



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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Stakeholders and Communication Division

Rules of procedure for the Patients and Consumers Working Party (PCWP) and the Healthcare Professionals Working Party (HCPWP)

1. Roles and responsibilities

Membership of the PCWP and HCPWP implies a commitment from its members, through their **appointed representatives**, to participate actively in the work of the working party, which includes:

- Identify relevant topics for information, discussion and reflection.
- Exchange views and positions from organisations, scientific committees and EMA on topics addressed by the working party.
- Participate in meetings and written consultations of non-confidential nature.
- Propose recommendations to EMA, scientific committees and organisations on topics addressed by the working party.
- Oversee fora (co-)chaired by EMA for information sharing and communication with patients', healthcare professionals' and/or their organisations.
- Inform their organisations and scientific committees about the activities of the working party.
- Agree on the mandate, work plan and any governance-related documents of the working party.

The working party shall have two **Chairpersons** (referred to as Co-Chairs, hereafter). 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/PCWP Co-Chair) will be elected amongst working party members, following the procedure described in point 4. The Co-chairs 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.
- Aim to achieve consensus on issues discussed by the working party and in exceptional cases, decide if a vote is necessary.



- Co-ordinate together with the EMA secretariat the work of this working party with that of other relevant working parties of the Agency.

The **EMA secretariat** shall support the operation of the working party, which includes:

- Provide technical and procedural support to Co-Chairs and other members of the working party.
- Prepare and co-ordinate the work of the working party in consultation with their Co-Chairs.
- 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 co-ordination between each working party, the Scientific Committee(s) and EMA departments.
- Prepare the agenda and minutes of the meetings of the working party in consultation with the Co-Chairs.
- Share any relevant communications to the working party for further dissemination.

2. General operation of the working party

Topics discussed will not be subject to confidentiality, must remain within the remit of the working party mandate and shall be preferably aligned with its adopted work plan.

The working parties shall meet up to 4 times (± 1) per year in accordance with the adopted work plan. Some of these meetings may be held jointly between PCWP and HCPWP.

2.1. Decision-making process

Generally these working parties do not adopt formal recommendations or positions as such, however in the case that this should be requested by any committee, or by EMA (in relation to non-confidential issues), then the working party shall seek to reach this by consensus.

The quorum required for the adoption of a recommendation(s) or position(s), shall be reached when two thirds of the total members of the Working Party eligible to vote are present (physically or remotely).

If however consensus cannot be reached and a member(s) objects or diverges, this should be noted in the minutes. In exceptional cases, the Co-Chairs may decide that a particular recommendation or position needs to be adopted by a majority of voting members.

2.2. Mandate

The mandate of the working parties will be prepared by the EMA secretariat, agreed by the members of the working parties and adopted by the Scientific Committees. It shall be reviewed, at the end of the 3 year term.

2.3. Work plan

The working parties shall prepare an annual work plan, which shall include topics within the scope and interests of EMA, the organisations and scientific committees. The work plan shall be regularly reviewed and updated as necessary. Upon mutual agreement by the HCPWP and the PCWP, work plans may be jointly prepared.

2.4. Topic Groups

- When a specific topic requires further consideration to prepare proposals the working party may convene a topic group constituted of members of the working party or additional participants, as appropriate.
- The topic group discussions may be held in the margin of the working party meetings or via teleconference or written procedure where appropriate/necessary.
- The working party will agree on a topic group lead(s) who shall report back to the working party.

3. Participation of members and observers in working party meetings

EMA will reimburse participation of one representative of each of the 31 members, the PCWP/HCPWP co-chair and observers identified in each working party's mandate, objectives and composition. Budget permitting, ad hoc observers and additional participants may be reimbursed.

Upon request from a working party member whose representative and alternate may otherwise not be able to travel to EMA, remote participation can be organised. Such participation will be counted for the purpose of voting procedures.

If an organisation member of the working party is not represented in 3 consecutive meetings (either physically or remotely), the membership will be revoked, and EMA may consider a membership request from another organisation.

Any members who would like to bring additional participants (e.g. speakers or observers) to the meeting should notify the EMA secretariat in advance. Participation will be subject to the agreement of the co-chairs, on the basis of motivation and relevance to topics to be addressed in the meeting, as well as to meeting logistics.

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

Observers (as per Section 3.2. of the working party mandate, objectives and composition) will be invited to all working party meetings.

Participation of *ad hoc* observers from EMA eligible organisations will be processed as follows:

- Once the annual calendar of meetings is fixed, eligible organisations will be asked to express their interest to attend the meetings.
- A priority list will be established annually based on a first come first served basis.
- Invitations will be sent out to the first three organisations for that year's meetings.

- Budget and capacity allowing, remaining organisations in the list will be offered a place per order of priority, per meeting.
- EMA will endeavour to diversify participation every year, as much as possible.

