EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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European Medicines Agency policy on the handling of competing interests of scientific committees' members and experts

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1. Introduction and purpose

The European Medicines Agency's long-standing experience with the handling of declarations of interests for its scientific committees' members and experts dates back in 1995 when EMA was established. The first policy was adopted in March 2004 and subsequently updated with the experience gained and legislative changes that affected the Agency's mandate. The policy is also closely embedded in the Agency's Code of Conduct[1].

Considering recent court judgments[2], the Agency did another comprehensive review of its policy. In particular, the addition of restrictions and exclusions related to certain interests and/or involvement in certain activities, such as participation in scientific advisory groups. This review also brings further clarity in the handling of potential competing interests that may stem from certain activities within research organisations.

In accordance with Article 63(2) of Regulation (EC) No 726/2004[3], members[4] of the scientific committees and experts shall not have financial or other interests in the pharmaceutical industry that 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 the

[1] The EMA Code of Conduct
[2] Appellate judgments of the Court of Justice in Joined Cases C-6/21 and C-16/21 P and Case C-291/22 P
[3] 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.
[4] The reference to members also applies to alternates.

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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[5]), EMA's scientific committees' consultation by notified bodies is foreseen for specific categories of medical devices/*in vitro* medical devices. The EMA's Extended Mandate Regulation (Regulation (EU) 2022/123[6]) also introduced new tasks for the Agency in the area of medical devices. These new tasks entail supporting the expert panels on medical devices and *in vitro* diagnostic devices (EXPAMED), handling of medical device shortages as well as the establishment of the Executive Steering Groups on Shortages and Safety of Medicines (MSSG) and on Shortages of Medical Devices (MDSSG). Members and experts involved in these activities may not have interests in the medical device industry that would affect their impartiality[7]. The Extended Mandate Regulation also established the Emergency Task Force (ETF) as a new scientific body[8] to which the same independence requirements apply.

With this policy, the Agency aims to reconcile two key elements, the requirement of impartiality and independence of its experts (Article 63(2) of Regulation (EC) No 726/2004) and the public interest (Article 57(1) of that regulation), relating to the need for the best possible scientific advice on any question relating to the evaluation of the quality, safety and efficacy of medicinal products for human or veterinary use referred to the Agency.

Having interests is not to be confused with having a competing interest, as those interests, experiences and activities contribute to an individual's expertise in a certain field. It is therefore critical for the Agency to maintain a robust and balanced framework to manage possible competing interests that guarantees an impartial assessment while not negatively affecting the fulfilment of the Agency's mandate and access to the best available expertise.

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, the medical device industry, the biotechnology sector as well as in research organisations.

It provides guidance on the handling of 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. ETF, MSSG and MDSSG).

Involvement in the Agency's activities means all activities carried out in the context of:

- the development, evaluation, supervision and maintenance of medicinal products for human and veterinary use;

[5] Regulation (EU) 2017/745 on medical devices and Regulation (EU) 2017/746 on in vitro diagnostic medical devices.
[6] Regulation (EU) 2022/123 on a reinforced role for the European Medicines Agency in crisis preparedness and management for medicinal products and medical devices.
[7] Medicines/Medical Devices Shortages Steering Group (MSSG and MDSSG) - Art 32 of Regulation (EU) 2022/123 *"The members of the MSSG and of the MDSSG and, where relevant, observers, shall not have any financial or other interests in the medicinal products industry or medical devices industry which could affect their independence or impartiality."*
Expert Panels on Medical Devices (EXPAMED) - Art 30 of Regulation (EU) 2022/123 *"The Agency shall (c) ensure that the work of the expert panels is carried out in an independent manner in accordance with Art 106(3), second subparagraph, and Art 107 of Regulation (EU) 2017/745 and with the systems and procedures established by the EC pursuant to that Regulation to actively manage and prevent potential conflicts of interest in accordance with Art 106(3), third subparagraph, of that Regulation."*.
[8] Emergency Task Force (ETF) – Art 15(8) of Regulation (EU) 2022/123 *"Article 63 of Regulation (EC) No 726/2004 applies to the ETF as regards transparency and the independence of its members."*

- preparing for, preventing, coordinating and managing the impact of public health emergencies and major events on medicinal products;
- preparing for, preventing, coordinating and managing the impact of public health emergencies on medical devices;
- monitoring, preventing, and reporting on shortages of medicinal products and medical devices.

