EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

18 April 2011
EMA/231456/2011
Patient Health Protection

Minutes of HCP WG meeting

4 March 2011 - chaired by Isabelle Moulon

Role	Name
Chair/Vice-chair	Isabelle Moulon
Present:	**Representatives from Healthcare Professionals' Organisations:** European Society of Cardiology (ESC), European Federation of Nurses Associations (EFN), European Academy of Paediatrics (CESP – EAP), Standing Committee of European Doctors (CPME), 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 of Endocrinology (ESE), The European Specialists Nurses Organisations (ESNO), The European League Against Rheumatism (EULAR), Pharmaceutical Group of The European Union (PGEU), European Union of General Practitioners (UEMO), European Union Geriatric Medicine Society (EUGMS), United European Gastroenterology Federation (UEGF), European Union of General Practitioners (UEMO) **Representatives and observers from the Agency's Scientific Committees:** Committee for Human Medicinal Products (CHMP), Committee on Herbal Medicinal Products (HMPC) **Observers:** Patients and Consumers Working Party (PCWP), Co-ordination Group for Mutual Recognition and Decentralised Procedures–Human (CMD(h)), European Commission, Management Board, Representatives from Competent Authorities of Albania, Croatia, Former Yugoslav Republic of Macedonia, Serbia

1. Welcome and introduction, adoption of the agenda

Isabelle Moulon, Head of Medical Information Sector, welcomed participants and introduced new representatives and observers to the audience.

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

The agenda was adopted with no additional comments.

2. New policy on conflict of interest

The Agency gave a presentation on the revised EMA Policy on the handling of conflicts of interests of scientific committee members and experts, endorsed by the Management Board in December 2010. In particular, participants were updated on the current status and scope of the policy, which will facilitate

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expert input to the Agency's activities while improving the system in terms of robustness, efficiency and transparency. The Agency also clarified that the participation of healthcare professionals' organisations in the HCP WG is not affected by the new policy as this is governed by eligibility criteria, to be adopted by the EMA Management Board.

The new electronic Declaration of Interests (e-DOI) form will be available on-line from 1 May 2011. It was clarified that the DOIs of the different experts will be made public on the EMA website in the future.

Some participants requested clarifications on some concepts. In particular the EMA explained that the involvement of an individual in the Agency's activities of experts may be restricted taking into account the declared interest (direct or indirect), the timeframe during which such interest occurred (current/past) and the type of activity for which involvement is required (Committee member/Working Party member/SAG member). The final objective is to satisfy demands for the Agency to strengthen its handling of conflicts of interests, while ensuring that the best scientific expertise can be involved in the assessment process. Furthermore, a new concept has been introduced: the expert witness, whose role is limited, but which allows some experts with declared (current, direct) interests to testify and provide specialist advice on a specific issue (providing information and replying to questions only). The Agency finally stressed that transparency will be the key-point of this new policy.

3. Framework for interaction between the Agency and healthcare professionals

The full document was presented. The chairperson highlighted that all the issues raised in the last months have been addressed and implemented. Following the extensive presentation given at the HCP WG meeting of 28 October 2010, the EMA secretariat summarised the objectives and areas covered by the framework and described the proposed network of European HCPs' organisations and the HCP WP. In addition, participants were updated on the main tools proposed, the working methodology and the eligibility criteria. The EMA finally outlined the steps to be undertaken in the next months, which will include the endorsement of the framework by the Management Board in June 2011 and its implementation from August-September 2011 onwards. In terms of transparency, the EMA explained that eligible organisations will disclose to the Agency their source of funding and will be encouraged to publish their financial statements on their websites.

Participants expressed the need for an increased level of involvement of HCPs in regulatory agencies at national level and the chairperson responded that although this issue is covered in the framework, the EMA's capacity in the area is very limited.

The Framework was adopted by the HCP WG with no additions.

4. Benefit/Risk communication by the European Medicines Agency: a study of influential stakeholders' expectations and attitude

The results of a research project performed during 2009/2010 on how the Agency communicates benefit/risk were presented. The study involved 102 different stakeholders and at least 77 in-depth interviews were carried out. A final report will be circulated to HCP working group once available, and subsequently published by the EMA.

Some participants discussed various aspects of challenges related to the benefit/risk communication highlighting the difficulty to communicate uncertainties to the public. There was general agreement on the fact that too often we focus on the benefit/risk of a treatment while low importance is given to the benefit/risk of a non-treatment. However it was reminded that the Agency's mandate is to

communicate on the medicines it evaluates. A further participant also commented on the particularities of communicating benefit/risk of vaccines as compared to other medicines.

It was recommended to establish a risk communication advisory board where medical and risk communication experts could take into consideration also cognitive factors in the development of communication strategies. It was also highlighted that fundamental requisites to build a strong credibility in terms of provision of information to the general public are fairness, competence and efficiency.