Remote participation may also be open to *ad hoc* observers on the basis of topics covered in the meetings' agendas.

4. Election of PCWP/HCPWP Chairperson

- The PCWP/HCPWP Co-Chair will be elected by and from amongst its members and alternates for a term of three years, which may be renewed once.
- A call for candidates for PCWP/HCPWP Co-Chair will be launched by EMA at least 6 weeks prior to the meeting where election will take place.
- Individuals appointed by an Organisation or nominated by a Scientific Committee as their representative on the working party are eligible candidates for election.
- Candidates shall express their interest in writing to the EMA secretariat by submitting a brief resume explaining background, experience and motivation in support of their candidature.
- Candidatures should be received by EMA no later than one week in advance of the meeting where election will take place. Any candidatures received after this time will not be considered as valid.
- Candidatures received will be circulated to working party members as soon as available.

If no candidatures are received by the deadline, the election will be postponed to the following scheduled meeting and a call for candidates re-launched.

- Members eligible to vote include:
 - Organisations (25)
 - Scientific committees (6)
- The meeting where the election will take place shall start once a quorum of two thirds of the working party members eligible to vote has been achieved.
- The election shall be by absolute majority of the members (i.e. favourable votes by at least half of the total number of the working party members eligible to vote plus one) and by secret ballot.
- At each voting round, the candidate(s) with the lowest number of votes is (are) removed from the list of eligible candidates at each round.
- In the case of a tie in the decisive round, another round is organised with the two remaining candidates.
- If after this round an absolute majority is not reached, election will be postponed to the following scheduled meeting and a call for candidates will be reopened.
- If, at the decisive round, the candidate with the highest number of votes does not get an absolute majority, a further voting is organised with this candidate only, where he/she needs favourable votes by at least half of the total number of working party members eligible to vote plus one
- If after this round an absolute majority is not reached, the election will be postponed to the following scheduled meeting and a call for candidates will be reopened.

After the election, the organisation to which the new Co-Chair is affiliated will nominate a new representative to replace the current representative in the working party.

In the event of resignation of the HCPWP/PCWP Co-Chair, the EMA Co-Chair shall take the chair until a new election is convened. When a new co-chair is appointed, this will only be for the remainder of the current mandate.

Proxy voting can be organised upon request of members as described below:

- Members and alternates who are entitled to vote but who are both exceptionally not able to attend the meeting in person may appoint another member of the working party as their proxy to vote on their behalf at the meeting.
- A proxy vote cannot be transferred to another member without express permission.

5. Organisation of meetings and reporting arrangements

- Working party meetings shall be held at the Agency.

The dates of meetings are proposed by the EMA secretariat and agreed with the Co-Chairs on an annual basis in consultation with the working party members. The dates of the meetings shall be included in the work plan of the working parties.

- The meetings will be held in English.
- Minutes of the meetings, including points for action, will be drafted by the EMA secretariat and published following consultation with the Co-Chairs and speakers.
- Any working party member may identify and propose topics for consideration by the working party at any time. Topics must remain within the remit of the working party mandate and preferably aligned with its adopted work plan.
- The draft agenda for every meeting will be circulated, by the EMA secretariat, in consultation with the Co-Chairs, 4 weeks before the meeting, if possible.
- The topics discussed will not be subject to confidentiality however in some cases may be subject to limited circulation.
- When considered appropriate by the working party, oral presentations by invited speakers can be made during working party meetings on matters directly related to the activities of the working party, following agreement by EMA.
- Agendas and summary reports of working party meetings 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.
- The EMA Executive Director and members of EMA secretariat may attend all meetings of the working party.
- When a member of the Working Party is unable to participate to a meeting, part of meeting, or a specific discussion topic due to conflict of interest, he/she must inform the Secretariat in advance. Such declarations will be recorded in the minutes of the respective meeting.

6. General provisions

- When participating in international or other fora not specifically on behalf of the working party, members' representatives shall make clear that the views expressed are their own views and not those of the PCWP/HCPWP.

The following disclaimer should to be displayed in any material or presentation:

"I attend this conference as an individual expert, and do not represent the PCWP/HCPWP>. The views expressed here are my personal views, and may not be understood or quoted as being made on behalf of the <PCWP/HCPWP> or reflecting the position of the PCWP/HCPWP>."

- More rarely, a member of the working party may participate in international or other fora and represent the working party, upon request or official agreement of the PCWP/HCPWP. In this case the working party representative shall ensure that the views expressed are those of the PCWP/HCPWP. He/she will be asked to report back to the working party at its next meeting or in writing.

The following disclaimer should to be displayed in any material or presentation:

"I attend this conference to represent the <CxMP/EMA>. The views expressed here are the current views of the <EMA/PCWP/HCPWP>, but in no way shall be binding for the <EMA/PCWP/HCPWP>."

- The final decision whether or not it is appropriate for a member to participate and represent the working party will be taken by the EMA secretariat. 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.