EUROPEAN MEDICINES AGENCY
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Patient Health Protection

Mandate, objectives and rules of procedure for the European Medicines Agency Human Scientific Committees' Working Party with Patients' and Consumers' Organisations (PCWP)

1. General considerations

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

The EMA Management Board endorsed in its 15 December 2005 meeting a *"Framework of interaction between the EMEA and Patients' and Consumers' Organisations" (*EMEA/354515/2005-Final). As indicated in the Framework, a dedicated forum needed to be established to build on the work already undertaken by the EMEA/CHMP Working Group with Patients' Organisations, to adequately deal with the activities of the five EMA Human Scientific Committees (CHMP, COMP, PDCO, CAT and HMPC). Hence, the creation of the *European Medicines Agency Human Scientific Committees' Working Party with Patients' and Consumers' Organisations* (PCWP).

From a general viewpoint, the EMA Human Scientific Committees' Working Party with Patients' and Consumers' Organisations (PCWP) is established to provide recommendations to the EMA and its Human Scientific Committees on all matters of direct or indirect interest to patients in relation to medicinal products and to perform the tasks described here-in.

Initially, the PCWP has focused on:

- Implementation of 'Recommendations and Proposals for Action' (EMEA/149479/2004/Final), stemming from the former EMEA/CHMP Working Group with Patients' Organisations in the areas of Transparency and Dissemination of Information, Product Information, Pharmacovigilance and Interaction between the EMA/Scientific Committees and Patients Organisations.
- Contribution to the implementation of the objectives identified in the "Framework on the interaction between the Agency and patients' and consumers' organisations" (EMEA/354515/2005-Final).

The PCWP will now collaborate with the Agency in the revision, implementation and monitoring of the framework of interaction.

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Furthermore, the PCWP may be asked to contribute to the implementation of Pharmaceutical Legislation, and the initiatives coming from the EMA Road Map to 2015.

2. Mandate and objectives

The EMA Human Scientific Committees' Working Party with Patients' and Consumers' Organisations (PCWP) is established to provide recommendations to the EMA and its Human Scientific Committees on all matters of direct or indirect interest to patients in relation to medicinal products including, but not limited to the tasks defined below:

- Implement and monitor the proposals within the 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.
- Contribute to increase awareness of patients in relation to the use of medicines.
- Contribute to promote a rational use of medicines.
- Contribute to the development and the training of a network of Patients' and Consumers' Organisations.
- Provide advice in relation to product specific matters, at the request of the EMA Human Scientific Committees.
- Liaise with interested parties (health-care professionals' organisations, learned societies, academia, pharmaceutical industry).
- Set up drafting groups, when necessary.
- Liaise with other Working Parties on matters of interest to patients in relation to medicinal products.
- Provide advice to the Co-ordination Group for Mutual Recognition & Decentralised Procedures – Human (CMD(h)) upon request, on matters of interest to patients in relation to medicinal products.

3. Composition and rules of participation

The PCWP is composed of the following members:

- Patients' and consumers' organisations which shall fulfil the eligibility criteria approved by the EMA Management Board.
- EMA Human Scientific Committees (CAT, CHMP, COMP, HMPC, PDCO and PRAC).
- EMA secretariat.

The EMA will decide on the organisations that will be represented in the group on the basis of their appropriateness to the subjects covered within the scope of the working party's mandate. The following areas will be covered: general consumers' organisations, general patients' organisations, organisations 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).

A maximum of 20 patients/consumers' organisations will be members. If several organisations in the same area are eligible, EMA may select only one/some of them, as appropriate.

Upon request from the EMA, patients' and consumers' organisations, which fulfil the criteria above, will nominate one representative. It would be preferred that the patients' organisations nominate a patient or carer as representative, whenever possible.

Each EMA Human Scientific Committee will be invited to nominate one representative to be part of the working party.

The EMA will nominate on representative to be part of the working party.

Members of the PCWP will be nominated for a term of 3 years, after which the membership can be renewed.

Members of the PCWP may nominate an alternate representative to participate in those exceptional cases where the official representative is unable to attend a meeting.

The representative of the organisation has the responsibility to liaise with their organisation as necessary in order to provide the position of the organisation on the topics to be addressed. It is also their responsibility to inform their organisation about the activities of the group.

Membership of the PCWP implies a commitment to participate actively in the work of the working party and to attend the meetings of the working party regularly. After a patients'/consumers' organisation has presented its apologies 3 consecutives times, the membership will be revoked, and the EMA would consider participation of another organisation.

