EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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Guidance on the handling of declarations of interests in case of a scientific committee member/other (scientific) forum member's intention to become an employee in a pharmaceutical company

Introduction

The European Medicines Agency policy on the handling of declarations of interests (DoIs) of scientific committees' members and experts (EMA/626261/2014, Corr.1) states the following:

"*Furthermore, if a scientific committee/working party/SAG/ad hoc expert group member intends to be engaged (either solicited or not) in occupational activities with a pharmaceutical company (such as employment) during the term of the mandate, the member shall immediately inform the Agency and refrain from any activities which may have an impact on the pharmaceutical company concerned, and shall comply with any additional conditions or limitations which the Agency may consider appropriate to impose.*"

In order to ensure a consistent approach to the handling of such situations, the need for further guidance in this field has been identified.

Rationale

Members and alternates of scientific committees are exposed to delicate and confidential discussions during the decision-making process of these committees. It would be imprudent for a person who knows that he or she will be working for a private company (and thus pursue only that company's interests) very soon, to join those discussions. In the conflicts of interests' evaluation, the perceived conflict of a committee member can be as harmful to the Agency as an actual conflict of interests.

Since it would be difficult to justify differentiating between the scientific committees and other (scientific) fora, taking into account that employment in a pharmaceutical company is incompatible with involvement in any Agency activity, the Agency will apply the same restrictions to all (scientific) fora. Therefore, when a member or an alternate of a scientific committee/working party/other forum informs the Agency that he/she is going to work in a pharmaceutical company, irrespective if an employment contract with a company has been signed or not, the Agency will fully restrict the member

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or alternate immediately from further involvement in any Agency activity from the date of the notification. In addition, the Agency will identify all ongoing procedures for which the person concerned is the (co)-rapporteur/the lead, check if the imminent employment in a particular company constitutes a conflict for any of the ongoing procedures, and if a conflict has been identified, the Agency will verify if the integrity of the scientific review could have been compromised and will subsequently inform the relevant scientific committee. The Agency also reserves its right to verify if the integrity of the scientific review of already finalised procedures for which the person concerned has been the (co)-rapporteur/lead could have been compromised.

Procedure

In practical terms, a.o. the following will be undertaken:

- Upon notification to the Agency of the intention to become an employee in a pharmaceutical company, the member or alternate shall inform the Agency in writing of the name of the company where he/she will work, as well as the last day of the contract with the current employer.
- The Agency will subsequently inform the member or alternate and the Nominating Authority that the concerned person can no longer be involved in the Agency activities due to conflicts of interests. The Nominating Authority will also be asked to delete the person concerned from the Agency experts database.
- As a next step a transfer of the rapporteurship/other lead role to the alternate (or vice versa as appropriate) will be undertaken. If restrictions apply to the alternate in case of rapporteurship, the work shall be undertaken by the co-rapporteur until a new rapporteur has been appointed.
- The Agency will ask the Nominating Authority to nominate a new member or alternate at the earliest convenience.

In addition, other situations than the one described above need to be considered depending on the role of the person concerned. Annex 1 addresses these other situations whereby similar arrangements have been put in place. 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” (EMA/151751/2010, Rev. 3), in particular in case a member or an alternate would resign from the committee or would no longer be available as rapporteur.

Annex 1

Role	Action(s)
If a Chair	Transfer responsibilities to the Vice-Chair until a new Chair is elected. Organise the election of a new Chair.
If a Vice-Chair	Organise the election of a new Vice-Chair.
If a member and (co-)rapporteur/co-ordinator/ lead for a medicinal product	Transfer the rapporteurship/co-ordination/lead for the medicinal product to the alternate from the same Member State until a new member is nominated.
If an alternate and (co-)rapporteur/co-ordinator/ lead for a medicinal product	Transfer the rapporteurship/co-ordination/lead for the medicinal product 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 for the medicinal product, but the medicinal product is not active	Keep the rapporteurship/co-ordination/lead 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 for the medicinal product, but the medicinal product is active	Request the (co-)rapporteur/other co-ordinator/other lead to take the lead on the medicinal product until a new member or alternate and hence (co-)rapporteur/co-ordinator/lead 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 for a medicinal product	Initiate a new appointment procedure for (co-) rapporteur/co-ordinator/lead.
If a co-opted member affiliated to a Member State and (co-)rapporteur for a medicinal product	Request the member or alternate from the same Member State to take over the rapporteurship for the medicinal product. 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	Initiate a new appointment procedure for (co-) rapporteur. Organise the nomination of a new co-opted member.

Role	Action(s)
If an independent scientific expert (PRAC) and (co-)rapporteur for a medicinal product	Initiate a new appointment procedure for (co-) rapporteur.
If a co-opted member but not acting as a (co-)rapporteur for a medicinal product	Organise the nomination of a new co-opted member.
If a member or alternate nominated by the European Commission	Liaise with the European Commission for the nomination of a new member or alternate.
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 peer reviewer for a product, 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.