These activities include meeting attendance, involvement in scientific assessments and guidance development, as well as participation in inspections, as applicable.

In line with the Memorandum of Understanding[9] concluded between National Competent Authorities (NCA) and the Agency, NCAs are responsible for handling conflicts of interest of the staff and experts involved at national level in the services provided to the Agency.

The policy does not cover the activities of the members of the expert panels on medical devices and *in vitro* diagnostic medical devices (EXPAMED) as these members and their activities are addressed by a dedicated policy[10] adopted by the European Commission.

3. Definitions

3.1. Abbreviations

- ATMP: Advanced Therapy Medicinal Product
- CAT: Committee for Advanced Therapies
- CHMP: Committee for Medicinal Products for Human Use
- COMP: Committee for Orphan Medicinal Products
- CRO: Contract Research Organisation
- CV: Curriculum Vitae
- CVMP: Committee for Veterinary Medicinal Products
- DoI: Declaration of Interests
- ETF: Emergency Task Force
- EMA: European Medicines Agency
- EU: European Union
- EXPAMED: Expert panels on medical devices and *in vitro* diagnostic medical devices
- HMPC: Committee on Herbal Medicinal Products
- MDSSG: Medical Devices Shortages Steering Group – Executive Steering Group on Shortages of Medical Devices
- MoU: Memorandum of Understanding

[9] Memorandum of Understanding between the European Medicines Agency and the National Competent Authorities of the Member States on the monitoring of the scientific level and independence of the evaluation carried out by the National Competent Authorities for services to be provided to the Agency where reference is made to Article 63(2) of Regulation (EC) No 726/2004.

[10] European Commission policy on the management of competing interests of members of the expert panels on medical devices and *in vitro* diagnostic medical devices (Expamed document D 4.3).

- MSSG: Medicines Shortages Steering Group – Executive Steering Group on Shortages and Safety of Medicinal Products
- NCA: National Competent Authority
- PDCO: Paediatric Committee
- PRAC Pharmacovigilance Risk Assessment Committee
- SAG: Scientific Advisory Group

3.2. Definitions

3.2.1. 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.

- **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.

- **Company in the biotechnology sector**: any legal or natural person involved in the biotechnology sector whose research, development, manufacturing, maintaining, marketing and/or distribution activities are closely linked to ATMPs, i.e.:

- Blood, cells and tissues establishments;
- Manufacturers of critical starting materials for ATMPs, e.g. viral vector manufacturers.

This definition also includes natural and legal persons to which activities relating to the research, development, manufacturing, maintaining, marketing and/or distribution closely linked with ATMPs (which might also be carried out in house) are outsourced on a contractual basis.

Consultancy companies providing advice or services relating to the above activities, fall under the definition of companies in the biotechnology sector.

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 company in the biotechnology sector), (ii) are controlled by or (iii) are under common control of a company in the biotechnology sector, shall be considered as a company in the biotechnology sector 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[11], 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[12] within a research organisation that develops or manufactures medicinal products (including ATMPs under the hospital exemption[13]) or medical devices[14] 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.
- **Repurposing of a medicinal product**: process of identifying a new therapeutic use for an existing medicinal product for which data exclusivity, market protection periods and basic patent / supplementary protection certificate (SPC) protection have lapsed.

3.2.2. 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: direct and indirect interests in a pharmaceutical company, a medical device company, a company in the biotechnology sector (hereafter referred to as interests in 'a company' unless otherwise specified) 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

[11] 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.
[12] The term unit may also refer to a section, department or entity, as defined within the specific research organisation.
[13] 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.
[14] 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.

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.

3.2.2.1. Direct interests

- **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 in declared condition(s)).
- **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. These activities pertain to either 'general matters' (i.e. non-product specific) or are 'product-related' (on one or more medicinal products or medical devices in declared condition(s)).

