May 2012
EMA/432052/2012
Patient Health Protection

Minutes of the HCP WG meeting of 08 May 2012

Role	Name
Chair/Vice-chair:	Isabelle Moulon (EMA)
Present:	HCP WG members: 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 Nurses Associations (EFN), European Haematology Association (EHA), European Society of Cardiology (ESC), European Society for Medical Oncology (ESMO), The European Specialists Nurses Organisations (ESNO), Pharmaceutical Group of The European Union (PGEU), United European Gastroenterology Federation (UEGF), European Union of General Practitioners (UEMO) Representatives of Agency's scientific committees: Committee for Medicinal Products for Human Use (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) Other invited patient/consumer organisations: European AIDS Treatment Group (EATG), European Cancer Patient Coalition (ECPC), European Organisation for Rare Diseases (EURORDIS) Invited speaker: Peter Mol (University Medical Center Groningen)
Apologies:	HCP WG members: Standing Committee of European Doctors (CPME), European AIDS Clinical Society (EACS), European Academy of Paediatrics (EAP), European Federation of Internal Medicine (EFIM), European Federation of Neurological Societies (EFNS), European Society of Endocrinology (ESE), European Society of Radiology (ESR), European Union Geriatric Medicine Society (EUGMS), The European League Against Rheumatism (EULAR) Other invited patient/consumer organisations: (BEUC)

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Introduction

The chair welcomed participants and invited a *tour de table* to introduce all representatives and observers.

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

The agenda was adopted with no additional comments.

The EMA Executive Director addressed the group members expressing his appreciation of the role of healthcare professional organisations in the work of the Agency. He acknowledged the growing importance of such contribution as a way to help bridging the gap with real clinical practice. He also referred to the implementation of the new pharmacovigilance legislation, where healthcare professionals play a crucial role (e.g. reporting adverse drug reactions). He also pointed out the need to strengthen the Agency's communication activities, including those directed to healthcare professionals. Finally, he encouraged organisations to come forward with their application to become eligible to work with the Agency in the near future.

1. Area of involvement in the Agency's activities

1.1. Call for expression of interest for HCPs organisations

Ivana Silva (EMA) gave an overview on the process by which organisations interested in participating in the Agency's activities are encouraged to submit an application and provide the necessary supporting information. The call for expression of interest was open in February 2012 and since then 7 applications have been received. The Agency is currently assessing these applications and will provide feedback to the applying organisations.

It was clarified that following the initial submission, eligible organisations will be asked to provide financial information on a yearly basis and a full-evaluation will take place every two years.

Members of the HCP WG were encouraged to consider submitting their applications during June.

2. Area of pharmacovigilance

2.1. Access to Eudravigilance data – demonstration

The Eudravigilance access policy (adopted by the EMA management board end of 2010) foresees the publication of collated adverse reaction data related to spontaneous reports for authorised medicines in the EU.

Steven Le Meur (EMA) presented an update of the Eudravigilance access policy implementation to date and gave a live demonstration of the web reporting which will be used by the public/healthcare professionals to access data on adverse drug reactions (see presentation). The different kinds of information that can be obtained were demonstrated and participants were informed that the website www.adrreports.eu will be live as of 31 May 2012.

Following the demonstration several HCP WG members congratulated the EMA for this work and asked what the plans to publicise the website were. It was clarified that the EMA communications team was working on this and that EMA stakeholders would be informed once the website goes live. The EMA would welcome any initiative from the WG members to raise awareness on the website (e.g. include link in their own websites). The EMA would like the healthcare professional organisations to use the

website and provide further feedback, which can be further discussed at the next PCWP/HCP WH joint meeting.

Members were also interest to know how the EMA would monitor the use of the website. Additional clarification was provided on how the data was collected, made available and updated on a monthly basis. It was also mentioned that researchers (including guideline developers) had been identified as a different stakeholder group and could have access to additional information upon request.

2.2. Update on PhVWP consultations with HCPs

Due to time limitations this agenda item was not taken. The chair informed that an update on all activities related with the HCP WG would be provided from now on at the beginning of each meeting.

3. Area of geriatric medicines

3.1. Feedback from the EMA workshop: ensuring safe and effective medicines for an ageing population

Francesca Cerreta (EMA) reported on the EMA workshop held in March 2012 (see presentation) to discuss aspects related with safety and efficacy of medicines for older people. The workshop brought together different stakeholders, including EU public bodies, regulators, academic researchers, patient and healthcare professional representatives as well as representatives from the pharmaceutical industry.

