EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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European Medicines Agency

Guidance on handling EMA scientific committee, Management Board or other group member's intention to engage in occupational activities

Introduction

The European Medicines Agency (EMA or Agency) Policy on the handling of competing interests of scientific committees' members and experts (Policy 0044) (link) includes the following with respect to intention to be engaged in occupational activities:

"*Members of a scientific committee/working party/SAG/ETF/MSSG/MDSSG shall immediately inform the Agency if they intend to engage (irrespective if a contract has been signed or not) in paid or unpaid occupational activities (such as employment) with a company or in activities in a research organisation that are incompatible with participation in any activities at the Agency.*

The Agency will fully restrict the member from further involvement in the Agency's activities from the date of notification. The nominating authority will be informed by the Agency that the member can no longer be involved in the Agency's activities."

The Agency Policy on the handling of competing interests of Management Board (MB) members (Policy 0058) has a similar statement:

"*Members of the MB shall immediately inform the Agency if they intend to engage (either solicited or not) in paid or unpaid occupational activities (such as employment) with a company (irrespective if an employment contract with a company has been signed or not).*

The Agency will fully restrict the MB member from further involvement in the activities of the MB from the date of notification. The nominating authority will be informed by the Agency that the member can no longer be involved in MB activities."

The purpose of this guidance is to ensure a consistent approach to the handling of such notifications made to the Agency.

Abbreviations

- ATMP: Advanced Therapy Medicinal Product

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- CAT: Committee for Advanced Therapies
- CHMP: Committee for Medicinal Products for Human Use
- COMP: Committee for Orphan Medicinal Products
- CRO: Contract Research Organisation
- CVMP: Committee for Veterinary Medicinal Products
- ETF: Emergency Task Force
- HMPC: Committee on Herbal Medicinal Products
- MB: Management Board
- MDSSG: Executive Steering Group on Shortages of Medical Devices (Medical Device Shortages Steering Group)
- MSSG: Executive Steering Group on Shortages and Safety of Medicinal Products (Medicine Shortages Steering Group)
- PDCO: Paediatric Committee
- PRAC: Pharmacovigilance Risk Assessment Committee
- SAG: Scientific Advisory Group

Scope

This guidance applies to chairs, vice-chairs, co-chairs, members and alternates (where applicable) of scientific committees, working parties, scientific advisory groups (SAGs) and other bodies (ETF, MSSG[1] and MDSSG[1] and their respective working parties). It applies also to the chair, vice-chair, members, alternates and observers[2] of the Agency's Management Board. Hereafter, use is made in this document of 'member' and 'EMA group', encompassing all above-mentioned categories of roles and groups. Policy 0044 and 0058 should be referred to for definitions.

Rationale

Members of EMA groups are exposed to delicate and confidential discussions in the course of their involvement in EMA's activities.

Although all are bound by an obligation of professional secrecy, even after their EMA duties have ceased, it would be imprudent for EMA to continue involving individuals, who intend to be engaged in an occupational activity that is not compatible with their membership and other involvement in EMA's activities according to Policy 0044 or Policy 0058.

Procedure

Notification to the Agency

The following steps should be undertaken by members of EMA groups:

[1] Including observers who are representatives from Iceland, Liechtenstein and Norway and from the Patients' and Consumers' Working Party ('PCWP') and Healthcare Professionals' Working Party ('HCPWP')
[2] Observers are representatives from Iceland, Liechtenstein and Norway

- Members of EMA groups should notify the Agency in writing of their intention to become engaged in occupational activities, irrespective of whether a contract has been signed or not, as:
  - an employee[3] in a pharmaceutical company (in line with the definition of pharmaceutical companies, this includes employee in a contract research organisation (CRO) or consultancy company);
  - an employee[3] in a medical device company (in line with the definition of medical device companies, this includes employee in a CRO or consultancy company or in a notified body);
  - *for CAT members*, an employee[3] in a company in the biotechnology sector (in line with the definition of company in the biotechnology sector, this includes employee in a consultancy company);
  - *for all members except Management Board members*, involvement in a unit within a research organisation that acts as a marketing authorisation applicant or holder for a medicinal product;
  - *for Management Board members*, involvement or affiliation in a research organisation that acts as a marketing authorisation applicant or holder for a medicinal product.
- The notification should be sent to the secretariat of the EMA group, with cc to ExpertsDB@ema.europa.eu. It should include the name of the company or organisation where the member will start the activity, the last day at their current employer and the start date of the occupational activity.

Handling of notifications received by the Agency

The Agency will undertake the following steps upon receipt of a notification on the intention to be engaged in occupational activities from a member of an EMA group:

- The Agency will immediately inform the member and their Nominating Authority (unless it is the Agency itself) that they can no longer be involved in the Agency activities and be registered in EMA Experts Management Tool due to competing interests as of the date of the notification. Consequently, their membership in the EMA group is terminated with immediate effect. The Nominating Authority will be asked to submit a request for deregistration of the person concerned from the EMA Experts Management tool. If EMA is the Nominating Authority, the Agency will proceed with the deregistration.
- The Agency will remind the member of their obligation of professional secrecy from the confidentiality undertaking included in their declaration of interests and their duty not to disclose any confidential information or confidential documents, even after their involvement in EMA activities has ceased, as per Article 76 of Regulation (EC) No 726/2004[4].
- The secretariat of the EMA group will identify whether the member held any (co-)Rapporteurship, leading/co-ordinating role or peer reviewer role and transfer them to a different member in the group.
- The Agency will review whether the imminent occupational activity in a particular company or organisation constitutes a conflict for any of the ongoing procedures where the member was (co-)rapporteur, co-ordinator, lead or peer reviewer. If a conflict for the company or organisation has