  It should be noted that (scientific) advice provided by a competent authority is not considered a consultancy activity.
- **Financial interests in a company** :
  - 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, a medical device or relating to the biotechnology sector 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 (through employment or collaboration) in a unit[14] of a research organisation that manufactures medicinal products (including ATMPs under the hospital exemption[15]) or medical devices[16].**
- **Involvement (through employment or collaboration) in a unit[14] of a research organisation that acts as a marketing authorisation applicant or holder for a medicinal product**.

- **Involvement in the conduct of research and development activities at a research organisation for a medicinal product or a medical device together 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.

3.2.2.2. 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 expert's organisation/institution**: any funding from a company received by the organisation/institution to which the member or expert belongs, or for which he/she performs any kind of activity, and which is used specifically to support any activity of the member or expert.

  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.
- **Regulatory engagement on academic research**: involvement in academic research (including those conducted as part of public-private partnerships) on a medicinal product or medical device subject to regulatory interactions with the Agency. This includes for example academic research subject to a request for scientific advice or qualification of novel methodologies, submission of paediatric investigation plan, submission of orphan designation request, request for support and advice on the repurposing of a medicinal product or early interaction tools offered by the Agency (e.g. Innovation task force, PRIME designation).

  This excludes submission of clinical trial applications to national competent authorities and support received with respect of their submission.
- **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.
- **Affiliation to a research organisation**: being employed by, associated with or otherwise belonging to a research organisation, part-time or full-time, paid or unpaid.

4. Policy statement

4.1. Objectives of the policy

The main objective of the policy is to ensure that the members and experts participating in the work of the Agency's scientific committees' and other bodies' have no interests in companies or research organisations which could affect their impartiality. This objective is guided by the principle of proportionality and must be balanced with the need to secure the best (specialist) scientific expertise for involvement in the Agency's activities related to medicinal products for human and veterinary use or medical devices. It is therefore critical to strive for the optimal balance when applying appropriate restrictions and cooling-off periods, where relevant, for the declared interests versus maintaining access to the best and relevant expertise.

4.2. Principles of the policy

The policy rests on 3 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 an individual in the Agency's activities is restricted taking into account 3 factors: the nature of the declared interest, its timeframe and the type of activity involved (e.g. advisory versus decision-making).

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 a member's mandate or at the time of involvement of an individual in a specific activity. 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 Agency's activities, whereas for others, involvement is possible but may be subject to certain restrictions. For certain interests, restrictions may also be applied during a 3-year cooling-off period after the interest has ended.

Stricter restrictions may apply to Chairs/vice-chairs of scientific committees, ETF, MSSG and MDSSG compared to the chairs/vice-chairs of other groups (e.g. working parties) and compared to the members of the scientific committees, ETF, MSSG and MDSSG and other groups. Rapporteurs[15] may also be subject to stricter restrictions.

Whilst the Agency will make every effort to involve experts who fully comply with the rules set out in this policy, there may be situations where specific expertise is required that can only be provided by a few individuals who have competing interests that would normally be incompatible or limit their involvement in the Agency's activities as a member or expert. In such cases, it may still be in the interest of public health to invite these individuals to provide written or oral testimony before scientific

[15] This shall also apply to co-rapporteurs and persons performing other roles considered as equivalent, and where applicable any Committees members formally appointed peer reviewers.

committees, working parties, scientific advisory groups or other bodies as an '*Expert witness'*. In these circumstances, the expert witness will not be considered a member or expert of the respective Agency body and will not be permitted to participate in the discussions, deliberations and conclusions of the respective Agency body. When invited to provide an oral testimony, the expert witness will only be able to participate to the part of the meeting which is attended by the company or research organisation, when product(s) are discussed; during this part of the meeting, the company will also be able to ask any questions to the expert witness invited.

Interests in pharmaceutical companies

Current interests

As a general rule, current employment, current consultancy/strategic advisory role on general matters or current financial interests in a pharmaceutical company are incompatible with involvement in the Agency's activities.

Individuals with other interests in a pharmaceutical company may be involved in the Agency's activities; however, exclusions or appropriate restrictions will be applied depending on the interest declared and the Agency's activity to be involved in.

If a current interest is declared for a medicinal product in a given condition, an individual may be allowed to participate in some Agency's activities as long as they do not pertain to the medicinal product concerned or medicinal products intended for the same condition as that declared in the interest.

