17 August 2016
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Stakeholders and Communication Division

Minutes of the EMA Human Scientific Committees' Working Party with Healthcare Professionals' Organisations (HCPWP) meeting

15 June 2016 – 08:45hrs to 10:30hrs, meeting room 3E

Role	Name
Co-chairs:	Isabelle Moulon (EMA) and Gonzalo Calvo (HCPWP)
Present:	**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 Society of Cardiology (ESC); European Society for Medical Oncology (ESMO); The European Specialists Nurses Organisations (ESNO); European Society of Radiology (ESR); Pharmaceutical Group of the European Union (PGEU); Standing Committee of European Doctors (CPME); United European Gastroenterology (UEG) **Representatives from the Agency's Scientific Committees**: Committee for Advanced Therapies (CAT); Committee on Herbal Medicinal Products (HMPC); Pharmacovigilance Risk Assessment Committee (PRAC) **Observers**: Co-ordination Group for Mutual Recognition & Decentralised Procedures – Human (CMD(h)); Patients' and Consumers' Working Party (PCWP); Spanish Agency (AEMPS)

Introduction

I. Moulon (EMA) welcomed all participants highlighting the start of a new three-year mandate for the HCPWP and the inclusion of two new organisations in the membership of the working party: the European Forum for Primary Care (EFPC) and the European Hematology Association (EHA).

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

The agenda was adopted with no additional points to be covered under A.O.B.

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1. HCPWP activities

1.1. New HCPWP mandate

I. Silva (EMA) presented the overall composition of the HCPWP and summarised the type of input expected from its members. She also outlined the process for the election of the HCPWP co-chair and the nomination of the HCPWP observer to the Patients' and Consumers' Working Party (PCWP) (see presentation).

As action points, members were invited to submit co-chair candidatures to the HCPWP secretariat by 20 September latest, including background, experience and motivation.

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

1.2. HCPWP members 'Tour de table'

I. Moulon (EMA) called for a *tour the table* to allow all members of the working party to introduce themselves and provide some background on the organisations and committees they represent within the HCPWP. EMA staff supporting and contributing to the HCPWP work also introduced themselves and the areas of work they cover within the EMA structure.

1.3. Revision of the framework for interaction between the European Medicines Agency and healthcare professionals

R. Giuliani (ESMO) outlined the key steps supporting the reflection on the need to review the EMA framework of interactions with healthcare professionals. She explained that the HCPWP topic group, tasked to consider the need for such a revision, had concluded that the 2011 Framework document should be updated to adapt to a more proactive role of healthcare professionals in drug development and monitoring. This should be put in the context of the ongoing development of an EMA framework of collaboration with academia in order to promote clarity on where each framework should put its focus without preempting obvious areas of inter-relation. She also listed a set of proposed guiding principles for the revision (see presentation).

Members were in agreement to revise the current framework.

I. Moulon (EMA) identified two themes of the EU Network strategy to 2020, which provide the underlying areas of focus for the revision of the framework:

- Theme 1: Contributing to human health – focusing on a life-span approach with clinical drug development, licensing, use in clinical practice and monitoring viewed as a continuum.
- Theme 3: Optimising the operation of the network – seeking for active involvement of the stakeholders (in particular patients, healthcare professionals, and the scientific community) in the work of the regulatory authorities.

S. Bonini (EMA) facilitated the discussion around key points to be considered when revising the current framework. These are summarised below:

- Facilitate the breaking down of barriers in patient care; principles and objectives of the framework should be defined on the basis of the patient journey and not on healthcare professionals' fields of activity

- Look at healthcare professionals as drug developers, prescribers, and monitors and how this brings value to EMA work
- Give more emphasis to primary care, exploring the opportunities patients have to contact with different healthcare professionals
- Introduce the dimension of communication between healthcare professionals – transfer of information along the patient journey as a mean to promote patient safety and best use of medicines
- Refine efforts in the domain of information on medicines and focus on more specific areas:
  - Reflect on new taxonomy of diseases based on genotypes and phenotypes and its impact on indications
  - How to include information related to managing side effects
  - Better explaining regulatory decisions; some drugs are approved where there seems not to be a need for it and the other way around; better explain negative decisions; how can healthcare professional organisations be intermediates in further explaining the reasons to their peers/communities
- Provide an environment that can support the identification of white spots in the clinical world and meet clinical needs
- Support a cyclic approach between drug discovery and clinical practice where new ideas for developing a medicine are put int the context of the use of that medicine in real world – personalised medicine
- Support awareness and understanding of EMA's policy on clinical data publication amongst healthcare professionals
- Ensure that the HCPWP is involved in the development of strategic documents/policies
- Establish panels of experts with the support of healthcare professional organisations
- Common principles and denominators should be addressed in the framework document; the framework should be complemented with an action plan where more specific activities and projects should be identified and described

Members were invited to come forward with any further suggestions by 10 July. All comments gathered will inform the drafting process.

A first proposal of the revised framework will be circulated to the HCPWP for review as soon as possible and the final draft will be put for HCPWP agreement at its September meeting.

2. A.O.B

There was no other business.

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

Close of meeting

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

20 September: PCWP/HCPWP joint meeting