Members who would like to bring additional participants with relevant experience for a specific topic should notify the EMA secretariat in advance of the meeting. Participation will be subject to the agreement of the Chairpersons.

Meeting documentation will be distributed to the participants.

Representatives of the European Commission may attend meetings of the PCWP.

Observers (e.g. from CMD(h), EMA Management Board, etc) may participate with the agreement of the Chairpersons. Additionally, other patients' and consumers' organisations may be offered the possibility to participate as observers on an ad-hoc basis to the PCWP meetings. Priority will be given to eligible organisations who are not PCWP members.

Members of the EMA Human Scientific Committees are encouraged to take an active role in the activities of the PCWP.

4. Meeting frequency

The PCWP shall meet up to 4 times (± 1) per year in accordance with the adopted Work Programme. Some of these meetings may be held jointly with the Healthcare Professionals Working Party.

The dates of the meetings shall be included in the Work Programme of the PCWP.

Drafting Groups of the PCWP can be held, if necessary.

5. Duration of activity (in the case of temporary working parties)

Not applicable.

6. Rules of procedure

6.1. Responsibilities of Chairpersons

The working party will have two Chairpersons. The Chairpersons are responsible for the efficient conduct of the business of the working party and shall in particular:

- Plan the work of the working party together with the EMA secretariat.
- Monitor, together with the EMA secretariat, that the rules of procedure are respected.
- Ensure that at the beginning of each meeting any potential conflict of interest is declared regarding any particular item to be discussed by the working party.
- Aim to achieve consensus on issues discussed by the working party.
- Decide in exceptional cases, when a vote is necessary.
- Ensure, together with the working party and the secretariat, the compliance with the legal/regulatory framework.
- Co-ordinate together with the EMA secretariat the work of this working party with that of the other relevant working parties of the Agency.
- Ensure that the activities of the working party are reported to the EMA Human Scientific Committees or other working parties as appropriate.

One Chairperson will deputise for the other Chairperson when one is unable to chair either all or part of the working party meeting. On such occasions the available Chairperson will seek the agreement of the other Chairperson as early as possible, prior to the meeting and the EMA secretariat shall be informed immediately.

The EMA secretariat will provide the necessary administrative and secretarial support to the Chairpersons to achieve the responsibilities listed above.

6.2. Election of Chairpersons

One Chairperson will be nominated by the EMA, and the other one will be elected by the PCWP. Both will stand for period of 3 years which may be renewed.

Candidates shall express their interest in writing to the EMA secretariat no later than the defined deadline for it.

The election of the Chairperson shall follow the same procedure as that for the election of the chairperson of Committee as stated in Article 3, paragraphs 1 to 4, of the Rules of Procedure of the CXMP.

6.3. Organisation of meetings and reporting arrangements

- The core PCWP meetings shall be held at the Agency.
- The dates of meetings are decided on an annual basis in consultation with the PCWP.
- The meetings will be held and minuted in English.
- The draft agenda for every meeting shall be circulated, by the EMA secretariat, in consultation with the Chairpersons, 4 weeks before the meeting, if possible.
- The working party may identify and propose topics for its consideration and inclusion within the Work Programme.
- The topics discussed will not be subject to confidentiality. When considered appropriate by the PCWP, oral presentations by interested parties can be made during working party meetings on matters directly related to the activities of the working party, following agreement with the EMA.
- The PCWP shall prepare an annual work programme, which shall include topics identified in accordance with point 5 above and any other specific tasks identified by the EMA Scientific Committees. It will be circulated to the EMA Scientific Committees for adoption. The work programme shall be regularly reviewed and updated as necessary.
- Agenda and minutes of the meetings of the working party shall be circulated to the EMA Scientific Committees for information, and then published on the EMA website together with other meeting-related documents (e.g. presentations). Other documents produced by the working party will also be circulated to the relevant EMA Scientific Committees for information. Those documents that directly relate to the work of the relevant EMA Scientific Committees will be adopted by the Committees (i.e. "Rules for involvement of members of patients' and/or consumers' organisations in Committees related activities" (EMEA/483439/2008 rev. 1).
- Topic-specific discussions may also take place via teleconference or by written procedure where appropriate/necessary.
- The Chairpersons will decide on the person who will report on the activities of the working party to the EMA Scientific Committees and will ensure the liaison with the Committees. Preferably one of the representatives from each Human Scientific Committees, member of the PCWP, will be in charge of this.
- The mandate of the PCWP will be prepared by the EMA secretariat and agreed by the PCWP. It will be adopted by the EMA Scientific Committees. It shall be reviewed, at the end of the 3 year term.