Individuals with a current close family member interest in a pharmaceutical company are not allowed to participate to activities pertaining to any medicinal products from the company concerned.

Chairs of scientific committees, ETF, MSSG, MDSSG and working parties will be replaced for discussions and decision making in relation to any medicinal products from a pharmaceutical company for which they have declared a current grant or other funding to their organisation/institution. Individuals who have declared such interest cannot act as Rapporteurs on any medicinal products from the pharmaceutical company concerned.

Past interests

Past employment in a pharmaceutical company, consultancy/strategic advisory role and (principal) investigator role are subject to restrictions during a 3-year cooling-off period after the interest has ended. During this cooling-off period, restrictions apply either to the medicinal product(s) or pharmaceutical company concerned, as applicable.

Chairs of scientific committees, ETF and MSSG may not hold such past interests. Chairs of working parties are replaced not only for any medicinal products for which they have declared an interest but also on medicinal products intended for the same condition as that declared in the interest. Similarly, individuals cannot act as Rapporteurs on the medicinal product in relation to which they declared interest and on medicinal products intended for the same condition as that declared in the interest during the cooling-off period.

For financial interests, grant or other funding to the expert's organisation/institution and close family member interests, no restrictions are applied once the interest has ended.

For MDSSG-related activities, no restrictions apply for past interests in a pharmaceutical company.

For further details on the handling of current and past interests in pharmaceutical companies, please refer to Annex 1.

Interests in medical device companies

Current interests

Current employment, consultancy/strategic advisory role or current financial interests in a medical device company are incompatible with involvement in the Agency's activities.

Individuals with other interests in a medical device company may be involved in the Agency's activities; however, exclusions or appropriate restrictions will be applied depending on the interest declared and the activity to be involved in.

Furthermore, in case of an interest declared on a medical device in a given condition, restrictions may apply to the individual's involvement in activities pertaining to medicinal products in the same condition.

Past interests

For MDSSG-related activities, past employment in a medical device company, consultancy/strategic advisory role and role as (principal) investigator are subject to restrictions during a 3-year cooling-off period after the interest has ended. For financial interests and other indirect interests in a medical device company, no restrictions are applied once the interest has ended.

For scientific committees, ETF, MSSG, working parties and inspection-related activities, no restrictions apply for past interests in a medical device company.

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

Interests in the biotechnology sector (for CAT only)

Article 22 of the ATMP Regulation[16] states that CAT members and alternates shall not have financial or other interests in the biotechnology sector and medical device sector that could affect their impartiality.

Consequently, current employment, current consultancy/strategic advisory role or current financial interests in a company in the biotechnology sector are incompatible with participation as a member/chair of the CAT. The Chair of the CAT may also not hold such past interests during a 3-year cooling-off period.

Interests in the medical device sector declared by CAT members will be subject to restrictions as mentioned in the corresponding section and detailed in Annex 2.

Interests in research organisations

Current employment in (or collaboration with) any unit[14] within a research organisation that manufactures medicinal products (including ATMPs under the hospital exemption[15]) or medical devices[16] or that is a marketing authorisation applicant or holder is incompatible with involvement in the Agency's activities.

Individuals with other interests in research organisations (as defined for the purpose of the policy) may be involved in the Agency's activities; however, exclusions or appropriate restrictions will be applied depending on the interest declared and the Agency's activity to be involved in.

Interests in a research organisation are subject to restrictions during a 3-year cooling-off period after the interest has ended.

[16] Article 22 of Regulation (EC) No 1394/2007 on advanced therapy medicinal products and amending Directive 2001/83/EC and Regulation (EC) No 726/2004.

Restrictions will be applied to members or experts affiliated to a research organisation on involvement in all activities related to applications from their organisation (e.g. request for scientific advice or qualification of novel methodologies, regulatory applications such as paediatric investigation plans or orphan designation, request for support and advice on repurposing of a medicinal product, early interaction meetings).

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

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 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[17].

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";
- "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.

EMA applies a proactive approach for scientific committees' and the Agency's other bodies' members for the identification of possible restrictions in involvement in the Agency's activities through mandatory pre-screening of the declared interests prior to any formal acceptance of a nomination from the nominating authority[18]. The Agency will provide feedback to the nominating authority on the outcome of the pre-screening for their consideration. Likewise, the possibility of pre-screening of any expert prior to involvement in the Agency's activities is offered to the nominating authority.

