EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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Minutes of the drafting meeting on the framework for the interaction between the Agency and Healthcare Professionals' Organisations

2 July 2010 – chaired by Isabelle Moulon

Role	Name
Chairperson:	Isabelle Moulon
Present:	**Representatives from Healthcare Professionals' Organisations:** European Association for Clinical Pharmacology and Therapeutics (EACPT), European Society for Medical Oncology (ESMO), European Association of Hospital Pharmacists (EAHP), European Union Geriatric Medicine Society (EUGMS), Standing Committee of European Doctors (CPME), Pharmaceutical Group of the European Union (PGEU). **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)).

1. Welcome and introduction

Isabelle Moulon, Head of Medical Information Sector, welcomed participants and thanked everyone for their positive reaction to attend the meeting.

The chairperson then explained that the meeting was intended to discuss the expectations of both the EMA and the healthcare professionals' organisations members of the HCP WG in order to progress in the development of a framework for interaction between the Agency and healthcare professionals' organisations. She highlighted the fact that healthcare professionals and learned societies were already involved in many EMA activities but there was still lack of awareness about this. She recalled that work had been done in the past to develop such a framework, replicating the model used for patients and consumer's organisations, and that it had been concluded that certain specificities of healthcare professionals' organisations (HCPOs) and learned societies needed a different approach.

2. Adoption of the agenda

The agenda was adopted without any amendments.

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3. EMA/HCP interactions

The Agency provided an overview of the experience gained in the last three years and invited participants to share their views on the value of the interactions, the level of work this represented for their organisations, how much feedback they would need from EMA and how could the interactions be strengthened in the future.

There was general positive feedback from participants on the value of the interactions with the Agency, but some level of frustration was expressed with regards the individual organisation's capacity to respond in time to the different requests coming from EMA (e.g. identification of experts for SAGs).

Participants shared information about their practices with regards the organisation's consultation mechanisms and the time needed to gather input from their constituencies. Some suggestions were made in relation to anticipating consultations which would allow better internal planning within the organisations and allow more time to gather input. In addition, more feedback on how their comments and contributions were used by the Agency was pointed out as an area that could be improved in the future and that would be most welcomed by the HCPOs. It was also mentioned that among and within the HCPOs there were different areas of interest and specialisation which could condition the level of input provided to particular EMA activities.

The PCWP and CMD(h) representatives identified the relevance of looking as well into ways where the experience gained so far at EMA level could be used to encourage HCPOs and national regulators networking, allowing better feedback on the use of medicinal products and the usability of the information tools put at their disposal.

4. Types of interaction in the context of EMA structure and areas for interaction in the context of EMA activities

The Agency presented a set of questions organised by type of interaction, covering the areas of evaluation of medicines, phamacovigilance/ risk management, information on medicines, and public awareness on EMA activities. Comments and suggestions were collected for each question and will be taken into consideration and inform the drafting of the framework.

In relation to activities within the area of evaluation of medicines, and taking into account that the timelines for identification of experts is generally very short, it was suggested to develop an annually updated list of experts identified by the HCP WG members who can be contacted with regards to scientific advisory groups (SAGs) in the following areas: HIV/Viral diseases; anti-infective (not HIV); cardiovascular; central nervous system; diabetes/endocrinology; oncology; and diagnostics. The Agency underlined that aspects of confidentiality and conflicts of interest would require careful attention and permanent update.

Members expressed continued interest on the topic of clinical trials and agreed this was an example of successful involvement and interaction between the Agency and HCPOs. In view of the revision of the clinical trials directive, the HCP WG could provide input to this process.

In relation to pharmacovigilance and risk management, there was a strong interest to become involved in the discussions leading to the implementation of the new legislation, particularly on how to encourage the provision of feedback to HCPs reporting adverse drug reactions and also how to collect feedback from HCPs on how safety information was used. This would be helpful when discussing the public interface of EudraVigilance. With regards to raising awareness about the European Network of Centres for Pharmacoepidemiology and Pharmacovigilance (ENCePP), participants mentioned this would be easy to do and that they would be willing to do so provided 'reader's digests' on this topic

would be provided by EMA. The involvement of HCPOs in aspects of direct healthcare professional communication (DHPC) should receive more attention and a dedicated discussion could be organised in an upcoming meeting of the HCP WG (e.g. quality of DHPC; identification of which DHPC are useful to HCPs). It was also mentioned that the Pharmacovigilance Working Party would like to have input from HCPs on practical issues.

