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EMA/747064/2021 Rev. 2

Procedure for the nomination and appointment of co-opted members of the CHMP, CVMP and HMPC

This document is a revision of the procedure agreed by the Committee for Medicinal Products for Human Use (CHMP), the Committee for Veterinary Medicinal Products (CVMP) and the Committee on Herbal Medicinal Products (HMPC) in July 2016. The document outlines the procedure for appointing co-opted members, following the end of the three-year term of a co-opted member, or further to the departure of a co-opted member from the Committee during the course of the three-year term. The changes in this revision include an alignment with the Committees' Rules of Procedure¹ regarding voting and the definition of majority, an update to take into account changes brought about by Regulation (EU) 2019/6 of the European Parliament and of the Council of 11 December 2018 on veterinary medicinal products², a clarification that staff members from EEA-EFTA State agencies cannot be appointed as co-opted members, a deadline for submission of nominations and a reference to the EMA policy on handling of competing interests.

1. Background

Article 61 (2) of Regulation (EC) No 726/2004 provides with regard to the selection and appointment of co-opted members for CHMP that:

The Committee may co-opt a maximum of five additional members chosen on the basis of their specific scientific competence. These members shall be appointed for a term of three years, which may be renewed, and shall not have alternates.

With a view to the co-opting of such members, the Committee shall identify the specific complementary scientific competence of the additional member(s). Co-opted members shall be chosen among experts nominated by Member States or the Agency.

The same rule is laid down in Articles 140(4) and (5) of Regulation (EU) 2019/6 and Article 16h (2) of Directive 2001/83/EC with regard to the selection and appointment of co-opted members for CVMP and HMPC respectively.

The general principles for the procedure on co-opted members are:

- Each Committee decides if it needs and wants to appoint co-opted members.

¹ Rules of Procedure for [CHMP](#), [CVMP](#) and [HMPC](#)

² [EUR-Lex - 32019R0006 - EN - EUR-Lex \(europa.eu\)](#)



- The need for co-opted members and the number (up to a maximum of five) and expertise of these members should be re-visited at the end of the three-year terms of the appointed co-opted member(s), or in the event of the departure of the co-opted member during their three-year term.
- Each Committee takes the decision on whom to appoint as co-opted member from a candidate list of nominated experts.
- The Committees can choose co-opted members among expert nominations from Member States and / or nominations by the Agency.

2. Procedure

Decision of the Committee on expertise and number of co-opted members

1. Within three months before the end of the three-year terms of the appointed co-opted member(s), or in the event of the departure of a co-opted member during their three-year term, the Committee shall discuss whether there is a need to appoint (a) new co-opted member(s). If agreed, the Committee shall decide on:
 - The specific complementary scientific expertise of the co-opted member(s);
Note: When deciding on the area of scientific expertise, the Committee may choose one or more possible areas for a co-opted member position. In case the Committee would choose more than one possible area, nominated experts would be expected to have expertise in at least one of the chosen areas, but not necessarily in all, unless this is specified at the time of decision on the expertise. The Committee may choose the same area of expertise as that of the previously appointed co-opted member.
 - The number of co-opted members (total number of co-opted members in the Committee and number of co-opted members per scientific expertise).
Note: It is not necessary to appoint the maximum of five co-opted members at the same time. However, it should be noted that each appointment is for a period of three years, which is renewable.

Existing co-opted members may participate in discussions and decisions on the specific complementary scientific expertise and number of new co-opted members.

In order to assist the Committee in taking the necessary decisions, as outlined above, the Committee may ask the Secretariat to prepare a synopsis of the Committee's current composition, listing the scientific expertise of the Committee members and alternates. The Secretariat may also put forward proposals for the specific complementary scientific expertise necessary, based on information on products in the pipeline, scientific advice requests, innovation task force requests, etc.

2. Upon decision that (a) new co-opted member(s) shall be appointed and upon the decision on the area(s) of scientific expertise, the Committee agrees to follow the selection procedure as outlined below and the date when the co-opted members shall be appointed.
3. In case the Committee decides not to appoint the maximum of five co-opted members or there is a gap between the departure of the previous co-opted member and the appointment of a new co-opted member, the quorum and majority for the Committee shall be adjusted to reflect the actual number of appointed co-opted members.

