1 July 2013
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Patient Health Protection

European Medicines Agency Human Scientific Committees' Working Party with Healthcare Professionals' Organisations (HCPWP) meeting

Minutes – 5 June 2013 - chaired by Isabelle Moulon

Role	Name
Acting chair:	Isabelle Moulon (EMA)
Present:	HCPWP members: Standing Committee of European Doctors (CPME), European Academy of Paediatrics (EAP), European Association for Clinical Pharmacology and Therapeutics (EACPT), European Association of Hospital Pharmacists (EAHP), European Association for the Study of Diabetes (EASD), European Association of Urology (EAU), European Federation of Neurological Societies (EFNS), European Society of Cardiology (ESC), European Society for Medical Oncology (ESMO), European Society of Endocrinology (ESE), European Union Geriatric Medicine Society (EUGMS), The European Specialists Nurses Organisations (ESNO), European Society of Radiology (ESR), The European League Against Rheumatism (EULAR), Pharmaceutical Group of The European Union (PGEU), United European Gastroenterology (UEG). Representatives of Agency's scientific committees: Committee for Human Medicinal Products (CHMP), Committee on Herbal Medicinal Products (HMPC). Observers: Co-ordination Group for Mutual Recognition & Decentralised Procedures – Human (CMD(h)), Patients and Consumers Working Party (PCWP), Medicines and Healthcare Products Regulatory Agency (MHRA)

Introduction

As the election/nomination of co-chairs has not yet taken place, Isabelle Moulon acted as chair and welcomed participants. This meeting is the first formal meeting of the working party after its establishment. Following the Decision from the Executive Director on 31 May 2013, the chair announced the names of the organisations that were now members of the working party for the term June 2013-2016 and invited all participants for a *tour de table* for a brief introduction.

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

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The agenda was adopted with no additional comments.

1. Establishment of the Healthcare Professionals Working Party (HCPWP)

1.1. Mandate and rules of procedure of the HCPWP

Ivana Silva (EMA) presented the final draft mandate that had been discussed with the Healthcare Professionals Working Group and which included comments received from internal consultation within the Agency. The text had also been scrutinised by the legal department and undergone adoption by all EMA human scientific committees.

It was clarified that once adopted the mandate should be reviewed after the end of the 3 year term. The review is intended to identify whether there is a need to reflect in the document new experience gained throughout the 3 year term and make adjustments related to the Agency's activities and procedures as necessary.

The mandate and rules of procedure were adopted by the working party.

1.2. The HCPWP vis-à-vis the Agency's structure and activities – roles and responsibilities of the HCPWP members

Ivana Silva (EMA) provided an overview of how input from healthcare professionals is channelled into the EMA structure and activities (see presentation). The working party is an important platform to collect such input and to process it according to specific requests from different EMA groups.

The presentation also summarised the roles and responsibilities of the HCPWP members, as follows:

- Reflecting on real-life/ clinical practice implications of regulatory decisions.
- Helping and assisting in decision making so that the best decision is taken.
- Increasing transparency and building confidence and trust in the regulatory process.
- Ensuring credibility by guarantying that scientific regulatory bodies act for the benefit of society.
- Continuously contribute and ask for changes in the system to improve reliability.
- Representing healthcare professionals' interests and providing a "healthcare professional perspective" view, on behalf of those directly affected by regulatory decisions.
- Identifying potential topics which may require or benefit from additional healthcare professionals' consultation.
- Actively contributing to healthcare professionals' information and communication related to medicines. Ensure that healthcare professionals and healthcare professionals' organisations can access useful and understandable information.
- Disseminating committees' outcomes when they become public; passing on information to other healthcare professionals and healthcare professionals' organisations.
- Bringing specific expertise from a healthcare professional communication-perspective (e.g. to put safety issues into context), including contribution to the decision on when to communicate.

- Advising and supporting regulators in its dialogue with industry and other stakeholders when identifying areas of medical need for target research.
- Contributing, in a general capacity, to public health (raising awareness, where appropriate, of the impact of regulatory decisions) in the context of their organisation.

The PCWP observer praised the establishment of the HCPWP and expressed the view that input from healthcare professionals was most important in medicines regulation.

It was recognised that expedite responses to consultations and review of documents constitute a challenge and that the identification of key contact people and experts within the organisations would facilitate communication and timely collection of input.

1.3. Procedure for election of chairs

Juan Garcia Burgos (EMA) presented the procedure for election of the co-chair (see presentation).

Members and alternates of the HCPWP will be invited to come forward with a candidate to co-chair the working party. Once the call has been launched candidatures should be received by the EMA secretariat no later than the start of the HCPWP meeting at which the election is to take place (25 September 2013). Candidatures should include a brief resume providing the background and experience of the candidate and a motivation statement. This will be circulated to the HCPWP members prior to the election.

It was clarified that the elected co-chair will not represent his/her organisation but rather guide the activities of the working party in collaboration with the other co-chair nominated by the Agency and supported by the EMA secretariat. In case the elected co-chair was previously the organisation's representative, a different representative should be nominated to be part of the working party.

1.4. Nomination of observers for PCWP, ENCePP, Enpr-EMA

Ivana Silva (EMA) described the procedure for nominating HCPWP observers to other EMA groups (see presentation). At present, the HCPWP has an observer role in three groups: the Patients' and Consumers' Working Party (PCWP); the European Network of Centres for Pharmacoepidemiology and Pharmacovigilance (ENCePP); and the European Network of Paediatric Research at the European Medicines Agency (Enpr-EMA).

Members of the HCPWP will be invited to express an interest in any of the three groups and observers will then be agreed by the co-chairs and EMA secretariat.

1.5. Practical information

Malika Holleyman (EMA) explained and clarified some of the practical issues related with the completion and yearly update of the electronic declaration of interest (eDoIs), the use of Eudralink for the secure transmission of EMA documents and the arrangements to participate in EMA meetings (see presentation).

2. Area of information and communication

2.1. Lessons learnt from the review of the labelling of pandemic vaccines

Monica Prizzi (EMA) presented the draft document outlining lessons learnt and proposals for improvement of the labelling of pandemic vaccines (see presentation). This was part of a wider lessons learnt exercise carried out by the Agency following the influenza pandemic in 2009.

There was general agreement that the proposals and recommendations point in the right direction to ensure safe use of vaccines in the event of the pandemic; however it was also acknowledge that their practical implementation must be balanced against the need to have the vaccines available as soon as possible once a pandemic is declared.

It was suggested that other supporting tools, such as laminated cards, could be developed to provide labelling information in larger font at mass vaccination sites and that the possibility to pre-test the proposed recommendations to improve the labelling of pandemic vaccines could be explored. These suggestions were noted.

Members of the HCPWP were invited to submit comments in the following two weeks.

AOB

There was no other business to be discussed.

Close of meeting

Next meeting: Joint PCWP/HCPWP meeting – 25-26 September 2013