The workshop's objectives were: to discuss the EMA's geriatric medicines strategy and related activities; to identify gaps and the priorities for action; to highlight synergy areas between stakeholders, as well as to obtain feed-back from stakeholders on the actions undertaken by and expected from EMA and its committees.

The workshop concluded that the current actions are supported by the existing legislative framework, however current guidance should be improved to address areas where deficiencies are identified. As for clinical trials, methodology needs to be adapted in order to ensure that a representative number of older patients are enrolled in clinical trials. There was also discussion around a definition of frailty and how this could be used as a valid selection tool and measure of outcome.

The implementation of the new pharmacovigilance legislation was also pointed out as an opportunity to strengthen the system for monitoring the safety and benefit-risk balance of medicines used by older patients. It was particularly emphasised that data collection should be optimised, as adverse drug reactions are generally underreported in older patients.

The workshop further highlighted that in order to improve adherence amongst older patients appropriate packaging, formulations or delivery/administration options need to be considered. Providing specifically tailored formulations helps increase adherence in this population.

It was acknowledged that, in order to improve informed prescription and adherence, healthcare professionals and older patients need to be provided with relevant and clear information on medicines. Finally, the workshop highlighted the need for cooperation at an international level amongst the different stakeholders to improve medicines for older people.

The different presentations delivered during the workshop are available in the EMA website. A detailed report will also be published and the EMA will inform members upon publication.

4. Area of information on medicines

4.1. Communicating risk effectively – the CORE project

Peter G. M. Mol (Department of Clinical Pharmacology, University Medical Center Groningen) presented some findings from the CORE project. The project was funded by an unconditional grant from the Dutch Medicines Evaluation Board and aimed to improve the current risk communication methods of medicines, specifically after market approval.

One of the first findings of the project is that in current literature there is great diversity as regards the methods used and therefore more studies are needed to get a better understanding of effectiveness of risk communication. The unintentional side effects of risk communication should also be taken into account.

Dr Mol studied in particular the effectiveness of Direct Healthcare Professional Communications (DHPCs), used to inform healthcare professionals about new safety information. Data was retrieved from DHPCs issued in The Netherlands from 2001 to 2008 and the analysis revealed that a third to a half of the DHPCs assessed led to a substantial change in medicine use (see presentation for more details). Dr Mol is currently further studying which elements of DHPCs have greater impact in risk communication.

The presentation generated some discussion which concluded with the idea that greater partnership among the health team (GP, pharmacist, nurse, speacialist, patient) is necessary to ensure safety information provided by regulators reaches all involved in patient care.

4.2. Information on medicines published by EMA

Juan Garcia (EMA) presented the feedback obtained during a teleconference held with several healthcare professional organisations in relation to some of the information which is made available for HCPs on the EMA website, in particular safety information (using the format of press releases and Q&A documents). It was felt that the implementation of the new Pharmacovigilance legislation would be a good opportunity to review existing practices and identify any areas for improvement. A similar teleconference was organised with patient and consumer organisations.

The EMA asked if these documents respond to HCPs' information needs and are written in an appropriate language and in sufficient detail. It was also enquired if the documents are easily located within the website and whether they are published in a timely manner. This brainstorming referred only to information on medicines in the context of the EMA's role and responsibilities and did not include EPARs, SmPCs or package leaflets.

The main feedback received during the teleconference was that the current information provided by the EMA is sufficient and of good quality but that improved targeting and increased accessibility would be welcomed. The language used is patient-friendly but it is also adequately written for healthcare professionals. It was felt also to have sufficient level of detail. Regarding information content however, healthcare professionals would welcome additional background/scientific data supporting EMA recommendations. HCPs would welcome a targeted alert system informing about new approvals, extensions and changes in indications.

It was felt that both the press release and the Q&A documents are useful but that the key information contained there-in should be made more prominent. It was also highlighted that the search functionalities on the website could be improved, especially disease-specific information (see presentation for more detail).

After the presentation, participants supported the main findings and some participants mentioned that they use and disseminate EMA information (one representative declared to do so on a daily basis). More recent information EMA has provided on shortages was acknowledged to be of much interest to them.

The Agency proposed to give a presentation at the next meeting (joint PCWP/HCPWG) with details on how EMA information is distributed. The Agency would also appreciate receiving information from healthcare professional organisations on how they disseminate EMA information and it was suggested to use a survey to gather this information, which could then also be presented and discussed at the next meeting.

AOB

There was no other business to be discussed.

Close of meeting

Next meeting: Joint PCWP/HCPWG meeting – 24/25 September 2012