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# Minutes of the European Medicines Agency/CHMP Working Group with Healthcare Professionals' Organisations (HCP WG)

29/10/2009 – chaired by Dr. 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 Society of Cardiology (ESC), European Association for the Study of Diabetes (EASD), The European Specialists Nurses Organisations (ESNO), European Society of Endocrinology (ESE), United European Gastroenterology Federation (UEGF), European Association of Hospital Pharmacists (EAHP), Pharmaceutical Group of the European Union (PGEU), European Federation of Nurses Associations (EFN), European Union of General Practitioners (EUGP).<br><br>**Representatives and observers from the Agency's Scientific Committees:** Committee for Medicinal Products for Human Use (CHMP).<br><br>**Observers:** Patients and Consumers Working Party (PCWP), Co-ordination Group for Mutual Recognition and Decentralised Procedures–Human (CMD(h)). |

## 1. Introduction

The sixth HCP WG plenary meeting was held at the Agency on 29th of October 2009.

Isabelle Moulon, Head of Medical Information Sector, welcomed participants and thanked HCP WG members for their contribution to the Agency's activities during 2009, in particular, regarding the pandemic influenza preparedness.

The agenda was adopted without any amendments.

## 2. Information on benefit-risk of medicines

### 2.1 The Agency's initiatives to strengthen the assessment and communication of benefits and risks of medicines

The Agency presented the current status of different projects and initiatives for improvement of benefit-risk assessment and communication. It was mentioned that some of them are being carried out in close collaboration with leading academic centres in medical sciences and information technologies. PROTECT (Pharmacoepidemiological Research on Outcomes of Therapeutics) which is under the umbrella of Innovative Medicines Initiative, is one of the examples of public-private partnership in research and innovation. It aims at developing a set of new methods that will enhance early detection and assessment of adverse drug reactions from different data sources, and enable the integration and presentation of data on benefit-risk.

It was underlined that there is a need to further improve the collaboration with other stakeholders in this area and the understanding of the decision supporting tools in the evaluation of medicines. It was recognised that the assessment of medicines' benefit in real circumstances requires strong collaboration with patients and healthcare professionals.

HCP WG acknowledged the Agency's efforts to strengthen the benefit-risk assessment and communication. HCP WG requested to be kept informed about the progress and the outcome of the Agency's initiatives in this area.

## 3. Innovative medicines and impact on Healthcare Professionals

The Agency gave an overview on advanced therapy medicinal products and innovative methods. HCP WG was informed about the current status and the obstacles in the development of these medicines as well as the most relevant initiatives aimed at boosting the scientific research in this field. It was noted that the strong patients´ demand for safe and better targeted therapies is one of the key drivers for the development of innovative medicines.

The therapeutic potential of these medicines was illustrated with some examples such as the successful use of monoclonal antibodies as antineoplastic and immunomodulating agents. Another promising therapeutic area is the nanomedicine, which advantages are derived from the unique properties of the nanoparticles. It was pointed out that medicines containing nanoparticles had been already assessed through the centralised procedure.

Healthcare professionals and patients should be aware of the benefits and possible adverse reactions of the advanced therapies and be involved at an earlier stage in their development. It was highlighted that regulators need healthcare professionals' and patients' support in order to facilitate the provision of information on these medicines and define appropriate risk management plans.

Special attention was paid to novel methods, such as the use of genomic biomarkers, in the discovery, development and post-authorisation of medicines. These methods allow better understanding of approved medicines' benefit-risk profile, guide dose selection, improve diagnosis and ensure more efficient and targeted treatment.

HCP WG warmly welcomed this presentation. Given the great interest toward innovative medicines and the necessity of further discussions, it was decided to organise, together with PCWP, a web conference and a dedicated meeting on this topic during the next year. HCP WG representatives will be informed and invited to participate in Agency's activities in relation with innovative medicines.

## 4. Presentation of the European Network of Centres for Pharmacoepidemiology and Pharmacovigilance (ENCePP)

The Agency gave an overview on the development of ENCePP. Bringing together the available expertise and research experience in the field of pharmacoepidemiology and pharmacovigilance, this the Agency -led project aims at further strengthening the post-authorisation monitoring of medicines by facilitating the conduct of high quality, independent studies focused on safety and benefit-risk.

The main objective for 2009 is to put in place an operational network system that would allow the conduct of ENCePP studies, which should fulfil specific methodological research standards (MRS) and be conducted in accordance with the rules of transparency and scientific independence reflected in the ENCePP Code of Conduct. It was mentioned that healthcare professionals' organisations could contribute to the dissemination of information on ENCePP studies in different countries.

HCP WG members were invited to send comments on the MRS Checklist and the ENCePP Code of Conduct.

