



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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Stakeholders and Communication Division

Mandate, objectives and composition of the Healthcare Professionals Working Party (HCPWP)

1. General considerations

The Regulation (EC) No. 726/2004 of the European Parliament and of the Council, in particular Article 78 (1), gives responsibility to the European Medicines Agency (EMA), its Management Board and its committees to develop contacts with healthcare professionals.

During its 15 December 2011 meeting, the EMA Management Board endorsed a *“Framework of interaction between the EMA and healthcare professionals”* (EMA/688885/2010) foreseeing the creation of a forum of exchange with healthcare professionals’ organisations within the Agency, with links to EMA Human Scientific Committees (CAT, CHMP, COMP, HMPC, PDCO and PRAC).

To meet this requirement, the Healthcare Professionals Working Party (HCPWP) was formally established as the EMA Human Scientific Committees’ Working Party with Healthcare Professionals’ Organisations (HCPWP) in 2013 and re-confirmed in the revised framework for interaction, adopted on 16 December 2016 (EMA/89918/2016).

The HCPWP mandate, objectives and composition are set out in this document.

2. Mandate and objectives

The HCPWP provides recommendations to EMA and its Human Scientific Committees on matters of direct or indirect interest to healthcare professionals in relation to medicines for human use and monitor the overall interactions between EMA and healthcare professionals.

The HCPWP will facilitate EMA’s dialogue and exchange with healthcare professional organisations on relevant issues related to medicines for human use within the European legal framework. Through the HCPWP, EMA will inform and will obtain input and feedback from healthcare professionals on various EMA activities. Ultimately, the HCPWP is expected to contribute to EMA’s strategic goal of advancing public health by supporting its initiatives to bringing real-life data into regulatory science and promoting a safer and more rational use of medicines.

The HCPWP will focus on 4 main tasks:



1. Support EMA to gain a better understanding of how medicines are being used in real clinical practice and how EU regulatory decisions impact clinical practice as well as how EMA can best communicate with healthcare professionals to support their role in the safe and rational use of medicines; this shall include but is not limited to
 - a) Obtain information on the current use of medicines in clinical practice and their therapeutic environment;
 - b) Provide advice on how avoidable medication errors could be prevented;
 - c) Input on the effectiveness of risk minimisation measures and their impact on the work of healthcare professionals;
 - d) Contribute to the provision of information adapted to healthcare professionals' needs, in particular safety-related information;
2. Contribute to EMA's scientific work intended to continuously improve benefit-risk assessment of medicines throughout their life-cycle; this shall include but is not limited to
 - a) Contribute as appropriate to EMA's initiatives to enhance the medicines-development process, bridge gaps in medicines development and supply as well as to address the challenges of new and emerging science;
 - b) Input as appropriate to EMA's initiatives addressing specific public-health needs (e.g. medicines for children; use of medicines by older people; options for new and effective antibiotic treatments);
 - c) Provide advice in relation to non-confidential product specific matters, at the request of the EMA Human Scientific Committees, for the purpose of benefit-risk decision-making;
 - d) Liaise with other working parties on matters of interest to healthcare professionals in relation to medicines, including their involvement in the development of new guidelines or in guideline revisions;
3. Enhance healthcare professionals' organisations understanding of the mandate and work of the Agency and of the European Medicines Regulatory Network; this shall include but is not limited to
 - a) Contribute to the development of appropriate communication tools;
 - b) Facilitate and encourage the cascade of information to the constituencies of healthcare professionals' organisations;
 - c) Contribute as appropriate to the implementation of pharmaceutical legislation, and the initiatives coming from the EU Network strategy and EMA's multiannual work programmes;
 - d) Liaise with interested parties (patients' and consumers' organisations, academia, pharmaceutical industry).
4. Monitor the implementation of the objectives identified in the "Framework for interaction between the European Medicines Agency and healthcare professionals and their organisations".

