16 December 2016
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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

20 September 2016 – 08:30hrs to 16:30hrs, meeting room 2A

Role	Name
Co-chair:	Isabelle Moulon (EMA)
Former Co-Chairs	David Haerry (PCWP), Gonzalo Calvo (HCPWP)
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); Myeloma Patients Europe (MPE); **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); Pharmaceutical Group of the European Union (PGEU); Standing Committee of European Doctors (CPME); The European Specialists Nurses Organisations (ESNO); United European Gastroenterology (UEG)

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Role	Name
	Representatives from the Agency's Scientific Committees: Committee for Advanced Therapies (CAT); Committee on Herbal Medicinal Products (HMPC); Committee for Medicinal Products for Human Use (CHMP); Committee for Orphan Medicinal Products (COMP); Pharmacovigilance Risk Assessment Committee (PRAC) **Observers**: EMA Management Board; Spanish Agency of Medicines and Medical Devices (AEMPS); Medicines Evaluation Board (MEB)

Introduction

I. Moulon (EMA) welcomed all participants.

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

The agenda was adopted with three additional points to be covered under A.O.B.: EMA workshop on adaptive pathways; shortages; Ditchley Group.

1. Election of HCPWP co-chair

1.1. HCPWP co-chair election proceedings

The election proceedings started once the quorum of 18 members was confirmed. There were 21 voting members in the room, including EMA who abstains to avoid conflict of interest.

I. Silva (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 two candidatures were received: one from G. Calvo, from the European Association for Clinical Pharmacology and Therapeutics (EACPT), and one from R. Stockbrugger, from the United European Gastroenterology (UEG). With no other candidates coming forward prior at the start of the meeting, the election took place by secret ballot.

G. Calvo was elected as the new HCPWP co-chair with a majority of 15 out of 20 votes.

1.2. Nomination of observers to the PCWP

D. Singer (EACPT) was appointed as the HCPWP observer to the PCWP.

1.3. EMA revised framework of interaction with healthcare professionals

I. Silva (EMA) gave an overview of the key changes introduced to the framework and its complementary nature to the framework of collaboration with academia. She also highlighted the planned actions towards implementation of the revised framework (see presentation).

Members welcomed the reinforced role of healthcare professionals as active participants in the work of EMA; the additional focus on primary care and general practitioners in particular, the continued efforts towards enhanced partnership with the representative European organisations and the crucial focus on the early onset of interactions.

The revised framework was agreed by consensus.

Adoption by EMA's Management Board is expected in December 2016.

2. Election of PCWP co-chair

2.1. PCWP co-chair election proceedings

The election proceedings started once the quorum of 18 members was confirmed. There were 20 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-Charalambous, from the European Patients' Forum (EPF), and F. Houyez, from European Organisation for Rare Diseases (EURORDIS). With no other candidates coming forward prior to the start of the meeting, the election took place by secret ballot.

No majority vote was achieved following a number of rounds of voting and the election proceedings were adjourned to the PCWP November meeting.

2.2. Nomination of observers to the HCPWP

Four candidates expressed interest in this role, J. Drabwell (IPOPI), H. Sundseth (EIWH), R. Swierzewski (ECPCP) and V. Cursaru (MPE), and a rota will be organised.

3. Personalised medicine

I. Moulon (EMA) explained that the objective of the two presentations was to provide preliminary background for organising a PCWP/HCPWP workshop on personalised medicines in March 2017.

3.1. Recent developments

M. Papaluca (EMA) raised the question of whether personalised medicine should be seen as '*hype or hope*' (see presentation) and the expectation that both PCWP and HCPWP could help to address this question. She stressed the need to gain a better understanding of how advances in science (such as the evolution of testing biomarkers for the selection of patients) are supported by the entire spectrum of stakeholders. She explained that the concept of personalised medicine is aimed at promoting and protecting individuals' health but could also be understood, in a wider sense, as promoting patient-centred sustainable health care with targeted treatment, early intervention and prevention. She identified a number of areas where input from patients and healthcare professionals (HCPs) should be sought:

- Patients' priorities and active role to interventional trials with personalised medicines: what has changed with -omics[1], how it is perceived, what are the needs and the preferences to address the implications for individual and family?

