12 April 2011
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Patient Health Protection

Minutes of HCP WG meeting

28 October 2010 –chaired by Isabelle Moulon

Role	Name
Chair/Vice-chair	Isabelle Moulon
Present:	**Representatives from Healthcare Professionals' Organisations:** 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 Federation of Neurological Societies (EFNS), European Haematology Association (EHA), 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).European Union of General Practitioners (UEMO) **Representatives and observers from the Agency's Scientific Committees:** Committee for Human Medicinal Products (CHMP). **Observers:** Patients and Consumers Working Party (PCWP), Co-ordination Group for Mutual Recognition and Decentralised Procedures–Human (CMD(h)).
Only for Agenda item 8	The European Older People's Platform (AGE), The European Consumers' Organisation (BEUC), European Cancer Patient Coalition (ECPC), European Patients Forum (EPF), Health Action International (HAI).

1. Introduction and adoption of agenda.

Isabelle Moulon, Head of the Medical Information Sector, welcomed participants and introduced the new representatives from the European Society of Radiology (ESR) and the European Haematology Association (EHA). The chairperson explained that the main focus of the meeting would be the discussion and agreement on the structure of the framework between the Agency and Healthcare Professionals to be presented to the Agency's Management Board. In addition, the meeting would allow for members of the HCP WG to exchange some views on several ongoing activities in the Agency. She also explained that for the discussion on the EudraVigilance Access Policy (Agenda item 8), patients' and consumers' representatives would be joining the meeting.

The agenda was adopted without any amendments and no conflicts of interest were disclosed in relation to the activities scheduled for this HCP WG meeting.

2. Framework for the interaction between the EMA and HCP and implementation plan

The Agency presented the structure and content of the framework, including its rationale, scope and objectives. It was underlined that all aspects included had been built upon previous discussions with the HCP WG and the experience the Agency had gained with the interaction with healthcare professionals since its creation in 1995. The dedicated meeting in July 2010 had also been very fruitful to develop a more detailed implementation plan as part of the framework. The active collaboration of Ingolf Cascorby (EACPT), Michel Delvaux (UEGF) and Michael Wilks (CPME) in commenting the proposed structure and content was also acknowledged.

The intention of the discussion at this point was to validate whether the proposed structure and content was in line with the HCP WG views. This step would then allow the Agency to go ahead with drafting the supporting document to be presented to the Management Board.

As part of the presentation, the Agency explained the proposed working methodology which focuses on three main elements: the establishment of a network of European healthcare professionals' organisations, the establishment of the European Medical Information Network, involving the EMA, the EC and all EU Regulatory Authorities, and the establishment of the Healthcare Professionals Working Party (HCP WP). The first element will imply the creation of a public online registry containing information on healthcare professionals' organisations that interact with the Agency. The establishment of the HCP WP will encompass a transition period from the informal status of the HCP WG to a full Working Party (WP).

During the discussion participants raised some questions about the eligibility criteria which would support the selection process. The particular case of umbrella organisations who do not have a specific focus on medicines as part of their activities but rather a coordination role among other healthcare professionals' organisations who do have this specific interest was addressed. It was clarified that these organisations would also be eligible and that it would also be possible for their member organisations to apply for eligibility so they wished.

The chairperson asked HCP WG members their views on the transparency criterion, included in the eligibility criteria to be used as a basis for the process, and particularly, how feasible it was for the organisations to publish on their websites their statutes and sources of funding. The general view was that this should be feasible and they were supportive of such a requirement coming from the Agency.

The Agency then continued with the presentation of the framework's implementation plan. This specifies in a prospective manner the different types of interactions to be enhanced and their respective performance indicators. The implementation plan covers HCPs in the Agency's Management Board, Scientific Committees, Working Parties, Scientific Advisory Groups and other expert groups; interactions related to Pharmacovigilance and Risk Management; interactions regarding the provision of information on medicines to HCPs; interactions related to the Agency's activities in the area of Clinical Trials; and interactions related to awareness raising on the Agency's activities.

Additionally, measures will be proposed to strengthen participation and presence of the EMA in European HCPs' organisations forums.

Overall, members agreed on the structure and content proposed for the framework and on the respective implementation plan.

The Agency provided an overview of the work plan for 2011 highlighting the new EU legislation on pharmacovigilance and the strengthening of the Agency as an authoritative source of information on medicinal products as the two main areas for 2011. In this regard, work undertaken in 2010 by the HCP WG towards the implementation of the recommendations and proposals for action in the areas of

information on medicines will be continued in 2011 and the HCP WG will revise the recommendations in the area of pharmacovigilance. The development and implementation of the framework for interaction between the Agency and healthcare professionals' organisations will receive special attention throughout 2011. In addition, the work undertaken in 2010 as regards early involvement of HCPs' organisations in guidelines development and in the identification of experts for scientific advisory groups will be continued. Finally, the HCP WG will continue to look into ways of raising awareness about the Agency's activities and how it can contribute to provide support to the strengthening of interactions between regulators and HCPs' organisations at national level.

The HCP WG's 2011 meetings have been scheduled for 4 March 2011, 16-17 June 2011 and 28 October 2011.

Members adopted the proposed work plan for 2011.

3. EMA/EC joint conference on the outcome of the Agency's assessment

The Agency presented a comprehensive assessment carried out by Ernst & Young during January-December 2009 and requested by the European Commission about the effectiveness and efficiency of the European Medicines Agency and the European medicines system as a whole in delivering high-quality scientific opinions on medicines for human and veterinary use. The report was published in April 2010 and is publically available at http://ec.europa.eu/health/files/pharmacos/news/emea_final_report_vfrev2.pdf

The general conclusion of the report described the EMA as "a successful EU story" with an effective and efficient organisation, able to provide an effective health protection and based on an effective EU network with concrete output. The recommendations were to improve the architectural capacity to cope with increased workload; to improve the linkage of scientific advice between scientific committees; to be prepared for future challenges and to ensure the long term sustainability of the system.