3. Composition

3.1. Members

The HCPWP consists of 30 members, of which:

- Twenty-two (22) are appointed from amongst the list of EMA eligible organisations by a Decision of the Executive Director
- Six (6) are appointed by each of the EMA Human Scientific Committees (CAT, CHMP, COMP, HMPC, PDCO and PRAC);
- One (1) Chairperson is elected from its members (HCPWP Co-Chair);
- One (1) Chairperson is nominated from amongst the EMA Secretariat by a Decision of the Executive Director (EMA Co-Chair).

3.1.1. Healthcare professional organisations

The Healthcare professional organisation members shall be selected from the list of EMA eligible organisations by the EMA Secretariat on the basis of their relevance to the subjects covered within the scope of the working party's mandate, and following a call for expressions of interest.

If several organisations in the same area are eligible, EMA shall select one or more, as appropriate.

The selected group shall have a balanced representation of different types of healthcare professionals (such as general practitioners, specialist doctors, nurses, hospital and community pharmacists) and of learned societies with specific interest in the mandatory scope of the centralised procedure (orphan drugs, HIV/Aids, cancer, diabetes, neurodegenerative disorders or autoimmune diseases and other immune dysfunctions).

HCPWP members will be nominated by a Decision of the Executive Director for a term of 3 years, which may be renewed.

Each organisation shall appoint one representative and one alternate.

The individuals appointed by the organisations act as their representatives for the purpose of the HCPWP activities and not on their own individual capacity. Therefore, the appointed representative is responsible for liaising with their organisation in order to provide the organisation's position on the topics to be addressed. In parallel, they should report back on the activities of the HCPWP.

All discussions within the working party are of a non-confidential nature and do not refer to any ongoing medicine specific evaluations, however each representative shall complete a public declaration of interests and be included in the Agency's Experts database for transparency purposes.

A representative or alternate cannot be employed by a pharmaceutical company, as this is not compatible with the activities of the working party.

If an HCPWP representative is involved as an expert (i.e. own individual capacity) in another EMA activity, a separate assessment of competing interests will be made for each activity, based on the EMA policy on handling of competing interests for scientific committees' members and experts.

3.1.2. EMA Human Scientific Committees

Each EMA Human Scientific Committee shall nominate one representative and one alternate to be part of the working party, preferably for as long as both the HCPWP and their respective Committee mandates overlap. The Committee may however nominate a different representative/alternate at any time if needed. Nominations can also be renewed.

The Committee representative is responsible for liaising with their Committee in order to contribute relevant topics (i.e. points for discussion and reflection) to be addressed to the working party as well as to inform the Committee of working party activities.

3.1.3. Chairpersons

The working party will have two Chairpersons (referred to as Co-Chairs, hereafter), who are responsible for the efficient conduct of the working party.

One Co-Chair (also referred to as the EMA co-chair) will be a representative of the EMA secretariat and will be nominated by a Decision of the Executive Director. The other co-chair (also referred to as the HCPWP Co-Chair) will be elected amongst working party members, as detailed in the Rules of procedure for the Patients' and Consumers' Working Party (PCWP) and Healthcare Professionals' Working Party (HCPWP). Both will stand for a period of 3 years which may be renewed.

3.2. Observers

The HCPWP has the following observers:

- EMA Management Board
- European Commission
- Coordination Group for Mutual Recognition and Decentralised Procedures - Human (CMDh)
- Patients' and Consumers' Working Party (PCWP)

The EMA Management Board member representing doctors' organisations will be invited to observe the activity of the working party.

The European Commission will be invited to nominate one representative to observe the activity of the working party.

The CMDh will be invited to nominate one of its members as the CMDh observer for the duration of the HCPWP mandate.

The PCWP will be invited to nominate up to two of its members as PCWP observers for the duration of the HCPWP mandate.

Ad-hoc observers may be invited to participate in HCPWP meetings with the agreement of the Co-Chairs and can include other healthcare professional organisations, national competent authorities, European agencies and any other relevant stakeholder.