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European Medicines Agency

Guidance on handling scientific committee/other (scientific) expert group member's declared intention to become an employee in a pharmaceutical company, a medical device company or in the biotechnology sector[1]

Introduction

The European Medicines Agency (EMA or Agency) policy on the handling of competing interests of scientific committees' members and experts (Policy 0044: EMA/136875/2022) includes within its scope the EMA scientific committees (CHMP, CVMP, COMP, HMPC, PDCO, CAT and PRAC) and working parties, scientific advisory groups, ad hoc expert groups, etc. as well as the Agency's other bodies, i.e. Emergency Task Force, Medicines Shortages Steering Group and Medical Devices Shortages Steering Group[2].

The policy states the following:

"*Furthermore, if a scientific committee/working party/SAG/ad hoc expert group/ETF/MSSG/MDSSG member intends to be engaged (either solicited or not) in occupational activities (such as employment) with a pharmaceutical company or for MDSSG members with a medical device company or for CAT members and alternates in the biotechnology sector or with a medical device company where the medical device is used or to be used in combined ATMPs, during the term of the mandate (irrespective if an employment contract with a company has been signed or not), or if a scientific committee/working party/SAG/ad hoc expert group/ETF/MSSG/MDSSG member intends to become involved in the repurposing of a medicinal product where their organisation is acting as the champion of the repurposing, during the term of the mandate, the member shall immediately inform the Agency*."

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

[1] In principle, the reference to the biotechnology sector shall apply to CAT members and alternates.
[2] For the purpose of the present document, the reference to "expert groups" shall include the groups and bodies mentioned under this paragraph other than the scientific committees.

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Abbreviations

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

Rationale

Chairs, vice-chairs, members and alternates (where applicable) of scientific committees and expert groups are exposed to delicate and confidential discussions in the course of their involvement in EMA's activities. It would be imprudent for a person who knows that he or she will be working for a pharmaceutical company, a medical device company or the biotechnology sector[3] or be involved in the repurposing of a medicinal product very soon, and thus pursue the company's/sector's/organisation's interests, to join those discussions. In the competing interests' evaluation, the perceived conflict of a member or alternate of a scientific committee/expert group involved in EMA's activities can be as harmful to the Agency as an actual conflict of interest.

In this regard, Policy 0044 states that:
- CROs or consultancy companies providing advice or services relating to research, develop, manufacture, maintain, market and/or distribute medicinal products, or to activities linked with marketing authorisation or other regulatory procedures (e.g. initial applications, variations) fall under the definition of a pharmaceutical company;
- notified bodies, CROs and consultancy companies providing advice or services relating to research, develop, manufacture, maintain, market and/or distribute medical devices or *in vitro* diagnostic medical devices, or to activities linked with certification or other regulatory procedures, fall under the definition of a medical device company;
- consultancy companies providing advice or services to the biotechnology sector[3] whose research, development, manufacturing, maintaining, marketing and/or distribution activities are closely linked to

[3] In principle, the reference to the biotechnology sector shall apply to CAT members and alternates.

ATMPs or to activities linked with marketing authorisation or other regulatory procedures (e.g. initial applications, variations) for ATMPs, fall under the definition of biotechnology sector.
For a full definition concerning the notions of pharmaceutical company, medical device company and biotechnology sector, reference is made to section 3.2 of Policy 0044.

Since it would be difficult to justify a differentiation between the scientific committees and other expert groups, 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 committees and expert groups.

In the scenario whereby a member or an alternate of a scientific committee or expert group informs the Agency that he/she is going to work in a pharmaceutical company, a medical device company or the biotechnology sector[4], irrespective of whether an employment contract with a company has been signed or not, the Agency will fully restrict the member or alternate immediately from further involvement in any Agency activities as of the date of notification or impose certain restrictions. The same procedure applies when a member or alternate of a scientific committee or expert group informs the Agency that he/she is to be involved in the repurposing of a medicinal product where their organisation is acting as the champion of the repurposing.

In addition, the Agency will identify all ongoing procedures for which the person concerned is the (co)-rapporteur, has a leading/co-ordinating role or is a peer reviewer, to check if the imminent employment in a particular company constitutes a conflict for any of the ongoing procedures. 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 or expert group. 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, the following will be undertaken:

- Upon notification to the Agency of the intention to become an employee in a pharmaceutical company, a medical device company or the biotechnology sector[4], 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. A member or alternate intending to be involved in the repurposing of a medicinal product, where his/her organisation is acting as the champion of the repurposing, shall inform the Agency in writing of the name of the medicinal product for repurposing as well as the start date of the involvement.
- The Agency will subsequently inform the member or alternate who intends to become an employee in a **pharmaceutical company** and the Nominating Authority that the person concerned can no longer be involved in the Agency activities due to competing interests. The Nominating Authority will also be asked to remove the person concerned from the EMA Experts Management tool.
- Regarding intended employment in a **medical device company**, the Agency will take appropriate actions depending on the role of the person concerned and the nature of the employment interest declared and will inform the person concerned of any restrictions imposed. In case the person concerned can no longer be involved in the Agency activities due to competing interests, the

[4] In principle, the reference to the biotechnology sector shall apply to CAT members and alternates.

Agency will inform the person concerned and the Nominating Authority. The Nominating Authority will also be asked to remove the person concerned from the EMA Experts Management tool.

- For CAT members and alternates and intended employment in the **biotechnology sector**, the Agency will subsequently inform the person concerned and the Nominating Authority that the person concerned can no longer be involved in the Agency activities due to competing interests. The Nominating Authority will also be asked to remove the person concerned from the EMA Experts Management tool.
- For a member or alternate intending to be involved in the **repurposing of a medicinal product**, where his/her organisation is acting as the champion of the repurposing, the Agency will subsequently inform the person concerned and the Nominating Authority that the person concerned can no longer be involved in the Agency activities due to competing interests. The Nominating Authority will also be asked to remove the person concerned from the EMA Experts Management tool.
- As a next step a transfer of the (co-)Rapporteurship, leading/co-ordinating role or peer reviewer role to the alternate (or vice versa as appropriate) will be undertaken. If restrictions apply to the alternate in case of (co-)rapporteurship, the work shall be undertaken by the (co)-rapporteur until a new (co-)rapporteur has been appointed.
- The Agency will ask the Nominating Authority to nominate a new member or alternate at the earliest convenience, in line with the applicable principles for membership of the relevant scientific committee/expert group.

In addition, other situations than the ones described above may need to be considered depending on the role of the person 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.

Changes since last revision

Changes introduced in the current revision result from the additional responsibilities for the Agency following its involvement in certain medical device and *in vitro* diagnostic 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. In particular, guidance relating to the intention to become an employee in a medical device company, the biotechnology sector or become involved in the repurposing of a medicinal product has been introduced as well as considerations relating to the existence of the following new bodies - ETF, MSSG and MDSSG. The reference to the EMA Experts Management tool has replaced the reference to the Experts database.

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 Vice-Chair (where applicable)	Organise the election of a new Vice-Chair.
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 (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 (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 a medical device procedure	Request the member or alternate from the same Member State to take over the rapporteurship for 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	Initiate a new appointment procedure for (co-)

Role	Action(s)
or a medical device procedure	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 (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.