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European Medicines Agency policy on the handling of competing interests of Management Board members

POLICY/0058
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1. Introduction and purpose

The European Medicines Agency's long-standing experience with the handling of declarations of interests dates back in 1995 when EMA was established. The first policy was adopted in 2006 and subsequently updated with the experience gained and legislative changes that affected the Agency's mandate as well as to ensure alignment (to the relevant extent) with the Policy for the handling of competing interests of scientific committees' members and experts (Policy 0044). The policy is also closely embedded in the Agency's Code of Conduct[1].

In accordance with Article 63(2) of Regulation (EC) No 726/2004[2], members[3] of the Management Board (MB) shall not have financial or other interests in the pharmaceutical industry which could affect their impartiality. They are to act in the public interest and independently and submit an annual declaration of their financial interests. In addition, all indirect interests which could relate to pharmaceutical industry shall be entered in a register held by the European Medicines Agency (EMA or the Agency).

In accordance with the Medical Device and *in vitro* Diagnostic Medical Device Regulations (Regulations (EU) 2017/745 and 2017/746[4]), EMA's scientific committees' consultation by Notified Bodies is foreseen for specific categories of medical devices/in vitro medical devices. The EMA's Extended

[1] The EMA Code of Conduct
[2] Regulation (EC) No 726/2004 laying down Community procedures for the authorisation and supervision of medicinal products for human use and establishing a European Medicines Agency. The responsibilities of the Agency in the veterinary area are set out in Regulation (EU) 2019/6 on veterinary medicinal products and repealing Directive 2001/82/EC.
[3] The reference to members also applies to alternates and observers.
[4] Regulation (EU) 2017/745 on medical devices and Regulation (EU) 2017/746 on in vitro diagnostic medical devices.

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Mandate Regulation (Regulation (EU) 2022/123[5]) also introduced new tasks for the Agency in the area of medical devices.[6]

The present policy takes into account the specific role and responsibilities of the MB, which differs from those of the Agency's scientific committee members and experts, insofar as the MB provides strategic coordination, adopts decisions and oversees corporate activities of the Agency.[7] In this respect, the MB is not a scientific body. It therefore is not responsible nor does it contribute to the provision of scientific advice or medicinal product specific matters. It should be recognised that MB members represent Member State or institutional interests.

The policy shall be reviewed within 3 years or at an earlier stage if considered necessary.

2. Scope

The policy focuses on competing interests in the pharmaceutical industry and in the medical device industry, as well as in research organisations and interests in other entities of relevance for the role of the MB.

The policy relates to the handling of competing interests of members and observers of the MB and their alternates[8] involved in the activities of the MB.

3. Definitions

3.1. General definitions

For the purpose of this policy, the following terms should be understood as:

- **Pharmaceutical company**: any legal or natural person whose focus is to research, develop, manufacture, maintain, market and/or distribute medicinal products. The definition also includes companies to which activities relating to the research, development, manufacturing, maintenance, marketing and/or distribution of medicinal products (which might also be carried out in house) are outsourced on a contractual basis.

  Contract Research Organisations (CROs) or consultancy companies providing advice or services relating to the above activities, or to activities linked with marketing authorisation or other regulatory procedures (e.g. initial applications, variations) fall under the definition of a pharmaceutical company.

  Legal or natural persons which do not fall within the scope of the above definition but (i) control (i.e. own a majority stake in, or otherwise exercise a significant influence in the decision-making processes of the relevant pharmaceutical company), (ii) are controlled by or (iii) are under common control of a pharmaceutical company, shall be considered as pharmaceutical companies for the purposes of this policy.

[5] Regulation (EU) 2022/123 on a reinforced role for the European Medicines Agency in crisis preparedness and management for medicinal products and medical devices.
[6] In accordance with Article 21 of Regulation (EU) 2022/123, the Agency has established the Medical Device Shortages Steering Group (the "MDSSG"). The requirement for members of the MDSSG (which includes representatives of Member States) to carry out their tasks in an independent, impartial and transparent manner is expressly foreseen by Article 32 of Regulation (EU) 2022/123.
[7] The role and responsibilities of the Management Board are explained under Articles 65, 66, 67 and 68 of Regulation (EC) No 726/2004.
[8] Observers are representatives from Iceland, Liechtenstein and Norway.

