



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

25 February 2010
EMA/MB/281553/2007Rev.2

Management Board consultation procedure for CHMP and CVMP nominations

Management Board meeting 18 March 2010

Background note

In accordance with Article 61 (1) of Regulation (EC) No 726/2004 "Each Member State shall, after consultation with the Management Board, appoint, for a three-year term, which can be renewed, one member and one alternate to the Committee for Medicinal Products for Human Use and one member and one alternate to the Committee for Medicinal Products for Veterinary Use".

Regulation (EC) No 726/2004 does not indicate the Management Board consultation process to be repeated on any renewed nominations to the CHMP and CVMP or on those nominations where an existing alternate member has been re-nominated to act as a member and vice versa.

Matters for consideration

The procedure EMA/MB/353835/Rev.1 on consultation of the Management Board on CHMP and CVMP appointments currently requires for *all* nominations, including re-nomination to be subject to the Board's consultation.

In view of Regulation (EC) No 726/2004, and in the spirit of process improvement, a proposal is made to remove this additional burden of repeat consultations placed on the Members and instead streamline the procedure.

For ease of reference, the two key elements proposed for change in the attached document are summarised below as follow:

- Members of the Management Board are consulted upon all new nominations received for the CHMP and CVMP.
- Members of the Management Board will be informed at the next available Board meeting of all additional re-nominations received for the CHMP and CVMP.

Minor linguistic changes and changes in line with the new corporate identity have also been made to the attached document.



Procedure for the consultation of the Management Board on new appointments of CHMP and CVMP members and alternates

This procedure relates to the consultation of the Management Board as part of the process for the appointment by Member States of CHMP and of CVMP members in accordance with Article 61(1) of Regulation (EC) No 726/2004, which provides that:

“Each Member State shall, after consultation of the Management Board, appoint, for a three year term which may be renewed, one member and one alternate to the Committee for Medicinal Products for Human Use and one member and one alternate to the Committee for Medicinal Products for Veterinary Use.

The alternates shall represent and vote for the members in their absence and may act as rapporteurs in accordance with Article 62.

Members and alternates shall be chosen for their role and experience in the evaluation of medicinal products for human and veterinary use as appropriate and shall represent the competent national authorities.”

The below listed procedure applies to the following instances: the appointment of a new member and a new alternate member either in response to a written invitation to nominate from the Executive Director, or as a result of a spontaneous nomination received by the Agency from the relevant nomination authority.

The below listed procedure does not apply to re-nominations of those members and alternates which currently hold memberships in the CHMP and CVMP; to those nominations where an existing alternate member has been re-nominated to act as a member and vice versa; and to those members and alternates which memberships in the CHMP and CVMP recently expired while in the process of re-nomination by the relevant nomination authority.

- The Executive Director receives a proposal of a new appointment of a member or an alternate for the CHMP or CVMP.
- The Management Board is consulted either in writing or at its next meeting, as relevant, once all appropriate documentation for the new nominee has been submitted to the Agency i.e. the Curriculum Vitae using the template provided, the completed EMA template “Nomination form for European Experts” and in the interest of transparency the completed EMA template “Public declaration of interests and confidentiality undertaken”, which will be attached to the written consultation procedure sent to the Management Board or be presented at the next meeting of the Management Board. When the Management Board is consulted in writing the result of the consultation shall be addressed to all members of the Management Board. Written observations shall be raised within seven calendar days unless otherwise specified in the document sent to the members of the Management Board. In case of observations, the Executive Director, in consultation with the chairman of the Management Board, decides whether the procedure for consultation should be suspended or whether the result of the consultation together with the observations should be circulated to the members of the Management Board. Within seven

calendar days, the members of the Management Board should decide if the consultation should be postponed to the next Management Board meeting.

- In case of consultation in writing, the appointment of a member or alternate will be effective as of the day following the finalisation of the procedure for consultation unless otherwise stated. If the consultation is taken as part of a meeting of the Management Board, the appointment will be effective as of the day following the meeting unless otherwise stated. Members of the Management Board will be informed of the outcome of the consultation which will be recorded in the minutes of the next meeting.
- Each individual member and each individual alternate is appointed for a three year term. The three year term mandate runs independently for members and their alternates.
- Regulation (EC) No 726/2004 provides only general criteria for the appointment of CHMP and CVMP members, relating to their role and experience in the evaluation of medicinal products for human and veterinary use as appropriate. Therefore, in order to facilitate the work of the Management Board, any request for additional information or for a hearing should be clearly justified and any observation should be detailed in order for the Management Board to be able to finalise the consultation procedure. It should be noted that the outcome of the consultation of the Management Board is not binding on the Member States proposing the appointments.

The Management Board is reminded that Article 61(1) refers only to the CHMP and CVMP. In addition, the consultation procedure only applies to new members appointed by Member States, and not to co-opted members of these two committees.

There is no provision for consultation of membership of other EMA scientific committees.

The Management Board will be informed at the next available meeting of any re-nominations received for the CHMP and CVMP memberships during a specified period and of those changes in membership where an existing alternate member has been re-nominated to act as a member and vice versa.

This decision replaces and supersedes the procedure for consultation on changes in the membership of CHMP and CVMP adopted by the Management Board on 28 September 2006 (EMA/MB/353835/2006) and on 29 June 2007 (EMA/MB/281553/2007/Rev.1).

Related documents:

1. Template "CV for CHMP and CVMP nominations"
2. EMA template "Nomination form for European Experts"
3. EMA template "Public declaration of interests and confidentiality undertaking"