With regards to information on medicines, it was mentioned that the EMA work related with labelling, package design, and review of the SmPC's section on instructions for use was of interest to organisations representing pharmacists and nurses. In order to respond to the short timelines of the Agency when evaluating a specific medicinal product, it was suggested to work together with the organisations to identify effective procedures of involvement. It was also suggested to organise workshops on specific issues, following the successful example of the workshop on recommendations on the expression of strength, which could gather the experience from different parts of Europe.

Participants welcomed the possibility to access in the future the EudraSmPC website – a website developed to support the review of SmPCs in line with the SmPC Guideline. It allows for queries related with the SmPC content to be submitted or searched in a queries database and provides access to training presentations and useful links. It was suggested that access by HCPs to this website would enable practitioners to provide feedback on specific population groups and identify, e.g., missing information in the SmPC that could be improved during a revision process. Participants also expressed strong interest on the eSmPC project.

In relation to the EPAR usability project, general interest was also expressed and it was suggested to further discuss this topic already at the next HCP WG meeting.

Interest was also expressed in the area of preparation of information for the public, particularly in order to anticipate the consequences for patients of regulatory actions and to enhance the cascade process among healthcare professionals' organisations on safety issues and respective feedback. The example of personalised medicines was referred as one where information to the public would be challenging and where the involvement of healthcare professionals would be even more relevant.

5. Interactions related to EMA guidelines

Within the area of evaluation of medicines, the Agency presented the specific case of EMA guidelines and what interactions could occur at this level, emphasising its interest to encourage involvement as earlier as possible in the development phase.

There was general agreement to focus on EMA scientific guidelines on safety and efficacy, and on aspects that within the remit of EMA activity could impact national therapeutic guidelines. It was identified that efforts should focus on the concept paper phase to involve relevant organisations. Based on the comments received at that early stage, meetings for additional discussion could be arranged.

Another aspect that was addressed was the dissemination of the guidelines, once these were approved, and the role HCPOs could play. This would depend on the interest such guidelines could generate among individual healthcare professionals, which was a different thing compared to the involvement of HCPOs in guidelines development.

6. Criteria to be fulfilled by HCPs' organisations involved in EMA activities (eligibility criteria)

There was general agreement with the definition of HCPs' organisations and the criteria for eligibility.

With the purpose of identifying whether the necessary information to comply with all the criteria was easily accessible for each HCPs' organisation and therefore simplify as much as possible the administrative burden of eligibility checking, the organisations were invited to test if the information requested was available on their respective WebPages. It was explained that an open call for eligibility would have to be done, as it had been the case for the Patients' and Consumers' Working Party.

In a future revision of the eligibility criteria it was suggested to include as an additional criterion the disclosure of the organisation's policy on the relationship with the pharmaceutical industry.

7. Supporting structures and tools for EMA/HCP interactions

Due to time limitations, this agenda item focused only on the HCP WG.

Participants agreed that the HCP WG allowed organisations to provide input to EMA but it could worked as well as a platform for members to exchange and discuss common areas of interest (e.g. use of medicines in geriatric populations), within the remit of the Agency's activity. On the other hand, the HCP WG is very important for the Agency as it is the only platform to interact with healthcare professionals and get a better understanding of how the Agency can contribute to improved interactions.

It was suggested to have meeting agendas and supporting documents sufficiently in advance to allow internal consultation within the organisations. It was also suggested to expand the duration of the annual joint meeting with the PCWP and to consider increasing the number of HCP WG observers at the PCWP to enable further interaction between healthcare professionals and patients and consumers. Joint meetings on specific topics of common interest could also be organised (e.g. new legislation on pharmacovigilance; eSmPC in the context of eHealth).

The possibility for the Agency to participate at the general assemblies of the HCPs' organisations was also very welcomed.

As a conclusion, it was recommended to: explore clustering organisations by type of EMA activity, as not all would be interested on the same activities; focus attention on the cascade effect HCPs' organisation can provide (e.g. to develop fact-sheets or other type of information that could be easily linked to the HCPs' organisations WebPages); and enhance the subscription to customised information in the EMA website.

8. Drafting process

The Agency explained that Ingolf Cascorbi, Michel Delvaux and Michael Wilks had kindly volunteered to actively work together with the EMA secretariat in the initial drafting of the framework. A first draft should be expected by end of September 2010 and a formal discussion would take place at the HCP WG meeting, on 28 October. The document should be finalised in December, to be considered by the Management Board.

Some discussion will still be needed on how to monitor the interactions.

9. Wrap up and final remarks

The chairperson thanked the participants for the fruitful discussions.

Close of the meeting