- **Medical device company**: any legal or natural person whose focus is to research, develop, manufacture, maintain, market and/or distribute medical devices or in vitro diagnostic medical devices. The definition also includes companies to which activities relating to the research, development, manufacturing, maintenance, marketing and/or distribution of medical devices or in vitro diagnostic medical devices (which might also be carried out in house) are outsourced on a contractual basis.

  Notified bodies, CROs and consultancy companies providing advice or services relating to the above activities, or to activities linked with certification or other regulatory procedures, fall under the definition of a medical device company.

  Legal or natural persons which do not fall within the scope of the above definition but (i) control (i.e. own a majority stake in, or otherwise exercise a significant influence in the decision-making processes of the relevant medical device company), (ii) are controlled by or (iii) are under common control of the medical device company, shall be considered as medical device companies for the purposes of this policy.

- **Research organisation**: any entity, including but not limited to public or private non-profit organisations, universities, hospitals or learned societies[9], whose primary goal is to pursue scientific research or to do so alongside the provision of educational and/or healthcare services. However, and by way of an exception, any unit[10] within a research organisation that develops or manufactures medicinal products (including ATMPs under the hospital exemption[11]) or medical devices[12] or acts as a marketing authorisation applicant or holder for a medicinal product may be considered in the same way as a pharmaceutical company or a medical device company for the purpose of this policy. Other parts of the organisation to which the unit belongs are not considered as a pharmaceutical or medical device company for the purpose of this policy.

3.2. Direct versus indirect interests

A competing interest exists whenever an individual has an interest that may affect or be reasonably perceived to affect their impartiality in relation to the activity in which they are involved at the Agency.

Considering the EU legislation, the Agency defines two categories of interests: i.e. direct and indirect interests in a pharmaceutical company or a medical device company (hereafter referred to as interests in 'a company') or in a research organisation.

These interests are further defined below. However, it should be emphasised that some of the definitions cannot address all the various scenarios which may arise. Furthermore, individuals may declare additional information regarding current or past activities, beyond the interests required to be declared as defined in the policy. They can decide, at their own initiative, not to participate in a specific activity. In any such cases or if other relevant information is brought to the attention of the Agency, EMA will apply appropriate measures in order to ensure compliance with the requirement of impartiality, as needed.

[9] The term "universities" covers public or private higher education establishments awarding academic degrees.
The term "hospital" includes (also) university hospitals.
The term "learned societies" covers non-profit organisations that exist to promote an academic discipline or profession, or a group of related disciplines or professions.
[10] The term unit may also refer to a section, department or entity, as defined within the specific research organisation.
[11] With the exception of ATMP under hospital exemption, activities related to certain medicinal products (e.g. magistral preparations) referred to in Article 3 of Directive 2001/83/EC are excluded from the scope of this policy.
[12] Manufacturing of medical devices used only within health institutions established in the Union as referred to in Article 5(5) of Regulation 2017/745 are excluded from the scope of this policy.

3.2.1. Direct interests

- **Employment with a company**: any form of occupation, part-time or full-time, paid or unpaid.
- **Consultancy or strategic advisory role to a company**: any activity where the individual concerned provides advice to a company regardless of contractual arrangements or any form of remuneration. This includes lectures, presentations or training organised by individual companies, participation (with a right to vote/influence the outputs) in a(n) (scientific) advisory board, steering committee or executive committee with the role of providing advice/expressing opinions on the (future) strategy, direction and development activities of the company concerned.

  It should be noted that (scientific) advice provided by a competent authority is not considered a consultancy activity.

- **Financial interests in a company** shall mean any economic stake in the form of:

  – Holding of stocks and shares, stock options, stock warrants, restricted stock units, equities, bonds, ownership or partnership interest in the capital of such company.

