



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

17 March 2016
EMA/MB/115339/2004/en/Rev.6

Rules of procedure of the Management Board (effective as of 1 May 2016)

THE MANAGEMENT BOARD OF THE EUROPEAN MEDICINES AGENCY,

Having regard to Regulation (EC) No 726/2004 of the European Parliament and of the Council of 31 March 2004 as amended, laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency, and in particular Article 65(7) thereof,

Having regard to the EEA Joint Committee Decision No 74/1999 of 28 May 1999 regarding the participation of the EEA-EFTA states in the work of the EMA,

HAS ADOPTED THESE RULES OF PROCEDURE:

Article 1 – Composition

1. The Management Board consists of one representative of each Member State, two representatives of the Commission, two representatives of the European Parliament, two representatives of patients' organisations, one representative of doctors' organisations and one representative of veterinarians' organisations appointed for a term of three years, which may be renewed.
2. Representatives of Member States and the Commission shall have an alternate who will replace the member in his absence and vote on his behalf.
3. The Management Board also includes one observer of each EEA-EFTA state appointed for a term of three years, which may be renewed.
4. Each observer shall also have an alternate who will replace the observer in his absence.

Article 2 - Chair and Vice-Chair

1. The Chair and Vice-Chair of the Management Board shall be elected by and amongst its members, for a period of three years, renewable once. The term of office expires when they cease to be a member of the Management Board.
2. Nominations for Chair and Vice-Chair shall be submitted in writing either by the candidates themselves or by other members of the Management Board to the EMA secretariat no later than the start of the Management Board meeting at which the election is to take place.
3. Candidates shall submit a brief résumé in support of their candidature at the time of the nomination.



4. The election shall be by two-thirds majority of Management Board members and by secret ballot.

Two tellers shall be designated amongst the members or observers to assist in the counting of the vote. At each round, the candidate with the lowest number of votes shall withdraw. Rounds will run until one candidate receives two-thirds majority of favourable votes of the Management Board members.
5. From the date of election, the Chair loses his voting right. After the election of the Chair, the corresponding voting right of the appointing Member State shall be exercised by the Chair's alternate member of the Board. In cases when the alternate is not able to attend a meeting he shall no later than one week before the meeting inform the secretariat in writing and give his proxy to a member who will vote on his behalf in accordance with Article 7.
6. The Vice-Chair shall deputise for the Chair when the latter is unable to chair either all or part of a meeting. In the absence of the Vice-Chair, the longest serving member or, in the event of equal length of service, the oldest of the longest serving members shall deputise for the Chair.
7. In the event of resignation of the Chair, the Vice-Chair shall take the chair until a new election takes place.
8. If the Vice-Chair takes the chair, their place and vote will be assigned to their alternate or another member by proxy.

Article 3 - Meetings

1. General meetings will be held at least twice a year. They are convened by the Chair in consultation with the Executive Director. The date of the meeting shall be agreed by the members in advance.
2. An agenda, accompanied by the relevant material for decision making, will be forwarded to members at least two weeks prior to each meeting. The agenda is published by the end of the week preceding the meeting and, at the latest, on the day of the Management Board meeting. In the case of new items included after publication of the agenda, such new items will only be reflected in the minutes of the meeting.
3. Members can request a topic for inclusion on the agenda by consulting the Chair 20 working days before the meeting.
4. When a member is unable to participate in a meeting, he should inform the Management Board secretariat in advance. His vote shall be assigned to his alternate or, in the absence of the alternate, by proxy to another member.
5. The quorum will be reached once at least two-thirds of the members are present or represented.

Article 4 - Urgent business

1. Between two meetings of the Board, urgent business that is essential for the functioning of the Agency may be submitted to the Board either by convening an extraordinary Management Board meeting or by written procedure. This shall take place at the request of at least one-third of the Management Board members or by decision of the Chair in consultation with the Executive Director or by decision of the Executive Director in consultation with the Chair.
2. In case of an extraordinary meeting the timelines related to provision of documents to the members of the Management Board set by these Rules may be shortened.