The European Medicines Agency and the European Commission held a joint one-day conference on 30 June 2010 to discuss the outcome of this evaluation of the Agency and how the findings of the exercise could be used in preparing the Agency for future challenges. A report of this conference will be published at the very beginning of 2011 and will be circulated to members of the HCP WG.

4. e-SmPC project

The Agency provided an overview of the e-SmPC (electronic Summary of Product Characteristics) project. This is a long-term vision, thought as an electronic, structured format for the text based SmPC that will allow information contained in it to interact with the other components of electronic healthcare systems, thereby enabling the use of SmPCs at the point of care. The Agency highlighted that for a full realisation of this tool, a change in the legislation will not be required, but a more structured thinking when writing SmPCs. A network of academic centres and healthcare providers/users, policy makers and regulators and more financial resources will be necessary for the implementation.

Members expressed strong interest in this presentation and underlined the need to include all healthcare professionals in the e-SmPC concept.

Members shared comments about existing public and private e-Health databases, but advanced the idea of a unique and harmonised tool.

Members were encouraged to inform the Agency about initiatives they were aware of in this field.

5. Update on clinical trials related activities

Members were updated on the Agency's clinical trials related activities, in particular on the version 9 of EudraCT, a database which contains information on all clinical trials in the European Union. It was announced that clinical trials from the database will be made accessible to the public next year via EudraPharm's EU Clinical Trials Register. This e-system will contain information on all European clinical trials with the exception of phase I Adult trials and the data-format will be similar to the one of www.clinicaltrials.gov. It is expected that early next year it will be possible to use this.

The Agency also provided feedback on the international workshop that was held on 6-7 September 2010 at the EMA on clinical trials in the context of global medicines development. The workshop was part of the consultation process on the Agency's 'Reflection Paper on ethical and Good Clinical Practice (GCP) aspects of clinical trials of medicinal products for human use conducted in third countries and submitted in marketing authorisation applications to the EMA'. A broad cross section of stakeholders from around the world participated to discuss a way forward for a global framework of clinical trials that has at its heart the protection of the rights, safety and wellbeing of patients participating in clinical trials anywhere in the world.

All comments received during the consultation phase, including the workshop, will be thoroughly reviewed. Finalisation of the Reflection Paper is expected by mid 2011.

6. Website – HCPs' dedicated area

The Agency presented an overview of the EMA website, the 2010 achievements and future planned developments. The new website was launched on 15th July 2010 with a number of new features including improved search and browse functionality, highlighted content for key target audiences, safety issues, news and events, etc. In 2011, work will focus on making the website a one stop shop for information on medicines, improved user centred design, dialogue and exchange of information. Moreover an improved system for measuring the impact, quality and promotion of the website will be set up.

Members shared opinions and experiences about the EMA website. In particular, some level of frustration was expressed about the lack of a unique search engine for both centrally and non-centrally authorised medicines and the necessity to refer to single National Competent Authorities' websites for information on non-centrally authorised medicinal products.

The Agency acknowledged the challenge to explain the complexity of EU medicines regulation to the general public.

7. A.O.B.

No other business arose.

8. EudraVigilance access policy

Patients' and Consumers' Organisations invited for this agenda item joined the meeting at this point.

Peter Arlett, Head of the Pharmacovigilance and Risk Management Sector, welcomed all participants and provided an overview of the new legislation on pharmacovigilance.

In the context of the EudraVigilance Users Group with patients, consumers and healthcare professionals the Agency provided an outline of the revised EudraVigilance Access Policy in the field of

medicines for human use. This Access Policy defines the overall principles of the provision of access to EudraVigilance data in line with the current legal framework taking into account that the use of data may vary between stakeholders. It is being developed to contribute to public health protection, to facilitate the implementation of the European transparency initiatives and to comply with EU personal data protection legislation. Once the EV Access Policy is adopted, an "EV Access Policy Users Group" will be established with representatives from the PC WP and the HCP WG to discuss implementation aspects.

Participants raised several aspects linked to the categorisation of adverse drug reactions by frequency and severity. Particular concerns were expressed about the absence of narrative text in the reports and the fact that currently only reports confirmed by healthcare professionals would be taken into account.

It was clarified that in the context of personal data protection, patients should not be identified or identifiable, and this could not be guaranteed with a system based on narrative text reports. The new version of EudraVigilance being developed for the new Pharmacovigilance legislation will take into account the different sources of spontaneous reports of adverse drug reactions, including those from patients and users of medicines which are not clinically confirmed. In order to help in the interpretation of the output that will be publicly available in EudraVigilance, a guideline would need to be developed.

A three step plan was proposed with regards to the EudraVigilance Access Policy Implementation:

Step 1: Review examples how other EU/non-EU regulators approach the publication of adverse reaction data – to this end, participants were presented examples from MHRA-UK, LAREB-NL, FDA-US and Health Canada-CA;

Step 2: Summarise useful implementation aspects;

Step 3: Define with the EudraVigilance Users Group requirements and possible implementation approach.

A follow up meeting will be organised in the next months for a preliminary discussion on adverse reaction reporting and continue the discussions on the EudraVigilance Access Policy Implementation.

Next meeting:

Friday 4 March 2011, 09h00 –16h30, meeting room 2G.