  The holding of financial interests through an investment fund, pension fund and/or interests in non-nominal unit trusts or similar arrangements do not need to be declared provided that they are diversified (i.e. not exclusively based on the sector concerned) and they are independently managed (i.e. the individual has no influence on their financial management).

  – Compensation, fees, honoraria, grant or other funding (including rents, sponsorships and fellowships) paid by a company to the individual in a personal capacity.

  – Intellectual property rights including patents, trademarks, know-how and/or copyrights for a medicinal product or a medical device owned by the individual or for which the individual is a direct beneficiary.

  Salaries, compensation, fees or honoraria received in the context of employment, consultancy or strategic advisory role shall be declared under the relevant activity as defined above and will be subject to restrictions foreseen for the respective direct interest.

  Payment or reimbursement of reasonable expenses directly related to a conference/seminar attendance (i.e. accommodation, meals and travel costs) are not considered as financial interests unless these go beyond reimbursement of reasonable expenses.

- **Involvement or affiliation in a research organisation that acts as a marketing authorisation applicant or holder for a medicinal product.**
- **Involvement or affiliation in a research organisation that manufactures medicinal products (including ATMPs under the hospital exemption[11]) or medical devices[12], or conducts research and development activities for a medicinal product or a medical device subject to an agreement with a company.** This includes, for example, an activity whereby an individual is involved within a research organisation in the clinical development of a medicinal product or a medical device through sponsorship or any form of commercial arrangement with a company.

  This excludes activities relating to the role of (principal) investigator or consultancy/strategic advisory roles to a company. This excludes arrangements with a company related to the provision of a medicinal product or medical device for e.g. investigator-initiated trials.

3.2.2. Indirect interests

- **Investigator**: an individual responsible for the conduct of a clinical study, clinical investigation or performance study instigated/sponsored by a company, at a specific site. If a clinical study is conducted by a team of individuals at a clinical study site, the investigator who is the responsible leader for the team is the **principal investigator**. Participation in data monitoring committees (composed of independent external experts reviewing unblinded clinical study or clinical investigation data independently of the sponsor/company) falls within this definition.
- **Grant or other funding to the member's organisation/institution**: any funding received from a company by the organisation/institution to which the individual belongs, or for which he/she performs any kind of activity, and which is used specifically to support any activity of the individual.

  Funding from a company received in the context of an individual's involvement in the conduct of research and development activities relating to a medicinal product or medical device subject to an agreement with a company shall be declared as a direct interest as defined above.
- **Close family members interests:** direct interests in a company held by first-line members of the individual's family (i.e. a spouse or a partner, children and parents). Partner is a natural person with whom the individual is registered as having a stable non-marital partnership legally recognised as such by a Member State or any competent authority of a Member State, acknowledging their status as non-marital partners.

4. Policy statement

4.1. Objectives of the policy

The main objective of the policy is to ensure that the MB members participating in the Management Bord have no interests in companies, research organisations or other entities which could affect their impartiality. This objective is guided by the principle of proportionality and must be balanced with the specific role and responsibilities of the MB.

4.2. Principles of the policy

The policy rests on three pillars, i.e.:

- robustness,
- efficiency, and
- transparency of the process for the handling of competing interests.

4.2.1. Achieving a robust process

General principles

Involvement of a member in the activities of the MB is determined taking into account 3 factors: the nature of the declared interest, its timeframe and the topic/type of activity.

For the purpose of this policy, a current interest shall mean an interest that exists at the time of completion of the declaration of interest during the term of the member's mandate. An engagement/contract with a company of a recurring nature is considered a current interest.

Certain interests declared can be incompatible with the participation in any of the MB activities, whereas for others, involvement is possible but may be subject to certain restrictions. or certain interests, restrictions may also be applied during a 3-year cooling-off period after the interest has ended.

Stricter restrictions may apply to the Chair and Vice-Chair compared to the members the MB.

