European Medicines Agency

Mandate of the Management Board task force on the 'Scientific qualifications of committee members'

EMEA/MB/673201/2008Adopted
5 March 2009

Background

At the 61st meeting of the EMEA Management Board, a proposal was made to set up a Task force on the scientific qualifications of committee members. This group should provide Members of the Board with a draft mandate for adoption at their next meeting on 5 March 2009. Extract from the minutes of the 61st meeting of the EMEA Management Board, held on 11 December 2008:

Scientific qualifications of committee members

The meeting discussed the profiles of members and alternates who are appointed to the scientific committees and the role that the Board can exercise in the nomination process. It was suggested that it would be important for the Management Board to receive more information about the academic, scientific and regulatory experience of nominees, which could be achieved through an improved CV template. A possible set of minimum requirements for members might be considered for guidance purposes however matching such criteria to the qualifications in practice is a challenge. Members also suggested that following the departure of a scientific committee member a gap in expertise should be identified and Member States can be invited to nominate a replacement member to fill in an identified gap. The members stressed that it is important to achieve a balanced of expertise in the committees.

In order to look deeper into the consultation process, the Management Board constituted a group of topic coordinators to prepare a reflection paper encompassing all associated issues. The following members and observers agreed to act as topic coordinators: Aginus Kalis, Björn Lemmer, Vasco Maria, Marcus Müllner, Guido Rasi, Lisette Tiddens-Engwirda and Gro Ramsten Wesenberg. The chairs of the committees may be approached during this work. The EMEA will provide secretarial and legal assistance. The group will draft terms of reference and will provide an update at the March meeting.

Agreed composition of the task force

Marcus Müllner (Austria) chairman of the task force
Björn Lemmer (European Parliament)
Guido Rasi (Italy)
Aginus A W Kalis (The Netherlands)
Vaco A J Maria (Portugal)
Gro Wesenberg (Norway)
Lisette Tiddens-Engwirda (Representative of doctors' organisations)
Arielle North (EMEA)
Vincenzo Salvatore (EMEA)
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Proposed terms of reference

Building on existing *Procedure for consultation of the Management Board on the appointment of members to the CHMP and the CVMP (EMEA/MB/281553/2007/Rev1)* and following the first "brainstorming" discussion held, via teleconference, on 27 January 2009 the task force's proposal for its terms of reference is as follow:

1. to clarify the role and duty of the Management Board when consulted on the appointment of members and alternates to the scientific committees
2. to ensure that Members of the Board know and understand their role when consulted on the appointment of members and alternates to the scientific committees
3. to ensure that the European Commission and the scientific committees agree with the Management Board's understanding on its role when consulted on the appointment of members and alternates to the scientific committees
4. to develop detailed proposals to improve the advisory process while making sure its efforts are in relation to the impact of the process

Proposed working approach

All contributions from task force members should be circulated by the EMEA Secretariat through: Zuzana.ocallaghan@emea.europa.eu

Background documents provided to date:

- Procedure for the consultation of the Management Board on the appointment of CHMP and CVMP members (EMEA/MB/281533/2007/Rev.1)
- Regulation (EC) No 726/2004, laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing EMEA ***(specific reference should be made to Article 61)***
- Rules of procedure of the Management Board (EMEA/Management Board/23/04/Rev.1)
- Role and responsibilities of the Management Board (EMEA/MB/186362/2007 Version 3) ***(specific reference should be made to paragraph 3.3 Management Board and scientific committees)***
- Rules of procedure for the Committee for Medicinal products for Human Use (EMEA/MB/87146/2007) ***(specific reference should be made to Article 1, point 1)***
- Rules of procedure for the Committee for Medicinal products for Veterinary Use (EMEA/MB/47098/2007) ***(specific reference should be made to Article 1, point 1)***
- Proposal for a Regulation amending, as regards pharmacovigilance of medicinal products for human use, Regulation (EC) No 726/2004 laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency [COM(2008) 664 final] ***(specific reference should be made to Article 61a)***
- Final reflection paper: CHMP Rapporteur/Co-Rapporteur appointment: principles, objective criteria and methodology (EMEA/124066/2005) ***(specific reference should be made to paragraph 3.1 Assessment Team Objective Criteria and 3.2 Individual Objective Criteria together with the Annex I)***