



EUROPEAN MEDICINES AGENCY  
SCIENCE MEDICINES HEALTH

18 December 2025  
EMA/154320/2012, Rev. 4 - Adopted  
European Medicines Agency

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

### Introduction

In accordance with Article 63(2) of Regulation (EC) No 726/2004<sup>1</sup>, 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.

To this effect, the European Medicines Agency (EMA or Agency) has adopted a policy on the handling of competing interests of scientific committees' members and experts (Policy 0044) which describes the arrangements put in place by the Agency to manage competing interests of members, alternates and experts involved in the activities of the Agency's scientific committees, working parties and other groups (e.g., scientific advisory groups, ad hoc expert groups) as well as other bodies (i.e., the Emergency Task Force (ETF), the Medicines Shortages Steering Group (MSSG) and the Medical Devices Shortages Steering Group (MDSSG)) established under Regulation (EU) 2022/123<sup>2</sup>.

In addition, and in accordance with Article 76 of Regulation (EC) No 726/2004, members of the Management Board and members and experts of scientific committees shall be required, even after their duties have ceased, not to disclose information of the kind covered by the obligation of professional secrecy. A specific duty of confidentiality has also been introduced by Article 34 of Regulation (EU) 2022/123 which applies to all parties involved in its application.

Prior to any involvement in the Agency's activities, members and experts are required to submit a declaration of interests (DoI) which includes a confidentiality undertaking.

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

---

<sup>1</sup> 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

<sup>2</sup> Regulation (EU) 2022/123 of the European Parliament and of the Council of 25 January 2022 on a reinforced role for the European Medicines Agency in crisis preparedness and management for medicinal products and medical devices. OJ L 20, 31.1.2022, pp. 1–37



## 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 experts (hereinafter, member/expert) of the Agency's scientific committees, working parties and other groups (e.g. scientific advisory board, ad hoc expert groups) as well as other bodies (i.e. ETF, MSSG and MDSSG and their respective working parties) that are subject to Policy 0044.

The breach of trust procedure will not apply to the Agency's staff members who participate in other bodies, e.g., ETF. They will be subject to the relevant provisions of the Staff Regulations and CEOS<sup>3</sup> and other decisions by the Agency applicable to staff.

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

- may have omitted information in their DoI that should have been declared in accordance with Policy 0044; and/or
- may have engaged in an interest incompatible with their involvement in EMA activities in accordance with Policy 0044; 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 person concerned from the Agency's activities, may be taken by the Agency to guarantee and/or reestablish its independence as well as the integrity of its activities.

## Procedure

### ***Preliminary steps (investigation)***

1. When the Agency considers that there is a *prima facie* breach of trust by a member/expert, it will inform them 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. In case the member/expert does not provide the requested clarifications within 14 calendar days, and depending on the gravity of the preliminary findings, the Agency may temporarily restrict or suspend their involvement in its activities until the receipt of such clarifications. The Agency will inform without delay both the Nominating Authority and the Chair of the respective scientific committee or group/body of such a temporary restriction and/or suspension.
3. The Agency may initiate the breach of trust procedure where, based on the analysis of all the information available, it appears that the member/expert, intentionally or through gross negligence, has:
  - omitted to declare the interest in their DoI in accordance with Policy 0044; and/or

---

<sup>3</sup> Regulation No 31 (EEC), 11 (EAEC), laying down the Staff Regulations of Officials and the Conditions of Employment of Other Servants of the European Economic Community and the European Atomic Energy Community. OJ 45, 14.6.1962, pp. 1385–1386

- engaged in an interest incompatible with their involvement in the Agency's activities and thus failed to meet their obligations under Policy 0044; and/or
- disclosed confidential information in breach of the obligation of professional secrecy.

If the Agency concludes that a breach of trust procedure should not be initiated, it may adopt other measures as necessary, e.g., requiring the member/expert 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**

4. The Agency will notify the member/expert and the Nominating Authority of its findings and rationale on the opening of a breach of trust procedure and, if applicable, of its decision to adopt a temporary restriction and/or suspension of their involvement in the Agency's activities until the finalisation of the breach of trust procedure.
5. The member/expert will be invited, within a reasonable timeframe, to a hearing in front of a Breach of Trust Board in order to provide further information on the facts under investigation. They will be given the right to provide information before and during the hearing. The Breach of Trust Board may decide to consult the member's/expert's Nominating Authority to seek its views on the facts under investigation.
6. The Breach of Trust Board will draft a report on its findings and a proposed decision and will give the member/expert the opportunity to submit any comments.
7. Following receipt of the member's/expert's comments, the Breach of Trust Board will finalise the report and adopt a decision. The Agency will inform the member/expert without delay of the adopted decision. The decision, depending on the facts and gravity of the breach of trust, may entail e.g., an exclusion from the Agency's activities for a defined period of time; the obligation to submit an updated DoI including the missing information prior to any new involvement in an EMA activity; the obligation to attend training on conflicts of interest, etc.
8. The Nominating Authority will be informed without delay of the decision. If the decision is to exclude a member/expert from a scientific committee, or other group/body, the relevant Chair will be informed thereof and the process to replace the member will be initiated.

#### **Appeal**

9. The member/expert may submit an appeal against the decision of the Breach of Trust Board to the EMA Executive Director within 14 calendar days from the day of notification of the decision, providing any additional documents and information to support the appeal. If no such appeal is received, the decision will be considered as final.
10. Following review of the report and decision of the Breach of Trust Board, and the information and documents submitted by the member/expert and if deemed necessary a consultation of the member's/expert's Nominating Authority seeking its views on the facts under investigation and the appeal, , the EMA Executive Director will adopt a final decision within 21 calendar days, and inform the member/expert.
11. The Nominating Authority will be informed without delay of the final decision. If the final decision is to exclude the member/expert from a scientific committee or other group/body, the relevant Chair will be informed thereof and the process to replace the member/expert will be initiated.

The Agency will report on the outcome of breach of trust investigations and procedures in the Annual Report on Independence. The Executive Director 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/expert'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 the 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 composition of the Breach of Trust Board.

## **Integrity of scientific assessments**

Irrespective of the initiation of a breach of trust procedure, or of its outcome, the Agency may decide to review the procedures in which the member/expert has been involved in order to confirm the integrity and independence of the relevant scientific assessments.

Where required, the EMA Executive Director will 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 of the outcome of the review and of any remedial action taken.

The guidance laying down the practical arrangements for the conduct of the breach of trust procedure will include the practical arrangements for the review of scientific assessments.

## **Document history**

In March 2012 at the 75<sup>th</sup> 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 Management Board endorsed a revision in March 2015, October 2018 and December 2022 to align it with the respective revisions of policy 0044 on the handling of declarations of interests of scientific committees' members and experts.

In December 2025, the Management Board endorsed a further revision to clarify procedural aspects in particular with respect to the appeal process and further enhance reporting of investigations and cases.