When a topic/activity of the MB is considered as having a possible impact on the pharmaceutical or medical device industry (or other entities as applicable), the following restrictions are applied in case of declared interests as required:

- MB members cannot be involved as topic co-ordinator.
- MB members will not be allowed to take part in the decision-making (i.e. adoption or endorsement) on the topic. This is also valid for adoption by written procedure.

Interests in pharmaceutical or medical device companies

Current interests

Current employment, consultancy/strategic advisory role or financial interests in a pharmaceutical or medical device company are incompatible with MB membership.

Individuals who declare current grant or other funding to their organisation/institution or a current close family member interest may be a member of the MB but restrictions will be applied.

Interests as (principal) investigator should be declared but will not be subject to restrictions unless otherwise required (see section 4.3 Specific arrangements in case of exceptional MB discussions on scientific/medicinal product/medical device related matters).

Past interests

Past employment or consultancy/strategic advisory role in a pharmaceutical company are subject to restrictions during a 3-year cooling-off period after the interest has ended.

For all other interests, no restrictions are applied once the interest has ended.

For further details on the handling of current and past interests in pharmaceutical and medical device companies, please refer to Annexes 1 and 2, respectively.

Interests in research organisations and/or certain other entities

Current interests

Current involvement or affiliation (through employment or participation in a strategic advisory or supervisory board) in a research organisation that acts as a marketing authorisation applicant or holder is incompatible with MB membership.

Current involvement or affiliation in a research organisation that manufactures medicinal products (including ATMPs under the hospital exemption[11]) or medical devices[12] or conducts research and development activities for a medicinal product or a medical device subject to an agreement with a company is allowed but restrictions will be applied.

In view of the MB's role and responsibilities in the oversight of corporate activities of the Agency, members should declare current interests (employment, consultancy/strategic advisory role, financial interests or close family members interests) in other entities possibly providing services to the Agency (i.e. in the areas of IT, infrastructure, catering[14]), as well as in other areas such as

diagnostics/reagents not linked with medicinal products[13]. Restrictions will be applied to relevant topics.

For transparency, members should also declare positions (either a managerial role or other influential roles) in a governing body (irrespective if such position is paid or not) of a professional organisation[14] with an interest in the field of pharmaceuticals other than a pharmaceutical or a medical device company. In exceptional cases such interests may result in restrictions, to be decided on a case-by-case basis.

Past interests

No restrictions are applied once the interest in research organisation or other entities has ended.

For further details on the handling of current and past interests in research organisations and/or certain other entities, please refer to Annex 3.

Intention to be engaged in occupational activities

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.

4.2.2. Achieving an efficient process

The handling of competing interests is a 2-step procedure: following receipt of the declaration of interest (DoI) an interest level is automatically assigned as follows:

- "direct interests declared";
- "indirect interests declared" (this includes interests declared in other entities);
- "no interests declared".

Subsequently, the level of participation in the Agency's activities is determined by the Agency's secretariat taking into account the assigned interest level and the restrictions to be applied to the activity based on the evaluation of the expert's DoI in accordance with this policy.

In order to facilitate the evaluation of declared interests and to optimise the handling of competing interests, MB activities/topics will be screened by the Agency to assess the likelihood of the impact of the MB decision on the pharmaceutical or the medical device industry.

EMA applies a proactive approach for the identification of possible restrictions in involvement in the MB activities by offering the possibility of a pre-screening of the declared interests of proposed MB members prior to any formal nomination by the nominating authority[15]. In such situation, the Agency will provide feedback to the nominating authority on the outcome of the pre-screening for their consideration when launching the formal nomination process.

[13] It should be noted that this is a non-exhaustive list.
[14] It should be emphasised that organisations such as patients', consumers' or healthcare professionals' organisations are covered under section 3.1.2 "Indirect interests", in particular the sub section "Grant or other funding to an organisation/institution".
[15] Nominating authority refers to the Member States, the European Commission, or the European Parliament.

4.2.3. Achieving a transparent process

Transparency is achieved through:

- Publication on the Agency's corporate website of the Declarations of Interests (DoIs) and CVs of MB members.
- Publication on the Agency's corporate website of the minutes of the MB meetings, including – where relevant – the restrictions applied to the involvement of the Chair/ Vice-Chair and members.

