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European Medicines Agency

Breach of trust procedure for competing interests and disclosure of confidential information by members of the European Medicines Agency's Management Board

Introduction

In accordance with Article 63(2) of Regulation (EC) No 726/2004, members of the Management Board and members and experts of scientific committees shall not have financial or other interests in the pharmaceutical industry that could affect their impartiality.¹

To this effect, the European Medicines Agency's (EMA or Agency) has adopted a *policy on the handling of competing interests of Management Board members* (Policy 0058) which describes the arrangements put in place by the Agency to manage competing interests of members² of the Management Board (MB).

In addition, Article 76 of Regulation (EC) No 726/2004 requires members of the MB, and members and experts of scientific committees not to disclose information of the kind covered by the obligation of professional secrecy even after their duties have ceased.

Prior to any involvement in their activities, members of the MB are required to submit a declaration of interest (DoI) including a confidentiality undertaking.

In order to strengthen further the robustness of the Agency's handling of competing interest and to ensure due observance of the duty of professional secrecy by members of the MB, a breach of trust procedure was established in 2012.

Scope

The breach of trust procedure for competing interests and disclosure of confidential information (hereinafter, the breach of trust procedure) applies to members, alternates and observers of the Management Board (hereinafter, members) that are subject to Policy 0058.

¹ Regulation (EC) No 726/2004 of the European Parliament and of the Council of 31 March 2004 laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency. OJ L 136, 30.4.2004, pp. 1–33.

² The reference to members also applies to alternates and observers. Observers are representatives from the EEA EFTA countries (Iceland, Liechtenstein and Norway).

This document describes the steps that will be followed whenever the Agency obtains knowledge and/or information that indicates that a member:

- may have omitted information in their DoI that should have been declared in accordance with Policy 0058; and/or
- may have engaged in an interest incompatible with their involvement in MB activities in accordance with Policy 0058; and/or
- may have committed a breach of the obligation of professional secrecy.

Such situations may be considered as a *prima facie* breach of trust towards the Agency and appropriate actions, including the exclusion of the member (hereinafter, the member concerned) from the MB activities, may be taken by the Agency to guarantee and/or reestablish its independence as well as the integrity of its activities.

If the MB Chair is subject to the present breach of trust procedure, the roles and responsibilities of the MB Chair defined in the procedure below will be assumed by the MB Vice-chair.

In cases where a member concerned is also subject to the breach of trust procedure under the EMA policy on the handling of competing interests of scientific committees' members and experts, corresponding parts of the procedure will be carried out jointly.

Procedure

Preliminary steps (investigation)

1. When the Agency considers that there is a *prima facie* breach of trust by a member, the Executive Director, after informing the MB Chair, will inform the member concerned in writing of its preliminary findings and ask them to provide clarifications within 14 calendar days, in particular on the rationale for:
 - the absence of the information to be declared in the DoI; and/or
 - their engagement in the interest; and/or
 - the disclosure of confidential information.
2. Where the member concerned does not provide the requested clarifications within 14 calendar days, and depending on the gravity of the preliminary findings, the Executive Director, after consulting the MB Chair, may temporarily restrict or suspend their involvement in the MB activities until the receipt of such clarifications. The Executive Director will inform without delay the Nominating Authority of such temporary restriction and/or suspension.
3. The Executive Director, after consulting the MB Chair, may initiate the breach of trust procedure where, based on the analysis of all the information available, it appears that the member concerned, intentionally or through gross negligence, has:
 - omitted to declare the interest in their DoI in accordance with Policy 0058; and/or
 - engaged in an interest incompatible with their involvement in MB activities and thus failed to meet their obligations under Policy 0058; and/or
 - disclosed confidential information in breach of the obligation of professional secrecy.
4. If a breach of trust procedure is not initiated, the Executive Director, after consulting the MB Chair, may adopt other measures as necessary, e.g. requiring the member concerned to submit

an updated DoI including the missing information, or requiring them to attend training on conflicts of interests, etc. The Agency will inform without delay the Nominating Authority of such decision.