[1] A definition of '-Omics' is offered by http://alttox.org/mapp/emerging-technologies/omics-bioinformatics-computational-biology/:
'Technologies that measure some characteristic of a large family of cellular molecules, such as genes, proteins, or small metabolites, have been named by appending the suffix "-omics," as in "genomics." Omics refers to the collective technologies used to explore the roles, relationships, and actions of the various types of molecules that make up the cells of an organism. These technologies include: Genomics, "the study of genes and their function" (Human Genome Project (HGP), 2003); Proteomics, the study of proteins; Metabonomics, the study of molecules involved in cellular metabolism; Transcriptomics, the study of the mRNA; Glycomics, the study of cellular carbohydrates; Lipomics, the study of cellular lipids.'

- HCPs' role in primary and secondary care: how to responsibly participate in clinical research and improve the interface with research communities (to validate new biomarkers, new pre-clinical and clinical methodologies)?
- Patients and HCPs support to the development of clinical (big) data gathering tools for early access to personalised medicines, the development of prescription support tools and the profiling of individuals over extended periods of time (both clinical status and tests for personalised medicines).
- Role of patients and HCPs in the evaluation, with regulators, health technology assessment (HTA) bodies, payers, and other stakeholders, of the impact of personalised medicines on public health: how to define at an early stage the value(s) of personalised medicines?
- Is personalised medicine a tool towards a sustainable health care?

3.2. Forward together: EAPM achievements and initiative (2016-17)

D. Horgan (European Alliance for Personalised Medicine - EAPM) provided an overview of the challenges and untapped potential of personalised medicine and how EAPM saw the way forward (see presentation). More details can be found on EAPM's document 'Forward Together: EAPM Achievements and Initiatives (2016-17)'.

3.3. What are the areas of interest and concern for patients and healthcare professionals

Participants made several comments, expressing the importance of going beyond discussing the principles behind personalised medicine and preferred to focus on how to bring it into practice considering the diversity of health care approaches across the European Union. Genomics was identified as the 'low hanging fruit' for personalised medicine but more needs to be done to compile examples of what patient-centred health care can really be. The 'participatory' dimension of personalised medicine should be further explored and be the focus of the PCWP and HCPWP discussions.

It was agreed to set up a joint topic group in preparation for the workshop in March 2017.

4. Committee feedback

4.1. Feedback from scientific committees

D. O'Connor (COMP) provided feedback on what the Committee is planning to discuss, in light of recent challenges and evolving classification systems, how to define an orphan condition (see presentation). He also pointed to the European Commission's public consultation on the concept of 'similar medicinal product' in the context of the orphan legislation and the need to adapt to technical progress.

K. Breen (CAT) outlined the activities of the Committee for Advanced Therapies and its foreseen involvement in the PRIME programme (see presentation).

F. Ventura (CHMP) summarised the CHMP positive recommendations for new medicines, focussing on those for which conditions for approval included further monitoring and supervision from healthcare professionals (see presentation).

S. Bager (HMPC) highlighted that in addition to patients/consumers reviewing the herbal summaries prior to their publication (since March) the involvement of patients in the HMPC activities will be further

extended and the pool of interested patient/consumer experts will be invited to attend and observe a HMPC meeting during 2017.

R. Anderson (PRAC) pointed to the safety referrals initiated in recent months and under discussion at PRAC level.

5. Members voice: sharing practices

5.1. Health Literacy, Young Patients with Asthma and Adherence to Treatment (Hey Ya!)

E. Botjes (EFA) presented on the key results and recommendations of EFA's project 'Hey Ya!' (see presentation). In order to study the underlying causes for non-adherence of adolescents in comparison to other age groups, EFA conducted a validated adolescent-patient-centred survey. Building on the results of the survey, EFA developed recommendations for improving adherence to treatment among adolescents with asthma in Europe. A full report is available on EFA's website.

