



EUROPEAN MEDICINES AGENCY  
SCIENCE MEDICINES HEALTH

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## European Medicines Agency breach of trust procedure for competing interests of and disclosure of confidential information by Management Board members

### Introduction

Reference is made to the European Medicines Agency (EMA or Agency) policy on the handling of competing interests of Management Board (MB) members (EMA/715362/2015, Rev 1).

This policy describes the arrangements put in place by the Agency to manage competing interests of MB members.

Reference is made to EMA's code of conduct that recognises the duty of confidentiality set out in Article 76 of Regulation (EC) No 726/2004 which states that "*Members of the Management Board, members of the committees referred to in Article 56(1), and experts and officials and other servants of the Agency, shall be required, even after their duties have ceased, not to disclose information of the kind covered by the obligation of professional secrecy*". The Public Declaration of Interests (DoI) and Confidentiality Undertaking signed by MB members, contains such duty of confidentiality.

In order to further strengthen the robustness of the Agency's handling of competing interest as well as the obligation of professional secrecy by MB members, a breach of trust procedure has been developed.

### Scope

The EMA breach of trust procedure for competing interests and disclosure of confidential information applies to MB members.

The scope of this breach of trust procedure concerns any incomplete and/or incorrect declarations of interests (DoIs), as well as any disclosure of confidential information by MB members. Failure to fill in the DoI in a complete and/or correct manner, or disclosure of confidential information may be considered as a *prima facie* breach of trust towards the Agency. Because of that failure or disclosure, appropriate actions, including the exclusion of the concerned person from the MB activities, may be taken by the Agency.

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In cases where a MB member 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

The following procedural steps apply:

1. In case the Agency,
  - has knowledge<sup>1</sup> of information that is not consistent with the information included in the DoI, and such information should have been declared, or
  - becomes aware that a MB member engages in an interest for which the Agency previously informed the member that the interest would be incompatible with his/her involvement in MB activities, or
  - has knowledge of a potential breach of professional secrecy,the Executive Director after informing the MB Chair will contact the MB member, asking the member to clarify the situation within fourteen calendar days, in particular by
  - providing the rationale for the absence of the information to be declared, and to complete the DoI with the missing information, or
  - by providing the rationale for engaging in the interest, or
  - by providing the rationale for disclosure of confidential information.
2. In case the requested clarification/additional information is not provided by the member within the fourteen calendar days timeframe, the MB Chair in consultation with the Executive Director may decide to restrict the member's involvement in the MB activities.
3. Once the aforementioned information has been received, the Agency shall assess this information in order to establish
  - whether the omission to declare the interest by the member or the engagement in the interest, or
  - the disclosure of the confidential informationneed to be considered as a breach of trust vis-à-vis the Agency.
4. If it is found that confidential information was disclosed intentionally or through gross negligence, or if it is found that:
  - the information missing from the DoI is a declarable interest according to the Agency's policy on the handling of competing interests, and
  - the member did not declare the missing information, or engaged in the interest intentionally or through gross negligence or he/she failed otherwise to meet his/her obligations under the Agency's policy on the handling of competing interests, the Agency shall initiate the breach of trust procedure.

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<sup>1</sup> In instances such as the outcome of an ex post control check, information provided by an external source (whistle-blower), or following an ex ante spot check.

5. If it is found, following assessment of the clarification/additional information provided by the MB member, that
- the member's omission to declare the interest, or engagement in the interest was not done intentionally or through gross negligence, or
  - the member did not fail otherwise to meet his/her obligations under the Agency's policy on the handling of competing interests, or
  - the member's disclosure of confidential information was not done intentionally or through gross negligence,

no further follow-up will be undertaken by the Agency, other than requesting the member to submit an updated DoI, where relevant. The Agency documents this finding. In such situation, the Nominating Authority will be informed and the updated DoI will be provided by the Agency to the Nominating Authority.

6. In case the Agency initiated the breach of trust procedure, the MB member and the Nominating Authority shall be notified of the opening of the procedure and of the possible consequences of this procedure. The MB Chair in consultation with the Executive Director may decide to suspend the member's involvement in the MB activities until the breach of trust procedure has been finalised. The MB member as well as the Nominating Authority will be notified of this suspension.
7. The MB member shall be invited to a hearing in order to gather his/her views on the facts in question. The hearing shall be organised with a group of MB representatives before any decision is taken. The group referred to above will consist of up to five MB members nominated by the MB Chair. The hearing can take place by teleconference or as a face-to-face meeting. During the hearing, the MB member shall have the possibility of expressing his/her point of view. The group shall take account of any comments or documents submitted before and during the hearing.
- The group will provide an opinion on whether or not there has been a breach of trust and will put forward a recommendation to the MB. The time period between the hearing and forwarding the recommendation to the MB shall be four calendar weeks.
8. Upon recommendation by the aforementioned group, the MB shall take a decision having due regard to all information provided. The decision shall be taken in the plenary MB meeting. The member concerned has the opportunity to present his or her views to the MB.
9. The member is given the possibility to appeal the decision. Following receipt of the reasoned decision the member can appeal within fourteen calendar days as of the day of notification of the decision, providing all the supporting documents and information. An appeal group will be set up consisting of up to five MB members nominated by the MB Chair. The members of the group will be different from those referred to in step 7. The group shall be delegated to subsequently assess all submitted documents and information within two calendar weeks. The group may seek views of the Nominating Authority before reaching its opinion. Unless the group recommends the MB to review its earlier decision, the decision reached in the plenary meeting will remain in force.
10. The MB Chair shall inform the MB member and the Nominating Authority of the outcome of the review. In case of the exclusion of the person from the MB membership, the Nominating Authority shall be invited to replace the membership.
11. In case of a breach of trust the Agency's Executive Director in consultation with the MB Chair reserves the right to make this information public.

12. Whenever a breach of trust will reveal a case of suspected fraud the Agency will inform the European Antifraud Office (OLAF) without delay.

## **Integrity of the Management Board decisions**

Irrespective of the outcome of the breach of trust procedure a decision will be taken by the MB Chair in consultation with the Executive Director whether to initiate a checking of the integrity of the MB decisions. In such situation the MB Chair shall ask the Executive Director to carry-out a checking of which MB decisions were adopted by the MB to which the member was providing his/her input in order to ensure that the decisions were not affected by the member.

A report will be prepared and the MB Chair in consultation with the Executive Director shall decide if any further remedial action is necessary, e.g. a re-adoption of certain MB topics. The Audit Advisory Committee will be informed on the outcome and any remedial action taken.

## **Document history**

In June 2012 at the 76th meeting of the MB, the MB adopted the breach of trust procedure on conflicts of interests for MB members.

In December 2015 at the 90th meeting of the MB, the MB adopted the first revision of the European Medicines Agency breach of trust procedure on declarations of competing interests for MB members to align it with the revised breach of trust procedure for scientific committees' members and experts.