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Procedure Management and Committees Support Division

## 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 both the Committee for Medicinal Products for Human Use (CHMP) and the Committee for Medicinal Products for Veterinary Use (CVMP) in May 2007. It also applies to the Committee on Herbal Medicinal Products (HMPC). 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.

### 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 and CVMP that:

*The committees 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 committees 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 Article 16h (2) of Directive 2001/83/EC with regard to the selection and appointment of co-opted members for HMPC.

- Each Committee decides if it needs and wants to appoint co-opted members.
- The need for co-opted members and the number (up to a maximum of 5) and expertise of these members should be re-visited at the end of the three year terms of the appointed co-opted members, or in the event of the departure of the co-opted member during his/her 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 3 months before the end of the three year terms of the appointed co-opted members, or in the event of the departure of a co-opted member during his/her 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 areas, 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 5 co-opted members at the same time. However, it should be noted that each appointment is for a period of 3 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 on the selection procedure (based on the procedure 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 5 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 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 interests in a pharmaceutical company at the time of their appointment which would prevent them from becoming a Committee member.  
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 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 can include alternates to a Committee member. (Where an alternate of a Committee member would be selected as co-opted member, another alternate can 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.

### ***Appointment of co-opted members by committees***

8. 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 in the EMA Expert database 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.
9. 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.
10. Proposed appointment procedure:
  - 10.1. 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.
  - 10.2. The selection of each co-opted member shall be by absolute majority of the members (i.e. favourable votes by at least half of the total number of Committee members, or alternates in the absence of the member, eligible to vote plus one) and by secret ballot.  
Note: In accordance with the CHMP/CVMP/HMPC Rules of Procedure, the members and alternates appointed by EEA-EFTA states may not vote. Existing co-opted members are entitled to vote.
  - 10.3. At each round, the nominee with the lowest number of votes shall withdraw.
  - 10.4. In the case of a tie in the decisive round, another round is organised between the two remaining nominees.
  - 10.5. If, at the decisive round, the nominee with the highest number of votes does not get an absolute majority, a further voting is organised with this nominee only, where he/she needs favourable votes by at least half of the total number of Committee members eligible to vote plus one, to be selected as co-opted member.

### ***Participation of Co-opted members in the Committee***

11. The Secretariat shall formally inform the successful nominee of his/her appointment as co-opted member and inform the unsuccessful nominees of the outcome of the appointment.

12. 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 his/her appointment or after the expiry of the mandate of the previous member.
13. 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.
14. Where a co-opted member is absent for 3 consecutive meetings, the Committee may wish to re-consider the membership of that co-opted member.
15. 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 30 May 2016

Agreed by CHMP on 11 July 2016

Agreed by CVMP on 14 July 2016

Date of entry into force: 1 August 2016