation on HTA. The other one is EUnetNTA; the European Network composed of 75 HTA bodies. EUnetHTA provides the technical and scientific content of the EU cooperation on HTA.

Both structures are adopting a new frame for stakeholders' involvement and a call for expression of interest should be made by the end of 2016 / beginning of 2017 to participate in their activities. Those patients' or consumers' organisations considering applying should plan to dedicate a minimum of 20 days a year to participate in the many activities.

Kaisa Immonen-Charalambous (EPF) explained that in the context of the implementation of the new clinical trial regulation, and subsequent to the work of the taskforce (including PCWP members) who have worked on the preparation of guidelines for the provision of 'Summaries of Clinical Trial Results for Laypersons' (previously presented by Amanda Hunn from the Health Research Authority, UK), the proposals are now out for public consultation and Kaisa invited members to comment: (http://ec.europa.eu/health/human-use/clinical-trials/developments/index_en.htm).

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

Close of meeting

Next PCWP meeting: 19 September 2016: PCWP/HCPWP joint workshop on social media

20 September 2016: PCWP/HCPWP joint meeting