Nomination of experts as candidates for co-opted members

4. Upon decision of the Committee that co-opted members shall be appointed, Committee members and alternates are invited to submit to the Committee and the Secretariat nominations for experts from the European experts list with the specific complementary scientific expertise requested. Any nomination by a Committee member or alternate shall be accompanied by a brief recommendation specifying the competence and a detailed CV to support the specific expertise required.
Note: Nominees should not have any competing interests in a pharmaceutical company at the time of their appointment which would prevent them from becoming a Committee member, based on a declaration of interest submitted in accordance with the EMA policy on handling of competing interests of scientific Committees' members and experts³.
Note: In accordance with the CHMP/CVMP/HMPC Rules of Procedure, the members and alternates appointed by EEA-EFTA states may not be elected co-opted member. This applies also to staff members of the EEA-EFTA states national competent authorities and experts nominated by EEA-EFTA states.
5. The Agency may propose nominations for candidates for co-opted members based on scrutiny of the European experts list. These nominations shall also be accompanied by a specification of competence and a detailed CV.
6. Any nominations for co-opted membership can include alternates to a Committee member from an EU Member State. Where an alternate of a Committee member would be selected as co-opted member, another alternate shall be nominated by the Member State concerned.
7. Given that co-opted members are appointed for a renewable three-year term, nominations can also include previously appointed co-opted members.
8. Nominations should be submitted in writing to the Secretariat no later than the start of the Committee's meeting at which the appointment is to take place.

Appointment of co-opted members by Committees

9. In preparation of the Committee decision, the Secretariat compiles all nominations for co-opted members received in separate lists indicating their expertise. These lists will be accompanied by the supporting information provided by Committee members or available from the European expert list specifying the expertise. The documentation will be circulated to the Committee prior to the meeting at which the co-opted members will be appointed. There will be no pre-selection process for nominations received.
10. Nominees for co-opted membership may be invited to present themselves to the Committee at the meeting at which the appointment takes place in advance of the voting on the appointment. Such presentation is preferably by teleconference or videoconference.
11. Appointment procedure:
 - 11.1. Each co-opted member is selected in a separate appointment procedure. All nominations received for a single co-opted member position shall be included in the appointment procedure, even if there is more than one area of expertise for the position.
 - 11.2. The selection of each co-opted member shall be by absolute majority of the members (i.e. favourable votes from more than half of the total number of Committee members eligible to vote) and by secret ballot.

³ [EMA Policy 0044 - Handling of competing interests \(europa.eu\)](#)

Note: In accordance with the CHMP/CVMP/HMPC Rules of Procedure, the members and alternates appointed by EEA-EFTA states may not vote. Existing nominated co-opted members are entitled to vote.

- 11.3. At each round, the nominee with the lowest number of votes shall withdraw.
- 11.4. If there is a tie amongst the nominees with the lowest number of votes, all tied nominees are eliminated, and a further voting round is organised with the remaining nominee(s) only.
- 11.5. In the case of a tie when only two nominees remain, a new voting round is organised with these two remaining nominees.
- 11.6. If, during the new round, the nominee with the highest number of votes does not get an absolute majority, a further voting is organised with this nominee only.
- 11.7. If there is only one (remaining) nominee, the nominee needs favourable votes from more than half of the total number of Committee members eligible to vote, to be selected as co-opted member.
- 11.8. If the remaining nominee(s) do(es) not get an absolute majority, the selection procedure is annulled, and a new selection procedure is organised for the next scheduled meeting of the Committee following the same appointment procedure as stated in paragraphs 4 to 11.

Participation of co-opted members in the Committee

12. The Secretariat shall formally inform the successful nominee of their appointment as co-opted member and inform the unsuccessful nominees of the outcome of the appointment.
13. The co-opted members shall start attending the Committee meetings from the next meeting following their appointment. The three-year term of the co-opted member is considered to start at the first committee meeting following their appointment or after the expiry of the mandate of the previous member.
14. Co-opted members may be elected as Chair or Vice-Chair of the Committee. If a co-opted member is elected as Chair, the Committee shall appoint a new co-opted member in accordance with this procedure.
15. Where a co-opted member is absent for three consecutive meetings, the Committee may wish to re-consider the membership of that co-opted member.
16. Rapporteurship appointments for co-opted members and transfer of rapporteurships held by a departing co-opted member shall be handled in accordance with the guidance on appointment of Rapporteurs applicable to the Committee.

Agreed by HMPC on 28 March 2022

Agreed by CHMP on 11 April 2022

Agreed by CVMP on 12 April 2022

Date of entry into force: 2 May 2022