6.4. Drafting Groups

- When further consideration is required in order to prepare proposals on specific topics the working party may convene drafting groups constituted of members of the working party or additional participants, as appropriate.
- The drafting group will preferably be held in the margin of the plenary PCWP meeting and will report directly to the PCWP.

6.5. Participation of Experts in meetings

- When necessary, the working party may avail itself of the services of experts or patients representatives with experience in specific fields. Experts shall have proven experience in their field of expertise. They will be included in the European Experts list.
- The names of these experts shall be notified to the EMA secretariat before the meeting that they are due to attend.

6.6. Guarantees of independence

- The members of the working party and experts referred to above shall not have any direct interests in the pharmaceutical industry, which could affect their impartiality. They shall undertake to act in the public interest and in an independent manner, and shall make an annual declaration of their financial interests.
- Members of the working party and experts attending these meetings shall declare at the beginning of each meeting any specific interests, which could be considered to be prejudicial to their independence with respect to the points of the agenda. These declarations shall be made available to the public.
- The patients' and/or consumers' organisations, to which the members of the working party belong, shall fulfil the criteria approved by the EMA Management Board.
- The specific provisions for handling declaration of interests as defined in the EMA Policy on the Handling of Conflicts of Interests for Committee Members and Experts, adopted by the Management Board are applicable to members of the working party participating in the activities of the working party.

6.7. Code of conduct

Members of the working party and experts participating in the EMA's activities shall abide by the principles set out in the EMA Code of Conduct. However, the members of the group are not bound to confidentiality with regard to the discussions held during the meetings of the PCWP and the work undertaken within the framework of the group, unless specifically highlighted to the contrary.

6.8. EMA secretariat

Under the authority of the Executive Director, the EMA secretariat shall provide technical, scientific and administrative support to the working party. This includes the following:

- Provide technical and scientific support to topic leaders, and other members of the working party.
- Provide legal, regulatory and scientific support to the working party when necessary.
- Prepare and co-ordinate the work of the working party in consultation with their Chairpersons.
- Ensure, if appropriate, that the periods laid down by European Union legislation for the implementation of actions are complied with.
- Organise meetings of the working party ensuring timely circulation of meeting documents.
- Facilitate the necessary contacts between the working party and the EMA Human Scientific Committees.

- Ensure adequate co-ordination of the work carried out within the working party, the Scientific Committee(s) and other concerned working parties and/or scientific advisory groups.
- Contribute to the overall quality assurance and assurance of regulatory consistency of the documents / recommendations of the working party in co-operation with the Chairpersons.
- Prepare the agenda and minutes of the meetings of working party in consultation with the Chairpersons.
- Communicate when necessary any Committee recommendations relevant to the working party to interested parties.
- Contribute to the identification of experts.

The Executive Director of the Agency and members of the EMA secretariat may attend all meetings of the working party.

6.9. Contacts with Interested Parties

- Where relevant, the working party will establish contacts, on an advisory basis, with parties concerned with the use of medicinal products, in particular health-care professionals' organisations and the pharmaceutical industry.
- Draft documents and other recommendations from the working party will be subject to public consultation of all interested parties (pharmaceutical industry, health-care professionals or other).
- When considered appropriate by the working party, oral presentations by interested parties can be made during working party meetings.
- In any case, the working party shall neither conduct any deliberations nor reach any decision in the presence of members of other interested parties.
- Before any consultation session, interested group representatives and working party members will communicate to the EMA secretariat the points they would like to be discussed, so that an agenda of the session can be prepared for agreement by the working party Chairpersons and circulation by the EMA secretariat.

6.10. General provisions

- When participating in international or other fora not specifically on behalf of the PCWP, members shall make clear that the views expressed are their own views and not those of the PCWP.
- More rarely, a member of the PCWP may participate in international or other fora and represent the PCWP, upon request or official agreement of the PCWP. In this case the PCWP member shall ensure that the views expressed are those of the PCWP. He/she will be asked to report back to the PCWP at its next meeting or in writing.
- The final decision whether or not it is appropriate for a member to participate and represent the PCWP will rely entirely on the PCWP. The decision will always be made on the basis of the EMA Code of Conduct. Only conferences organised by non-profit organisations will be considered; invitations for conferences organised by individual pharmaceutical companies will not be accepted.
- In every case, the "Policy on representation of EMA Scientific Committees by CXMP Members" (EMEA/231477/2005 rev. 1) will be followed.