The Agency processes personal data in accordance with Regulation (EU) No 2018/1725 on the protection of natural persons with regard to the processing of personal data by the Union institutions and bodies and offices and agencies and on the free movement of such data. Further information is provided on the Agency's website under "Data protection notice".

4.3. Specific arrangements in case of exceptional MB discussions on scientific/medicinal product/medical device related matters

In case of exceptional discussions at the MB on scientific/medicinal product or medical device related matters rules similar to those applicable to the handling of DoIs of the Agency's scientific committees are put in place. As MB members do not need to declare upfront specific medicinal product or medical device information in their DoIs, in light of their roles and responsibilities, the protocol outlined below is followed in those exceptional cases where scientific/medicinal product or medical device related discussions at the MB take place.

Proceedings for declaring interests:

- Prior to the discussion, the MB Chair/Vice-Chair and the MB members will be invited first to declare if there are any updates to the already declared interests (as per the latest publicly available DoI).
- Subsequently, the MB Chair/Vice-Chair and the MB members will be invited to declare any current or past (within the past three years) direct or indirect interests in relation to the medicinal product(s) as well as current direct or indirect interests in relation to the medical device(s) which is/are subject to discussion at the MB.

In case of declared interests pertaining to the product or products concerned in the same declared condition:

(i) the MB Chair must be replaced by the MB Vice-Chair for the relevant medicinal product or medical device-related agenda item;

(ii) the MB members will not be allowed to participate in the agenda item.

The applicable restrictions will be minuted.

4.4. Operational arrangements

Before any work can be undertaken by the Agency on the checking of declarations of interests, MB members need to be first nominated after which they need to be included in the Agency's Experts Management tool.

Inclusion in the Experts Management Tool is only possible once the following information have been submitted to the Agency:

- Public declaration of interests which includes a confidentiality undertaking; and
- CV.

MB members should update their DoI annually or as soon as their interests change and MB Secretariat will inform the MB Chair of any changes to their declared interest without undue delay. In case where, following the expiry of a DoI, a MB member is late to provide an updated declaration, meeting documents and correspondences will not be sent to the member.

The MB members' DoIs are evaluated in accordance with this Policy and in particular the annexes, in order to identify any restrictions, as applicable, to their participation in the activities.

The MB Chair (in case of absence/unavailability the MB Vice-Chair) will be informed prior to the MB meeting on the outcome of the assessment on the declared interests performed by the Agency as regards the allowed involvement of MB members in the MB meeting.

The MB will be informed at the start of each meeting of the competing interests declared by MB members and the resulting restrictions. This information will be recorded in the MB meeting minutes. At the start of each meeting the MB Chair will also ask MB members to declare any additional competing interests not yet declared in the DoI in relation to the items on the agenda. Such additional competing interests will be minuted and the MB member will be asked to submit an updated DoI without delay for subsequent publication on the Agency's website. In addition, MB members will be asked by the MB Chair to declare interests which can be considered prejudicial to their independence with respect to the items on the agenda at the beginning of each MB meeting and any declared interests will be recorded in the MB meeting minutes.

To ensure the correctness of the information contained in the DoIs, the Agency has introduced a quality assurance system, hereby applying *ex ante* and *ex post* control checks.

The system for handling of competing interests held by MB members is based on the completeness and the correctness of the declarations of interests submitted by those individuals.

In the scenario whereby the Agency receives information concerning a possible conflict of interest for a MB member, it will take the appropriate steps to investigate the veracity of that information and to adopt any follow-up actions if necessary. The Agency may also adopt any provisional measures whilst the investigation remains ongoing.