4.2.3. Achieving a transparent process

Transparency is achieved through:

- Publication on the Agency's corporate website of all the DoIs of nominated experts (including those who serve on EMA's scientific committees and other bodies) with the declared direct and/or indirect interests and resulting assigned interest levels, together with their CVs.

[17] Further information is provided in the document "Guidance on handling scientific committee/other (scientific) expert group member's declared intention to become an employee in a pharmaceutical company, medical device company or in the biotechnology sector".
[18] Nominating authority refers to both the Member States and the European Commission, and refers to the scientific committee in case of co-opted members (CHMP, CVMP and HMPC) and ETF, MSSG and MDSSG members.

- Publication on the Agency's corporate website of the minutes of the scientific committees', MSSG and MDSSG meetings, including – where relevant – the specific restrictions applied to the involvement of the chairs, members and experts.

The list of scientific committees' and the Agency's other bodies' members and experts with their declaration of interests, CV and assigned interest level is published on the Agency's website[19].

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. Operation of the policy

The Agency can only start checking the DoIs of scientific committees' and the Agency's other bodies' members and experts following receipt of nomination as a European expert and inclusion in the Agency's Experts Management tool. The roles and the responsibilities of both the nominating authority and the Agency are summarised in the aforementioned MoU.

4.3.1. Nomination process

4.3.1.1. Appointment process for scientific committees', ETF, MSSG and MDSSG members

Scientific committees' members[20, 21] (and, where relevant, alternates), as well as MSSG and MDSSG members, are appointed by Member States for a term of three years, which may be renewed[22]. The Management Board is consulted on nominations prior to the appointment of CHMP and CVMP members. Scientific committees' members, as well as MSSG and MDSSG members, shall be chosen based on their role and experience in the Agency's activities relating to medicinal products for human and veterinary use and medical devices, as appropriate. ETF members are nominated by the entities they represent based on their expertise (e.g. representatives from EMA's scientific committees are nominated by the scientific committee concerned).

4.3.1.2. Nomination process for experts

Member States shall nominate experts with proven experience in the areas of expertise required for the Agency's activities relating to medicinal products and medical devices, as appropriate, in order to serve on working parties or SAGs, or to act as additional experts to scientific committees, working parties, MSSG, MDSSG, ETF or SAGs. Nominations should be accompanied by the experts' qualifications and their specific areas of expertise.

In addition, situations can arise where the need for additional expertise, not covered by nominations made by the Member States, is identified at the level of the scientific committees. In such circumstances, the nomination of the identified expert is undertaken by the Agency.

4.3.2. Inclusion in the Agency's Experts Management tool

All scientific committees' and the Agency's other bodies' members and experts must be included in the Agency's Experts Management tool prior to the first appointment resulting in involvement in activities

[19] https://www.ema.europa.eu/en/about-us/how-we-work/european-medicines-regulatory-network/european-experts
[20] It should be noted that some scientific committees' members are nominated by the European Commission.
[21] It should be noted that at the level of some scientific committees (CHMP, CVMP and HMPC), the committee may appoint co-opted members.
[22] In case of the PRAC, the mandate may be prolonged once and thereafter renewed.

at the Agency (meeting attendance, scientific assessment, inspections, guidance development, etc.). Such inclusion is only possible once the following information have been submitted to the Agency:

- Nomination with areas of expertise;
- Public declaration of interests which includes a confidentiality undertaking; and
- CV.

The nominating authority must ensure, in close collaboration with the nominated member/expert, that all relevant information necessary for the Agency's review is available prior to the member's/expert's involvement in any activity of the Agency.

The Agency undertakes the inclusion in the Experts Management tool for individual patients and healthcare professionals, for representatives of patients' and healthcare professionals' organisations and for other experts not covered by nominations by the Member States but by the European Commission or the Agency.

4.3.3. Quality assurance and non-compliance

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 members' and experts' DoIs are evaluated in accordance with this policy and in particular its annexes, to identify any restrictions, as applicable, to their participation in the activities.

