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Stakeholders and Communications Division

Mandate, objectives and composition of the Patients and Consumers Working Party (PCWP)

1. General considerations

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

During its 15 December 2005 meeting, the EMA Management Board endorsed a *"Framework of interaction between the EMEA and Patients' and Consumers' Organisations" (*EMEA/354515/2005-Final) foreseeing the creation of a forum of exchange with patient and consumer organisations within the Agency, with links to the EMA Human Scientific Committees (CAT, CHMP, COMP, HMPC, PDCO and PRAC).

To meet this requirement, the Patients and Consumers Working Party (PCWP) was established (formerly known as the EMA Human Scientific Committees' Working Party with Patients' and Consumers' Organisations) in 2006 and re-confirmed in the revised framework for interaction, adopted in December 2014 (EMA/637573/2014).

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

2. Mandate and objectives

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

The PCWP will facilitate EMA's dialogue and exchange with patient and consumer organisations on relevant issues related to medicines for human use within the European legal framework. Through the PCWP, EMA will inform and will obtain input and feedback from patients and consumers on various EMA activities. Ultimately, the PCWP 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.

30 Churchill Place ● Canary Wharf ● London E14 5EU ● United Kingdom
Telephone +44 (0)20 3660 6000 **Facsimile** +44 (0)20 3660 5555
Send a question via our website www.ema.europa.eu/contact

The PCWP role includes, but is not limited to the tasks defined below:

- Implement and monitor the proposals within the revised Framework of interaction between EMA and patients and consumers organisations.
- Contribute to the provision of information adapted to patients' and consumers' needs.
- Contribute to the development of appropriate communication tools and facilitate the cascade of information throughout the organisation and membership.
- Contribute to increase awareness of patients in relation to the use of medicines.
- Contribute to the development and the training of a network of Patients' and Consumers' Organisations.
- Provide advice in relation to non-confidential medicine specific matters, at the request of the EMA Human Scientific Committees.
- Liaise with interested parties (health-care professionals' organisations, learned societies, academia, and pharmaceutical industry).
- Set up topic groups, when additional and/or more in-depth discussion within the group is needed, including the option to invite others from eligible organisation to join.
- Contribute as appropriate to the implementation of pharmaceutical legislation, and the initiatives coming from the EU Network strategy and EMA's multiannual work programmes.
- 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).
- 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.

3. Composition

3.1. Members

The PCWP 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 (PCWP 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. Patient and Consumer organisations

The Patient and Consumer 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.

The following areas will be covered: general consumers' organisations, general patients' organisations and organisations with a specific interest in the mandatory scope of the centralised procedure (orphan medicines, HIV/AIDS, cancer, diabetes, neurodegenerative disorders or autoimmune diseases and other immune dysfunctions).

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

PCWP members will be nominated by a Decision of the Executive Director for a term of three 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 PCWP 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 PCWP.

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 a PCWP 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 PCWP 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 (non-confidential) 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 PCWP 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 three years which may be renewed.

3.2. Observers

The PCWP has the following observers:

- EMA Management Board
- European Commission
- Coordination Group for Mutual Recognition and Decentralised Procedures - Human (CMDh)
- Healthcare Professionals' Working Party (HCPWP)

The EMA Management Board members representing patients' organisations will be invited to observe the activities of the working party.

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

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

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

Ad-hoc observers may be invited to participate in PCWP meetings with the agreement of the co-chairs and can include other patient and consumer organisations, national competent authorities, European agencies or any other relevant stakeholder.