In addition, in case of incomplete and/or incorrect DoIs, a breach of trust procedure may be initiated by the Agency.[16]

5. Related documents

- EMA Code of Conduct
- European Medicines Agency policy on the handling of competing interests of scientific committees' members and experts – Policy 0044
- European Medicines Agency breach of trust procedure on declarations of competing interests for Management Board members
- Engagement Framework: EMA and patients, consumers and their organisations

[16] European Medicines Agency breach of trust procedure on declarations of interests for Management Board members

- Revised framework for interaction between the European Medicines Agency and healthcare professionals and their organisations.
- Framework of collaboration between the European Medicines Agency and academia.

6. Changes since last revision

A comprehensive review of the policy been made following recent court judgments. The review includes changes to the policy to bring further clarity in the management of potential competing interests that may stem from certain activities within research organisations.

Amsterdam,

[Signature on file]

Lorraine Nolan
Chair of the Management Board

Annex 1 – Handling of current and past interests in pharmaceutical companies

Declared interest in a pharmaceutical company	Time since declared interest ended	MB (Vice) Chair	MB member	MB topic coordinator
Employee	Current	X	X	X
	Past (0-3 yrs)	X	XD	XTC
Consultancy/strategic advisory role	Current	X	X	X
	Past (0-3 yrs)	X	XD	XTC
Financial interests	Current	X	X	X
	Past (0-3 yrs)	F	F	F
Grant/other funding to organisation/institution	Current	RC	F	XTC
	Past (0-3 yrs)	F	F	F
Close family member	Current	RC	XD	XTC
	Past (0-3 yrs)	F	F	F
(Principal) investigator	Current	F	F	F
	Past (0-3 yrs)	F	F	F

X = No involvement in MB allowed.

RC = To be replaced as MB (Vice) Chair for the discussions and decisions related to the specific MB topic

XD = Cannot take part in MB decision for the specific MB topic

XTC = Cannot act as topic coordinator for the specific MB topic

F = Full involvement

Annex 2 – Handling of current and past interests in medical device companies

Declared interest in a medical device company	Time since declared interest ended	MB (Vice) Chair	MB member	MB topic coordinator
Employee	Current	X	X	X
	Past (0-3 yrs)	F	F	F
Consultancy/strategic advisory role	Current	X	X	X
	Past (0-3 yrs)	F	F	F
Financial interests	Current	X	X	X
	Past (0-3 yrs)	F	F	F
Grant/other funding to organisation/institution	Current	RC	F	XTC
	Past (0-3 yrs)	F	F	F
Close family member	Current	RC	XD	XTC
	Past (0-3 yrs)	F	F	F
(Principal) investigator	Current	F	F	F
	Past (0-3 yrs)	F	F	F

X = No involvement in MB allowed.

RC = To be replaced as MB (Vice) Chair for the discussions and decisions related to the specific MB topic

XD = Cannot take part in MB decision for the specific MB topic

XTC = Cannot act as topic coordinator for the specific MB topic

F = Full involvement

Annex 3 – Handling of current and past interests in research organisations and/or certain other entities

Declared interest in research organisations and/or certain other entities	Time since declared interest ended	MB (Vice) Chair	MB member	MB topic coordinator
Involvement or affiliation in a research organisation that acts as a marketing authorisation applicant or holder for a medicinal product	Current	X	X	X
	Past (0-3 yrs)	F	F	F
Involvement or affiliation in a research organisation that manufactures medicinal products or medical devices, or conducts research and development activities for a medicinal product or a medical device subject to an agreement with a company	Current	X	XD	XTC
	Past (0-3 yrs)	F	F	F
Interests (employment, consultancy/strategic advisory role, financial interests or close family members interests) in other entities possibly providing services to the Agency (i.e. in the areas of IT, infrastructure, catering), as well as in other areas such as diagnostics/reagents not linked with medicinal products	Current	RC	XD	XTC
	Past (0-3 yrs)	F	F	F
Position in a governing body of a professional organisation	Current	F	F	F

X = No involvement in MB allowed.
RC = To be replaced as MB (Vice) Chair for the discussions and decisions related to the specific MB topic
XD = Cannot take part in MB decision for the specific MB topic
XTC = Cannot act as topic coordinator for the specific MB topic
F = Full involvement