The system for handling of competing interests held by members and experts 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 an expert who is involved in its activities, it will take the appropriate steps to investigate the veracity of that information and adopt any follow-up actions if necessary. The Agency may also adopt any provisional measures whilst the investigation remains ongoing.

In addition, a Breach of Trust Procedure is available in case of observed failure by a scientific committees' and the Agency's other bodies' member or expert to fill in the DoI in a complete and/or correct manner.[23]

5. Related documents

- EMA Code of Conduct
- Engagement Framework: EMA and patients, consumers and their organisations
- 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
- European Medicines Agency breach of trust procedure for competing interests of and disclosure of confidential information by scientific committees' members and experts

[23] European Medicines Agency breach of trust procedure for competing interests of and disclosure of confidential information by scientific committee's members and experts

- 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
- Procedural guidance on inclusion of declared interests in the European Medicines Agency's electronic declaration of interests form (for scientific committees' members and experts)

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]

Emer Cooke
Executive Director

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

Declared interest in a pharmaceutical company	Time since declared interest ended	Committee[1] / ETF / MSSG (vice-)(co-) chair	Working Party / MSSG Working Party (vice-) chair	Committee[1] / ETF /MSSG / Working Party/ MSSG Working Party Rapporteur	Committee[1]/ ETF / MSSG / Working Party /MSSG Working Party Member/ expert	SAG/ad-hoc expert group Chair / member	Inspector
Employee (general matters)	Current	X	X	X	X	X	X
	Past (0-3 yrs)	X	RC	XRappC	XC	XC	XI
Employee (product-related)	Current	X	X	X	X	X	X
	Past (0-3 yrs)	X	RC RP+	XRappC XRappP+	XC	XC	XI
Consultancy/strategic advisory role (general matters)	Current	X	X	X	X	X	X
	Past (0-3 yrs)	X	RC	XRappC	XC	XC	XI
Consultancy/strategic advisory role (product-related)	Current	X	X	X	X	XP+	X
	Past (0-3 yrs)	X	RP+	XRappP+	XP	XP	XI
Financial interests	Current	X	X	X	X	X	X
	Past (0-3 yrs)	F	F	F	F	F	F
(Principal) investigator	Current	X	RP+	XRappP+	XP+	XP+	XI
	Past (0-3 yrs)	X	RP+	XRappP+	XP	XP	XI
Grant/other funding to organisation/institution	Current	RC	RC	XRappC	F	F	F
	Past (0-3 yrs)	F	F	F	F	F	F
Close family member	Current	RC	RC	XRappC	XC	XC	XI
	Past (0-3 yrs)	F	F	F	F	F	F

(1) In addition, for the CAT chair, members and alternates, current employment, current consultancy/strategic advisory role or current financial interests in a company in the biotechnology sector are not allowed. The Chair of the CAT may also not hold such past interests during a 3-year cooling-off period.

X= No involvement in the activity allowed.

RC= To be replaced as (vice)(co)chair for the discussions, final deliberations and voting as appropriate in relation to any medicinal product from the declared company.

RP+ = To be replaced as (vice)(co)chair for the discussions, final deliberations and voting as appropriate in relation to the declared medicinal product and any medicinal product in the declared condition.

XRappC = Cannot act as rapporteur in relation to any medicinal product from the declared company.

XRappP+ = Cannot act as rapporteur in relation to the declared medicinal product and any medicinal products in the declared condition.

XC = No involvement (i.e. no part in discussions, final deliberations and voting as appropriate) in relation to any medicinal product from the declared company.

XP+ = No involvement (i.e. no part in discussions, final deliberations and voting as appropriate) in relation to the declared medicinal product and any medicinal product in the declared condition.

XP = No involvement (i.e. no part in discussions, final deliberations and voting as appropriate) in relation to the declared medicinal product.

XI = Cannot participate in inspections relating to any medicinal product from the declared company.

F = Full involvement.