5. Direct Healthcare Professionals' Communications (DHPC)

An EMA representative gave a presentation on a proposal to publish DHPCs on the EMA website. A definition of DHPC, how this tool is currently used and the potential benefits of the publication of DHPCs on the EMA website were outlined.

The floor was opened for discussions and members expressed interest on this tool. They rose however some concerns of having MAH communicating directly to HCPs, and welcomed involvement of regulatory agencies in the process.

Participants proposed channels and ways for the dissemination of DHPCs such as organisations' websites and the use of RSS feeds. They confirmed that as per their experience, DHPCs do not reach their organisations.

The Agency suggested that DHPCs should be ideally published when other communication material is released (e.g. the press release and the Q&A). It was agreed that there is a need to return on this topic in the next meetings to also discuss possible involvement of HCPs in this field.

6. ENCePP – summary from plenary meeting of Nov 2010

A member from PGEU presented an overview on the ENCePP (The European Network of Centres for Pharmacoepidemiology and Pharmacovigilance) plenary meeting held in November 2010. A complete report of this meeting is available on the following website:
http://www.encepp.eu/publications/documents/Report_ENCePPPlenary_18Nov2010.pdf

7. Pharmacoepidemiological research on outcomes of therapeutics – update on the PROTECT projects

An EMA representative gave an overview of the PROTECT Project, which is a collaborative European project funded by the Innovative Medicines Initiative Joint Undertaking (IMI JU) and involving both public parties and private organisation (EFPIA). The objective of this project is to strengthen the monitoring of benefit-risk of medicines in Europe by developing innovative methods in the area of pharmacoepidemiology and pharmacovigilance which will be tested in real-life situations. The project has a 5-year tenure and is approaching the end of its second year. The Agency provided participants with an outline of the seven work packages included in this project, namely: project management and administration, framework for pharmacoepidemiological studies, methods for signal detection, new tools for data collection from consumers, benefit-risk integration and representation, validation studies involving an extended audience and training and communication. As the research agenda of the project is very large and complex, only high level information was presented on the scope and the main achievements so far.

Participants were informed that more information on the PROTECT project is available at www.imi-protect.eu.

8. eHealth: Experience from PGEU

In the context of information on medicines, PGEU presented the experience gained on eHealth with particular focus on solutions that were using information on medicines implemented in the community pharmacies in the EU. The presentation focused on electronic decision-support systems, which are electronic tools introduced to assist healthcare professionals in their clinical practice at the point of care. Several examples of electronic systems used in EU countries were outlined and some screenshots of the tool used in 80% of Spanish pharmacies were shown.

PGEU highlighted the potential of such electronic decision support systems when crossed with patients' health record in particular in reducing medicine-medicine interactions and preventing adverse drug reactions by illustrating a pilot study carried out in French community pharmacies.

9. The new package leaflet template

The Agency gave a presentation on the revision of the new package leaflet (PL). It was highlighted that this new template is more flexible and user friendly with respect to the older version and will also include more useful information such as information on benefits of the medicine.

A participant mentioned the importance of including for example information on the onset and duration of effect of a medicine which the EMA clarified that will now be captured in the new template.

The CMDh representative asked for clarification around the implementation of this new template. It was informed that a draft implementation guideline has been prepared which will be published together with the new template. This draft implementation will be sent to CMDh for their information.

The Agency finally informed participants that the template will be published by the end of April 2011.

10. Involvement of healthcare professionals in the review of labelling

The Agency highlighted the importance of the involvement of healthcare professionals in the review of product labelling. This type of interaction can be particularly useful in order to address practical aspects of prescribing, dispensing and handling of products at the time of the revision of the product labelling. This can be of particular utility to help preventing potential medication errors. Some recent examples confirmed the usefulness of the healthcare professionals' input in the review process.

The audience agreed that there are grounds to further develop such an interaction and the EMA was invited to propose a procedure. During the discussion, it was highlighted that the key aspect to consider would be the need to identify in advance which specific cases would really benefit from HCPs' input.

11. Values and preferences for health states amongst patients and HCPs: EMA project on benefit-risk methodology

An EMA representative presented an overview of a benefit/risk methodology research study which is being carried out at the Agency. The study, which is focusing on three therapeutic areas, is analysing patients' preferences and values for efficacy and safety attributes for different treatments. The method

will involve interviews and questionnaires to stakeholders and will introduce quantitative elements with the ultimate aim of achieving better health outcomes.

The questionnaire will be launched later on in 2011.

12. A.O.B.

The EMA secretariat presented the draft agenda for the Joint Meeting of 16th – 17th June 2011.

An observer from the PCWP gave a presentation entitled “Where do you get information on how to prescribe a medicine to patients taking illicit drugs?”. Recent statistics on the use of illicit drugs in Europe were shown and an overview of the problem was described highlighting a lack of information among Healthcare professionals and users in this field. A number of issues were raised by participants and there was general agreement on the need to further reflect on this topic.

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

Close of meeting

Next meeting: 16-17 June 2011