3. A written procedure shall be initiated by the Executive Director in consultation with the Chair and shall only concern matters already addressed during previous meetings. Draft decisions shall be addressed to members and, for information, to observers after approval of the Chair. Written objections shall be raised within seven calendar days unless otherwise specified depending on the urgency of the matter.
4. In case of serious objections, the Chair in consultation with the Executive Director decides whether the written procedure should be suspended and convenes an extraordinary Board meeting or whether the draft decision, together with the serious objections, should be re-circulated to all Board members. In that case, the deadline for adoption shall be seven calendar days.
5. A full report on the outcome of the written procedure shall be made at the following meeting.

Article 5 - Attendance at meetings

1. The Executive Director or his representative shall be entitled to attend all meetings of the Management Board as well as staff members of the Agency's secretariat at the discretion of the Executive Director.
2. The Management Board may invite the chairs of the scientific committees or any other person to attend its meetings.
3. At the discretion of the Chair, members may be accompanied by an additional participant at their own expense. Notification should be made to the secretariat at least three working days in advance, together with a public declaration of interests.

Article 6 - Adoption of decisions and voting arrangements

1. Decisions of the Board shall be adopted by a two-thirds majority of its members.
2. In situations where there is absence of obvious consensus the Chair will ask members whether they wish to vote following a closure of a debate. Such a vote will be open and meeting minutes will indicate members who voted in favour, against and abstained.

Article 7 - Vote by proxy

1. In addition to his own vote each member may receive a maximum of two votes by proxy.
2. The proxy shall be notified to the Chair at the beginning of the meeting and shall be recorded in the minutes.

Article 8 - Minutes of meetings

1. Minutes of each meeting shall as a general rule indicate in respect of each item on the agenda:
 - documents submitted to the Management Board
 - a summary record of the proceedings; at the request of Members the minutes may also provide further details of the discussion of any dissenting views.
 - the decisions taken or the conclusions reached by the Management Board;
 - the list of attendees.
2. Preparation and adoption of the draft minutes:

- draft minutes shall be prepared in English and sent to all members by e-mail within 3 weeks of the meeting, for adoption by written procedure.
- members shall send written objections or comments on the minutes to the Secretariat during a period of 2 weeks.
- minor and editorial issues shall be resolved at the discretion of the Chair in consultation with the concerned member(s) and Executive Director.
- major issues shall be forwarded to all members, together with a proposal from the Chair, in consultation with the member(s) and Executive Director, on how to resolve the matter. This could be either not to accept the concerns raised by a member, propose amendments to the minutes, or that adoption the minutes is postponed to the next meeting of the Board.
- members shall have a further period of one week to agree to or reject the proposed revised minutes. Any further objections shall result in adoption being postponed to the next Management Board meeting.
- once adopted, minutes shall be published on the EMA website.

Article 9 - Secretariat of the Management Board

The Executive Director shall be responsible for providing the secretariat for the Management Board.

Article 10 – Management Board Sub Groups

The Management Board can create subgroups to assist with planning, decision-making and monitoring of specific areas of the Agency's work. Such groups may take on the form of a committee, topic coordinators group or task force. The Chairs of these groups shall be appointed by the Board. The mandates for these groups shall be adopted by the Board.

Article 11 – Code of conduct

1. Members of the Management Board shall abide by the relevant parts of the EMA code of conduct.
2. Members of the Management Board shall comply with the provisions laid out in the EMA policy on the handling of competing interests of Management Board members.
3. Members of the Management Board providing incorrect or incomplete declarations of interest may be considered in breach of trust towards the Agency and may be subject to the provisions laid out in the EMA breach of trust procedure on declarations of competing interests for Management Board members.

Article 12 – Transparency

The names of members and alternates of the Management Board shall be published on the Agency's website, along with their declarations of interest and curriculum vitae.

All final and/or non-confidential Management Board meeting documents shall be published on the Agency's website.

Article 13 – General provisions

These rules of procedure shall be published on the EMA website.

Revision history and changes since last revision

This document replaces the following previous versions: EMA/MB/115339/2004/en adopted on 13 December 2007; EMA/MB/115339/2004/en/Rev.1 adopted on 12 December 2008; EMA/MB/115339/2004/en/Rev.2 adopted by the Management Board on 10 December 2009, EMA/MB/115339/2004/en/Rev.3 adopted by the Management Board on 15 December 2011, EMA/MB/115339/2004/en/Rev.4 adopted by the Management Board on 20 September 2012 and EMA/MB/115339/2004/en/Rev.5 adopted on 13 February 2014.

London, 17 March 2016

Signature on file

Christa Wirthumer-Hoche
Chair of the Management Board