[3] Employment with a company: any form of occupation, part-time or full-time, paid or unpaid. The activities undertaken during the employment pertain to either 'general matters' (i.e. non-product specific) or are 'product-related' (on one or more medicinal products or medical devices).
[4] 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

been identified, the Agency may decide to verify if the integrity of the ongoing (scientific) review could have been compromised. If so, the Agency will subsequently inform the chair of the relevant EMA group. The Agency also reserves its right to verify if the integrity of the (scientific) review of already finalised procedures for which the member concerned has been the (co)-rapporteur, co-ordinator, lead or peer reviewer could have been compromised.

- The Agency will ask the Nominating Authority to nominate a new member or arrange for the replacement of the member at the earliest convenience, in line with the applicable membership rules of the relevant EMA group.

Other situations than the ones described above may need to be considered depending on the role of the member concerned. **Annex 1** provides examples of other situations whereby similar arrangements have been put in place, in a non-exhaustive list. It should be noted that some of the described actions are already covered in the "Procedural advice on CHMP/CAT/PRAC Rapporteur/Co-Rapporteur appointment principles, objective criteria and methodology in accordance with Article 62(1) of Regulation (EC) No. 726/2004", in particular where a member or an alternate may resign from the committee or would no longer be available as (co-)rapporteur, or lead role.

The Agency will report on the number of notifications on the intention to be engaged in occupational activities in the Annual Report on Independence.

Changes since last revision

The scope of the document was extended to Management Board members. Changes introduced result also from the revision of Policy 0044 and Policy 0058. A reference to the obligation of professional secrecy after ceasing activities with EMA was added.

Annex 1

Role	Action(s)
If a Chair	Transfer responsibilities to the Vice-Chair where applicable and if available until a new Chair is elected. Organise the election of a new Chair.
If a Co-Chair (where applicable)	Transfer responsibilities to the other Co-Chair until a new Co-Chair is elected. Organise the election of a new Co-Chair.
If a Vice-Chair (where applicable)	Organise the election of a new Vice-Chair.
If a topic coordinator	Transfer the coordination of the topic to the alternate from the same Member State until a new member is nominated.
If a member and (co-)rapporteur/co-ordinator/ lead/peer reviewer for a medicinal product or for a medical device procedure	Transfer the rapporteurship/co-ordination/ lead/peer review for the medicinal product or the medical device procedure to the alternate from the same Member State until a new member is nominated.
If an alternate and (co-)rapporteur/co-ordinator/ lead/peer reviewer for a medicinal product or for a medical device procedure	Transfer the Rapporteurship/co-ordination/ lead/peer review for the medicinal product or the medical device procedure to the member from the same Member State until a new alternate is nominated.
If the aforementioned alternate or member from the same Member State has a restriction on rapporteurship/co-ordination/lead/peer review for the medicinal product, but the medicinal product is not active	Keep the rapporteurship/co-ordination/lead/peer review vacant until a new member or alternate from the same Member State is nominated.
If the aforementioned alternate or member from the same Member State has a restriction on rapporteurship/co-ordination/lead/peer review for the medicinal product, but the medicinal product is active	Request the (co-)rapporteur/other co-ordinator/other lead/other peer reviewer to take the lead on the medicinal product until a new member or alternate and hence a (co-)rapporteur/co-ordinator/lead/peer reviewer from the original Member State is nominated.
If the aforementioned alternate or member from the same Member State cannot take over the rapporteurship/co-ordination/lead/peer review for a medicinal product or for a medical device procedure	Initiate a new appointment procedure for a (co-) rapporteur/co-ordinator/lead/peer reviewer.
If a co-opted member affiliated to a Member State and (co-)rapporteur for a medicinal product or for	Request the member or alternate from the same Member State to take over the rapporteurship for

Role	Action(s)
a medical device procedure	the medicinal product or the medical device procedure. Organise the nomination of a new co-opted member.
If a co-opted member not affiliated to a Member State and (co-)rapporteur for a medicinal product or a medical device procedure	Initiate a new appointment procedure for a (co-) rapporteur. Organise the nomination of a new co-opted member.
If an independent scientific expert (PRAC) and (co-)rapporteur for a medicinal product	Initiate a new appointment procedure for a (co-) rapporteur.
If a co-opted member but not acting as a (co-)rapporteur for a medicinal product or a medical device procedure	Organise the nomination of a new co-opted member.
If a committee member or alternate and representative in another committee or working party	Request the relevant committee to nominate a new representative in the committee or working party.
If a member or alternate of a working party for which membership is adopted by a committee	Initiate the nomination of a new member or alternate and the adoption by the committee.
If a lead/co-ordinator/peer reviewer for a guideline or for any other topic	Transfer the lead, co-ordination or peer review role to another member or alternate of the committee, working party or other forum from the same or another Member State as appropriate.