Initiation and conduct of breach of trust procedure

5. The Executive Director will notify the member concerned and the Nominating Authority of the findings and rationale for the opening of the breach of trust procedure and, if applicable and after consultation of the MB Chair, of its decision to adopt a temporary suspension of the member's involvement in the MB activities until the breach of trust procedure has been finalised.
6. The member concerned will be invited, within a reasonable timeframe, to a hearing in order to provide further information on the facts under investigation.
7. The Agency will organise the hearing. The hearing will include five members nominated by the MB Chair, one of whom will chair the hearing, and EMA representatives nominated by the Executive Director.
8. The member concerned will be given the right to provide information before and during the hearing. Following conclusion of the hearing, the hearing participants will draft a report on the findings and a proposed decision, on which the member concerned will be given the opportunity to submit any final comments. The proposed decision, depending on the facts and gravity of the breach of trust, may entail e.g., an exclusion from the MB activities for a defined period of time; the obligation to submit an updated DoI including the missing information prior to any new involvement in MB activity; the obligation to attend training on conflicts of interest, etc.
9. The chair of the hearing will present the report and proposed decision to the MB during a meeting *in camera* where the member concerned will have the opportunity to present their views. The MB shall take a decision having due regard to all the information provided.
10. The Agency will notify without delay the member concerned and the Nominating Authority of the MB decision. If the decision is to exclude the member concerned from the MB, the Nominating Authority will be requested to replace the member.

Appeal

11. The member concerned may submit an appeal against the decision within 14 calendar days from the day of notification of the MB decision, providing any additional documents and information to support the appeal. If no such appeal is received, the decision will be considered as final.
12. The MB Chair will nominate an appeal group consisting of five members, different from those who participated in the hearing, to assess the appeal supported by EMA. The appeal group will have 14 calendar days to review and propose a recommendation on the appeal, during which it may decide to seek the views of the Nominating Authority.
13. Following the recommendation of the appeal group, the MB will adopt a final decision during a meeting *in camera*.
14. The Agency will notify, without delay, the member concerned and the Nominating Authority of the final decision. If the decision is to exclude the member concerned from the MB, the Nominating Authority will be requested to replace the member.

The Agency will report on the outcome of breach of trust investigations and procedures in the Annual Report on Independence. The Executive Director, in consultation with the MB Chair, will reserve the right to make public any information on specific individual cases.

The Agency will report without delay to the European Antifraud Office (OLAF) or to the European Public Prosecutor's Office (EPPO) any information that it may acquire in the process of assessing a member's omission to declare an interest, engagement in an interest or disclosure of confidential information, and that could reveal a case of suspected fraud, corruption or irregularities. In that case, the Agency will suspend its assessment, or conduct of the breach of trust procedure, until receipt of further instructions from OLAF or EPPO.

The Agency will adopt guidance laying down the practical arrangements for the conduct of the breach of trust procedure.

The Executive Director will adopt a decision on the EMA representatives nominated to participate in hearings described in the present procedure.

Integrity of the Management Board decisions

Irrespective of the initiation of a breach of trust procedure, or its outcome, the MB Chair, in consultation with the Executive Director, may decide to review the MB decisions and procedures in which the member concerned has been involved in order to confirm their integrity and independence.

The MB Chair will ask the Executive Director to assess the MB decisions for which the member concerned provided input with a view to ascertaining their integrity and whether or not the independence of the MB in adopting them could have been affected.

Where required, the MB Chair, in consultation with the Executive Director, will decide if any further remedial action is necessary, e.g. a re-adoption of certain MB decisions.

The guidance laying down the practical arrangements for the conduct of the breach of trust procedure will include the practical arrangements for such reviews.

Document history

In June 2012 at the 76th meeting of the MB, the MB first adopted the breach of trust procedure on conflicts of interests for MB members. The MB adopted revisions of this breach of trust procedure in 2015, 2019 and 2022 to align with the revisions of the breach of trust procedure for scientific committee members and experts.

In December 2025, the Management Board adopted a further revision to clarify procedural aspects and further enhance reporting of investigations and cases.