Declared interest in a pharmaceutical company	Time since declared interest ended	MDSSG (Co)chair	MDSSG Working Party (Vice)chair	MDSSG / MDSSG Working Party Rapporteur	MDSSG / MDSSG Working Party Member /expert
Employee (general matters)	Current	X	X	X	X
	Past (0-3 yrs)	F	F	F	F
Employee (product-related)	Current	X	X	X	X
	Past (0-3 yrs)	F	F	F	F
Consultancy/strategic advisory role (general matters)	Current	X	X	X	X
	Past (0-3 yrs)	F	F	F	F
Consultancy/strategic advisory role (product-related)	Current	X	X	X	X
	Past (0-3 yrs)	F	F	F	F
Financial interests	Current	X	X	X	X
	Past (0-3 yrs)	F	F	F	F
(Principal) investigator	Current	X	RP+	XRappP+	XP+
	Past (0-3 yrs)	F	F	F	F
Grant/other funding to organisation/institution	Current	RC	RC	XRappC	F
	Past (0-3 yrs)	F	F	F	F
Close family member	Current	RC	RC	XRappC	XC
	Past (0-3 yrs)	F	F	F	F

X= No involvement in the activity allowed.

RC= To be replaced as (co)(vice)chair for the discussions, final deliberations and voting as appropriate in relation to any medicinal product from the declared company.

RP+= To be replaced as (vice)chair for the discussions, final deliberations and voting as appropriate in relation to the declared medicinal product and any product in the declared condition.

XRappC = Cannot act as rapporteur in relation to any medicinal product from the declared company.

XRappP+ = Cannot act as rapporteur in relation to the declared medicinal product and any product in the declared condition .

XC = No involvement (i.e. no part in discussions, final deliberations and voting as appropriate) in relation to any medicinal product from the declared company.

XP+ = No involvement (i.e. no part in discussions, final deliberations and voting as appropriate) in relation to the declared medicinal product and any product in the declared condition.

F = Full involvement.

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

Declared interest in a medical device company or notified body	Time since declared interest ended	Committee / ETF / MSSG (vice-)(co-) chair	Working Party / MSSG Working Party (vice)chair	Committee / ETF / MSSG / MSSG Working Party Rapporteur	Committee / ETF / MSSG / Working Party / MSSG Working Party member/ expert	SAG/ad-hoc expert group Chair / member	Inspector
Employee (general matters)	Current	X	X	X	X	X	X
	Past (0-3 yrs)	F	F	F	F	F	F
Employee (product-related)	Current	X	X	X	X	X	X
	Past (0-3 yrs)	F	F	F	F	F	F
Consultancy/strategic advisory role (general matters)	Current	X	X	X	X	X	X
	Past (0-3 yrs)	F	F	F	F	F	F
Consultancy/strategic advisory role (product-related)	Current	X	X	X	X	XD	X
	Past (0-3 yrs)	F	F	F	F	F	F
Financial interests	Current	X	X	X	X	X	X
	Past (0-3 yrs)	F	F	F	F	F	F
(Principal) investigator	Current	X	RD	XRappD	XD	XD	XI
	Past (0-3 yrs)	F	F	F	F	F	F
Grant/other funding to organisation/institution	Current	RC	RC	XRappC	F	F	XI
	Past (0-3 yrs)	F	F	F	F	F	F
Close family member	Current	RC	RC	XRappC	XC	XC	XI
	Past (0-3 yrs)	F	F	F	F	F	F

X= No involvement in the activity allowed.

RC= To be replaced as (vice)(co)chair for the discussions, final deliberations and voting as appropriate in consultation procedures involving any medical device from the declared company.

RD = To be replaced as (vice)chair in consultation procedures involving the declared medical device.

XRappC = Cannot act as Rapporteur in consultation procedures involving any medical device from the declared company.

XRappD = Cannot act as rapporteur in consultation procedures involving the declared medical device and if relevant in relation to any medicinal product in the declared condition.

XC = No involvement (i.e. no part in discussions, final deliberations and voting as appropriate) in consultation procedures involving any medical device from the declared company.

XD = No involvement (i.e. no part in discussions, final deliberations and voting as appropriate) in consultation procedures involving the declared medical device and if relevant in relation to any medicinal product in the declared condition.

XI = Cannot participate in inspections relating to any medicinal products from the declared company.

F = Full involvement.