5.2. State of Health in the EU: the Community Pharmacy Contribution

J. Wilkinson (PGEU) informed about an event to take place at the European Parliament on 15 November, to discuss the current and future challenges facing European health systems and outline of how community pharmacists can contribute to addressing those challenges (see presentation).

6. Working party organisational matters

6.1. Progress report from PCWP and HCPWP topics groups

N. Bere (EMA) summarised progress achieved by the PCWP and HCPWP topics groups (see presentation). It was agreed that a reflection on how to implement recommendations already endorsed should now be organised.

6.2. PCWP and HCPWP work programmes for 2017

I. Silva (EMA) outlined the key elements of the work programmes (see presentation), which had been previously circulated to all members for comments.

Both work programmes were agreed.

The working parties will be meeting in 2017 on the following dates:

- 14 March - Joint PCWP/HCPWP workshop on personalised medicines
- 15 March – Joint PCWP/HCPWP plenary meeting
- 27 June – PCWP plenary meeting
- 28 June – HCPWP plenary meeting
- 19 September – Joint PCWP/HCPWP session on antimicrobial resistance
- 20 September – Joint PCWP/HCPWP plenary meeting
- 21 November – Training session for patients
- 22 November – PCWP plenary with all eligible patients and consumer organisations

It was agreed to set up a joint topic group on antimicrobial resistance in preparation for the information session in September 2017.

6.3. EMA framework of collaboration with academia

M. Ensini (EMA) provided an update on progress achieved with the consultation process informing the drafting of the framework and outlined its foreseen scope, objectives and working methodology. The framework will be submitted to the EMA management board in December for adoption.

Participants emphasised the importance of including practice-based research in the scope of such collaboration.

7. A.O.B

7.1. EMA workshop on adaptive pathways

F. Cerreta (EMA) presented the rationale for organising this workshop, scheduled for 8 December 2016. The aim is to gather the views and proposals from stakeholders on the adaptive pathways approach, in light of the practical experience gained during the pilot project EMA ran between March 2014 and August 2016 (please refer to the final report on the pilot), and to plan the next steps in the exploration of this concept. Adaptive pathways is a scientific concept of medicines development and data generation intended for medicines that address patients' unmet medical needs.

PCWP and HCPWP members were asked to rank the 5 top issues to be discussed during the workshop.

7.2. Shortages

F. Houyez (EURORDIS) informed about the upcoming Slovak Presidency Conference to take place on 18 November, which will focus on the availability of medicines and will discuss medicine shortages. It was suggested to follow up on the conclusions of the conference.

7.3. 10th anniversary of the PCWP

M. Mavris (EMA) updated the PCWP and HCPWP about the work in progress to compile testimonies describing collaboration between members from the two working parties. All members were invited to send their contributions to illustrate the added value of the combined working party meetings.

7.4. Ditchley group

D. Haerry (EATG) reported on the presentation he made in June at the 'Ditchley Group', a multidisciplinary group gathering different stakeholders to discuss transparency and risk communication by regulators. He used this opportunity to share the key messages emerging from the PCWP/HCPWP session on medicines information and communication organised in March 2016 (see presentation).

7.5. Upcoming meetings organised by PCWP/HCPWP members

A. Santos Quintano (HAI) informed about HAI's conference on clinical drug trials, to take place on 30 September 2016.

D. Singer (EACPT) informed about the EACPT focus meeting on 6-8 October 2016 on “How to Assess Medicines from Research to Clinical Practice? Efficacy, Effectiveness, and Economic – 3E Assessment”.

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

Close of meeting

Next meetings:

PCO training: 29 Nov 2016

PCWP meeting with all eligible organisations: 30 Nov 2016