



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

15 December 2022
EMA/154320/2012, Rev. 3 - Adopted
European Medicines Agency

European Medicines Agency breach of trust procedure for competing interests of and disclosure of confidential information by scientific committees' members and experts

Introduction

Reference is made to the European Medicines Agency (EMA or Agency) policy on the handling of competing interests of scientific committees' members and experts (EMA/136875/2022).

This policy describes the arrangements put in place by the Agency to manage competing interests of scientific committees' members and experts and which also applies to members of the Agency's other bodies.

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 scientific committees' members, experts and members of other bodies, contains such duty of confidentiality. Moreover, a specific duty of confidentiality has been introduced by Article 34 of Regulation(EU)2022/123; such duty extends to all bodies of the Agency and individuals, including the Management Board members.

In addition, EMA's policy on scientific publication and representation for European Medicines Agency's scientific committees and their members explicitly states that any scientific committee member/expert will abide by the principles set out in the Agency's code of conduct, whatever the type of scientific publication and representation.

In order to further strengthen the robustness of the Agency's handling of competing interests as well as the obligation of professional secrecy by scientific committees' members and experts, a breach of trust procedure has been established since 2012.

In accordance with the policy on the handling of competing interests, prior to any involvement in the Agency's activities, scientific committees' members, experts and members of other bodies need to be nominated and included in the Agency's experts management tool. Such inclusion is only possible once



the following documents have been submitted to the Agency: Nomination form, Public DoI and confidentiality undertaking form, and Curriculum Vitae.

The Nominating Authority has to ensure, in close collaboration with the nominated member/expert, that all relevant material necessary for the Agency's review of the DoIs and confidentiality undertakings has been made available to the Agency prior to the member's/expert's involvement in any activity of the Agency.

Scope

The EMA breach of trust procedure for competing interests and disclosure of confidential information applies to scientific committees' members, experts and to other bodies of the Agency ie the Emergency Task Force (ETF), the Medicines Shortages Steering Group (MSSG) and the Medical Devices Shortages Steering Group (MDSSG), that are subject to Policy 0044.

The scope of the EMA breach of trust procedure concerns any incomplete and/or incorrect eDoIs, as well as any disclosure of confidential information by scientific committees' members and experts. Failure to fill in the eDoI 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 Agency's activit(y)ies, may be taken by the Agency.

Procedure

The following procedural steps apply:

1. In case the Agency,

- has knowledge^[1] of information that is not consistent with the information included in the eDoI, and such information should have been declared, or
- becomes aware that an expert engages in an interest for which the Agency previously informed the expert that the interest would be incompatible with his/her involvement in EMA activities, or
- has knowledge of a potential breach of professional secrecy,

the Agency will inform the member/expert in writing, asking the member/expert to clarify the situation within 14 calendar days, in particular by

- providing the rationale for the absence of the information to be declared, and to complete the eDoI 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/expert within the 14 calendar days timeframe, the Agency may decide to restrict the member's/expert's involvement in the Agency's activit(y)ies.

3. Once the aforementioned information has been received, the Agency shall assess this information in order to establish

^[1] 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.

- whether the omission to declare the interest by the member/expert or the engagement in the interest, or
 - the disclosure of the confidential information
- needs 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 eDoI is a declarable interest according to the Agency's policy on the handling of competing interests and additional guidance included in the document "Procedural guidance on inclusion of declared interests in the European Medicines Agency's electronic declaration of interests form (for scientific committees' members and experts)", and
 - the member/expert 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.
 5. If it is found, following assessment of the clarification/additional information provided by the member/expert, that
 - the member's/expert's omission to declare the interest, or engagement in the interest was not done intentionally or through gross negligence, or
 - the member/expert did not fail otherwise to meet his/her obligations under the Agency's policy on the handling of competing interests, or
 - the member's/expert'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/expert to submit an updated eDoI, where relevant. The Agency documents this finding. In such situation, the Nominating Authority will be informed and the updated eDoI, where relevant, will be provided by the Agency to the Nominating Authority.
 6. In case the Agency initiated the breach of trust procedure, the member/expert and the Nominating Authority shall be notified of the opening of the procedure and of the possible consequences of this procedure. The Agency may decide to suspend the member's/expert's involvement in the Agency's activities until the breach of trust procedure has been finalised. The member/expert as well as the Nominating Authority will be notified of this suspension.
 7. The member/expert shall be invited to a hearing in order to gather his/her views on the facts in question. The hearing shall be organised before any decision is taken. During the hearing, he/she shall have the possibility of expressing his/her point of view. The Agency shall take account of any comments or documents submitted before and during the hearing.
 8. The EMA Executive Director shall take a decision having due regard to all information provided.
 9. The member/expert is given the possibility to appeal the decision. Following the receipt of the reasoned decision the member/expert can appeal within 14 calendar days as of the day of notification of the decision, providing all the supporting documents and information. The Agency will subsequently assess all submitted documents and information before reaching a final decision.
 10. If the final decision of the Agency is that there is a breach of trust:

- For a member of any of the scientific committees or the Agency's other bodies, the EMA Executive Director shall consult the Management Board (where relevant through written procedure) on the EMA Executive Director's decision to exclude the person from the membership of the concerned scientific committee/body and any other Agency activity.
 - For any other expert the EMA Executive Director shall take the decision and inform the expert and the Nominating Authority of the exclusion of the expert from the membership of the concerned scientific forum (e.g. Working Party, Scientific Advisory Group) and/or any (other) Agency activity. The Nominating Authority shall be invited to replace the membership.
11. Following the consultation with the Management Board in case the breach of trust relates to a member of any of the scientific committees or other Agency body, the EMA Executive Director shall inform the member and the Nominating Authority of the exclusion of the person from the membership and any other Agency activity. The Nominating Authority shall be invited to replace the membership.
 12. In case of a breach of trust the Agency's Executive Director reserves the right to make this information public.
 13. 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 Scientific Review

Irrespective of the outcome of the breach of trust procedure a decision will be taken by the EMA Executive Director to initiate a checking of the integrity of the scientific review. In such situation the EMA Executive Director shall ask the concerned operational Division(s), in liaison with the Chief Medical Officer and the Legal Department, to carry-out a checking of the scientific outputs adopted by the scientific fora or other Agency body to which the member/expert was providing his/her input in order to ensure the integrity of the scientific review process. Where considered necessary, the Agency can involve external expertise.

The concerned operational Division(s) will be asked to prepare a report within a timeline specified by the EMA Executive Director. Upon receipt of this report the EMA Executive Director shall decide if any further remedial action is necessary, e.g. a scientific re-evaluation by the concerned scientific committee/body with regard to the medicinal products or medical devices whose assessment may have been affected. The Management Board will be informed on the outcome and any remedial action taken.

Document history

In March 2012 at the 75th meeting of the Management Board, the Management Board endorsed the breach of trust procedure on conflicts of interests for scientific committee members and experts. The MB endorsed a revision in March 2015 to align it with the 2015 revision of policy 0044 on the handling of declarations of interests of scientific committees' members and experts.

In December 2022, the Management Board adopted the further revision of the EMA breach of trust procedure to align it to the revision of policy 0044 to reflect the additional responsibilities for the Agency following its involvement in certain medical device and IVD procedures as set out in Regulations (EU) 2017/745 and 2017/746, as well as from its extended mandate in accordance with Regulation (EU) 2022/123.