29 May 2013
EMA/255634/2013
Patient Health Protection

Healthcare Professionals Working Group (HCP WG) meeting

Minutes – 27 February 2013 - chaired by Isabelle Moulon

Role	Name
Chair/Vice-chair:	Isabelle Moulon (EMA)
Present:	HCP WG members: Standing Committee of European Doctors (CPME), 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) (via teleconference), European Federation of Internal Medicine (EFIM), European Society of Cardiology (ESC), European Society for Medical Oncology (ESMO), The European Specialists Nurses Organisations (ESNO), European Society of Radiology (ESR), The European League Against Rheumatism (EULAR), Pharmaceutical Group of The European Union (PGEU). Representatives of Agency's scientific committees: 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)

Introduction

The chair welcomed participants and introduced the agenda topics.

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

The agenda was adopted with no additional comments.

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1. Area of involvement in the Agency's activities

1.1. Establishment of the Healthcare Professionals Working Party - mandate and rules of procedure

Ivana Silva (EMA) presented the proposed mandate and rules of procedure for the EMA Human Scientific Committees' Working Party with Healthcare Professional Organisations (HCPWP).

The mandate focuses on 4 main areas:

1. Support the Agency to gain a better understanding of how medicines are being used in real clinical practice;
2. Contribute to the Agency's scientific work;
3. Enhance healthcare professional organisations' understanding of the mandate and work of the Agency and the EU Regulatory Network;
4. Monitor the implementation of the Framework for the interaction between the Agency and healthcare professionals.

It was clarified that the working party is expected to discuss general topics of common interest to healthcare professionals and the Agency. No confidential information is to be discussed and as such product-specific matters may only be discussed if these are in the public domain and in the context of broader discussion topics (e.g. communication; pharmacovigilance). The working party will, however, serve as a permanent platform to reach out to experts who may then be involved in benefit-risk assessment, as appropriate (e.g. participation in scientific advisory groups).

The EMA will incorporate comments received during the meeting to strengthen specific points in the draft mandate and will put the final document for adoption at the first meeting of the working party (June 2013).

1.2. Progress report on the implementation of the framework for interaction between the Agency and healthcare professionals

Ivana Silva (EMA) reported on the progress made throughout 2012 regarding the involvement of healthcare professionals in the activities of the Agency (see presentation).

The most significant achievement in 2012 was the strengthening of the EMA interaction with a network of European healthcare professional organisations. By end of 2012, twenty-one (21) organisations were included in the list of eligible organisations published in the EMA website and contacts established with other organisations expressing an interest to become involved in EMA activities.

The network of European healthcare professional organisations has proven to be a valuable source of independent expertise. Several clinical experts have been identified in particular areas of expertise for EMA scientific advisory group meetings. In addition, a pool of experts in medication errors was set up and involved in specific consultations throughout 2012.

A number of consultations covering specific questions to healthcare professionals in the areas of diabetology, nephrology, radiology and anaesthesiology were also carried out as per request of the EMA Pharmacovigilance Working Party.

Healthcare professionals' organisations were also engaged in the EMA surveys on communication documents and on communication practices during a pandemic influenza crisis.

In addition, several representatives from healthcare professionals' organisations participated in EMA workshops and conferences.

2. Area of information on medicines

2.1. Public SmPC webpage

Olayinka Fasanya (EMA) showed and navigated the EMA webpage launched in January 2013 which provides information on the preparation and review of a summary of product characteristics (SmPC).

The webpage is intended to enable companies to make sure that the information in SmPCs is of high quality when they submit them to the Agency as part of applications for new marketing authorisations or updates to existing marketing authorisations. The guidance consists of a set of presentations detailing the information that should be included in each of the sections of the SmPC, together with background information on SmPCs both as a presentation and a video.

The webpage was considered as a good resource to also raise awareness of the information provided in SmPCs among healthcare professionals.

2.2. Cross-reference to SmPCs - consultation with HCPOs

Olayinka Fasanya (EMA) presented a consultation requested by the SmPC Advisory Group to collect the views of healthcare professionals in relation to the need to make a reference to the SmPC of another product when two or more medicines are indicated in combination.

Members of the HCP WG were invited to submit their comments in the following three weeks.

AOB

There was no other business to be discussed.

Close of meeting

Next meeting: HCPWP meeting – 5 June 2013