Declared interest in a medical device company	Time since declared interest ended	MDSSG (Co)chair	MDSSG Working Party (Vice)chair	MDSSG / MDSSG Working Party Rapporteur	MDSSG / MDSSG Working Party Member /expert
Employee (general matters)	Current	X	X	X	X
	Past (0-3 yrs)	X	RC	XRappC	XC
Employee (product-related)	Current	X	X	X	X
	Past (0-3 yrs)	X	RC	XRappC	XC
Consultancy/strategic advisory role (general matters)	Current	X	X	X	X
	Past (0-3 yrs)	X	RC	XRappC	XC
Consultancy/strategic advisory role (product-related)	Current	X	X	X	X
	Past (0-3 yrs)	X	RD	XRappD	XD
Financial interests	Current	X	X	X	X
	Past (0-3 yrs)	F	F	F	F
(Principal) investigator	Current	X	RD	XRappD	XD
	Past (0-3 yrs)	X	RD	XRappD	XD
Grant/other funding to organisation/institution	Current	RC	RC	XRappC	F
	Past (0-3 yrs)	F	F	F	F
Close family member	Current	RC	RC	XRappC	XC
	Past (0-3 yrs)	F	F	F	F

X= No involvement in the activity allowed.
RC= To be replaced as (vice)(co)chair in relation to any medical device from the declared company.
RD= To be replaced as (vice)chair in relation to the declared medical device.
XRappC = Cannot act as rapporteur in relation to any medical device from the declared company.
XRappD = Cannot act as rapporteur in relation to the declared medical device.
XC = No involvement in relation to any medical device from the declared company.
XD = No involvement in relation to the declared medical device.
F = Full involvement.

Annex 3 –Handling of current and past interests in research organisations

Declared interest in a research organisation	Time since declared interest ended	Committee / ETF / MSSG / MDSSG (vice-)(co-) chair	Working Party / MSSG Working Party / MDSSG Working Party (vice-) chair	Committee / ETF /MSSG / MDSSG / Working Party/ MSSG Working Party / MDSSG Working Party Rapporteur	Committee/ ETF / MSSG / MDSSG / Working Party /MSSG Working Party / MDSSG Working Party Member/ expert	SAG/ad-hoc expert group Chair / member	Inspector
Involvement in a unit that manufactures medicinal products or medical devices	Current	X	X	X	X	X	X
	Past (0-3 yrs)	X	RRo RP+	XRappRo XRappP+	XRo	XRo	XI
Involvement in a unit that acts as a marketing authorisation applicant or holder for a medicinal product	Current	X	X	X	X	X	X
	Past (0-3 yrs)	X	RRo RP+	XRappRo + XRappP+	XRo	XRo	XI
Involvement in the conduct of research and development activities subject to an agreement with a company	Current	X	X	X	X	XP+	X
	Past (0-3 yrs)	X	RP+	XRappP+	XP	XP	XI
Regulatory engagement on academic research	Current	X	RP+	XRappP+	XP+	XP+	XI
	Past (0-3 yrs)	X	RP+	XRappP+	XP	XP	XI
Affiliation to a research organisation	Current	RRo	RRo	XRappRo	XRo	XRo	XI
	Past (0-3 yrs)	F	F	F	F	F	F

X= No involvement in the activity allowed.

RRo= To be replaced as (vice)(co)chair for the discussions, final deliberations and voting as appropriate in relation to any medicinal product/medical device from the declared research organisation.

RP+ = To be replaced as (vice)chair for the discussions, final deliberations and voting as appropriate in relation to the declared medicinal product or medical device and any medicinal product or medical device in the declared condition.

XRappP+ = Cannot act as rapporteur in relation to the declared medicinal product or medical device and any any medicinal product or medical device in the declared condition.

XRappRo = Cannot act as rapporteur in relation to any medicinal product/medical device from the declared research organisation.

XRo = No involvement (i.e. no part in discussions, final deliberations and voting as appropriate) in relation to any medicinal product/medical device from the declared research organisation.

XP+ = No involvement (i.e no part in discussions, final deliberations and voting as appropriate) in relation to the declared medicinal product or medical device and any medicinal products or medical devices in the declared condition.

XP = No involvement (i.e no part in discussions, final deliberations and voting as appropriate) in relation to the declared medicinal product or medical device.

XI = Cannot participate in inspections relating to any medicinal product from the declared research organisation.

F = Full involvement.