## 5. Area of involvement in the Agency's activities

### 5.1 The European Medicines Agency Road Map to 2015: the Agency's Contribution to Science, Medicines, Health

The Road Map to 2015 was presented to HCP WG. Built on the current achievements in the implementation of the Road Map to 2010, this document reflects the Agency's longer term strategy for the evaluation and supervision of medicinal products. The document identifies four strategic areas which encompass different challenges in the fields of science, medicines and health. These areas are: further improving the operation of the core business, addressing public health needs, facilitating access to medicines and optimising the use of medicines.

HCP WP members were of the opinion that in this strategic document the role of healthcare professionals is not very prominent, despite there are a great number of fields in which HCP can be involved, such as the medicines development for unmet medical needs, benefit-risk assessment and especially communication to the public, etc. HCP WG members were invited to participate actively in the public consultation on the Agency's Road Map to 2015 which will start at the beginning of 2010.

### 5.2 How HCP can be involved in the Agency's activities - framework for interaction

HCP WG held a discussion on how to involve healthcare professionals´ organisations in the Agency's activities. It was acknowledged that the Agency's model for interaction with patients cannot be applied to healthcare professionals due to their different interests and expectations as a group, and the fact that they are already largely represented at the Agency (e.g. committee members, experts, etc). However, the input from organisations is very often missing, and there are still many areas where their involvement is expected to bring an added value (e.g. discussion at early stage of guideline preparation, communication issues, etc). In addition, regular participation of HCPs' organisations in workshops and conferences organised by the Agency needs to be guaranteed.

It was agreed that clear criteria for eligibility will help to select healthcare professionals' organisations for interaction

With regard to the HCP WG it was suggested to introduce more flexibility within the group, by encouraging an active participation of healthcare professionals in dedicated meetings on specific issues. The interest of the Joint meeting with PC WP was confirmed.

Comments and suggestions, stated above and made during the discussion, will be taken into consideration for the preparation of a framework of interaction between the Agency's and healthcare professionals´ organisations. It was decided that the first draft of this document would be prepared by an ad hoc group composed of the Agency's secretariat and three HCP WG members: Ivana Silva (GPUE), Ingolf Cascorbi (EACPT) and Michel Delvaux (UEGF). The framework will define the scope and the objectives of the interaction with healthcare professionals´ organisations and will include an action plan. In 2010 the document will be discussed and finalised by the HCP WG, and afterwards it will be adopted by the Management Board.

### 5.3 Draft Work Plan for 2010

The draft Work Plan for 2010 was adopted by the HCP WG. It focuses on the development of the framework of interaction and in the implementation of the Final Recommendations and Proposals for Action (EMEA/185036/2008), in particular in the area of information on medicines. In addition, HCP WG recommendations in the field of pharmacovigilance would be revised in light of the legal proposal from the European Commission.

HCP WG members would be periodically informed about the Agency's workshops, seminars and other activities in which they could be involved. Furthermore, it is expected to foster HCP WG contribution, to the preparation of the Agency's guidelines, at an earlier stage.

The Work Plan for 2010 would be presented to the CHMP for adoption in November 2009, and subsequently published on the Agency's website.

## 6. Clinical trials

### 6.1 Update on the activities of the Agency's ad-hoc Working Group on Third Country Clinical Trials

The Agency gave a presentation on the activities of its ad-hoc Working Group on clinical trials in third countries. Composed of representatives of different scientific committees and working groups of the Agency, including HCP WG and PCWP, this group was created with the purpose of developing practical proposals in four action areas identified in the Agency's Strategy Paper on the acceptance of clinical trials conducted in third countries (EMEA/228067/2008). These areas include ethical standards for clinical trials, provision of guidance and advice in drug development and marketing authorisation phases, and international cooperation in the regulation of clinical trials.

The Agency informed that the outcome of the discussions and the proposals in the four areas would be presented in a single reflection paper, which will be divided into four chapters, one for each area.

The Agency thanked HCP WG representatives for their participation and contribution to Working Group, and invited all members to propose experts in bioethics, who would be consulted during the elaboration of the final document.

### 6.2 Update on the EudraCT public interface construction

The Agency informed about the current stage of development of EudraCT public interface. It was agreed to show the public interface to selected stakeholders during the first quarter of 2010. The public interface is finally expected to be publicly available in 2Q2010.

## 7. The European Medicines Agency transparency policy

EAHP presented the healthcare professionals' contribution to the recent Agency transparency policy workshop held on 19th October 2009. Healthcare professionals' organisations strongly support this initiative, which aimed at introducing more openness in the Agency's activities. It was acknowledged that a right balance between transparency and protection of commercial confidentiality should be achieved. Special attention was paid to the necessity of strengthening the interaction with the Agency's stakeholders and a closer cooperation with the national competent authorities on transparency related issues. The use of information and communication technologies for health – e-health initiatives was also discussed. Everyone agreed that healthcare professionals should remain the reference source of information on medicines.

HCP WG would continue collaborating to the development of the Agency transparency policy and the implementation of the transparency measures throughout 2010.

## 8. Conclusions

The chairperson thanked the participants for the fruitful discussions.

Close of the meeting