15 December 2022
EMA/136875/2022 corr* - Adopted

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

POLICY/0044
Status: Public
Effective date: 1 January 2023
Review date: No later than 1 January 2026
Replaces: Policy/0044, dated 11 June 2020 (EMA/MB/89351/2020)

1. Introduction and purpose

EU legislation[1] clearly states that the members[2] of the scientific committees and experts shall not have financial or other interests in the pharmaceutical industry that could affect their impartiality. They shall make an annual declaration of their financial interests. In addition, all indirect interests which could relate to the pharmaceutical industry shall be entered in a register held by the European Medicines Agency (referred to in this document as "Agency" or "EMA"), which is accessible to the public, on request, at the Agency's offices.

In accordance with the Medical Device and *in vitro* Medical Device Regulations (Regulations (EU) 2017/745 and 2017/746[3]), EMA's scientific committees' consultation by Notified Bodies is foreseen for specific categories of medical devices/*in vitro* medical devices. EMA's Extended Mandate Regulation (Regulation (EU) 2022/123[4]) introduced new tasks for the Agency in the area of medical devices.

* EMA document reference on page 7 and footnote 13 corrected and EMA document title and reference in footnote 14 updated in October 2023
[1] Regulation (EC) No 726/2004 of the European Parliament and of the Council of 31 March 2004 laying down Community procedures for the authorisation and supervision of medicinal products for human use and establishing a European Medicines Agency. The responsibilities of the Agency in the veterinary area are set out in Regulation (EU) 2019/6 of the European Parliament and of the Council of 11 December 2018 on veterinary medicinal products and repealing Directive 2001/82/EC.
[2] The reference to members also applies to alternates.
[3] Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices and Regulation (EU) 2017/746 of the European Parliament and of the Council of 5 April 2017 on in vitro diagnostic medical devices.
[4] Regulation (EU) 2022/123 of the European Parliament and of the Council of 25 January 2022 on a reinforced role for the European Medicines Agency in crisis preparedness and management for medicinal products and medical devices.

Official address Domenico Scarlattilaan 6 ● 1083 HS Amsterdam ● The Netherlands
Address for visits and deliveries Refer to www.ema.europa.eu/how-to-find-us
Send us a question Go to www.ema.europa.eu/contact **Telephone** +31 (0)88 781 6000 An agency of the European Union

These new tasks specifically 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[5]. The Extended Mandate Regulation also established the Emergency Task Force (ETF) as a new scientific body[6].

The Agency's Code of Conduct[7] provides general guidance on several aspects related to declarations of interests. Information is made available about what should be declared by whom and at what moment in time. In addition, clarification about some operational aspects is given by stating the tasks of the Agency's secretariat, the obligations of the individuals concerned and the meeting proceedings.

The implementation of a policy on handling of competing interests allows the Agency to restrict or exclude, in an appropriate and timely manner, the involvement of experts in the Agency's activities due to their declared interests.

Experience with the handling of declarations of interests for the scientific committees' members and experts has been gained since the establishment of the Agency in 1995. With a view to continuously improving the processes in the context of its integrated quality management system, the Agency decided to review at regular intervals the procedures and arrangements in place and to strengthen its handling of declarations of interests taking into account the outcome of these reviews.

A policy on the handling of conflicts of interests for the scientific committee members and experts was established in March 2004 and subsequently reviewed and updated in the light of experience gained. The policy was first revised in December 2005 and on 29 September 2011, 3 April 2012, 30 January 2015, 6 October 2016 and 11 June 2020, respectively. The latter was effective from 1 January 2021.

Changes introduced in the current revision result from the additional responsibilities for the Agency following its involvement in certain medical device and IVD 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.

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

2. Scope

The scope of the policy relates to the handling of competing interests of scientific committees' (i.e. CHMP, CVMP, COMP, HMPC, PDCO, CAT and PRAC) members (including, where relevant, alternates) and experts involved in activities at the level of the Agency (e.g. scientific committees, working parties, scientific advisory groups, ad hoc expert groups). In addition, its scope applies to the Agency's other bodies, i.e. Emergency Task Force (ETF), Medicines Shortages Steering Group (MSSG), Medical Devices Shortages Steering Group (MDSSG). Involvement in the Agency's activities means all activities carried out at the Agency in the context of:

[5] 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."*.

[6] 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*."

[7] The EMA Code of Conduct

- the evaluation, supervision and maintenance of medicinal products for human and veterinary use,
- 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 the scientific assessment and guidance development, as well as participation in inspections, as applicable. Throughout this policy, the use of the term 'expert' encompasses the above-mentioned scientific committee and Agency's other bodies members (including, where relevant, alternates) and experts involved in activities at the level of the Agency.

The policy focuses on competing interests in the pharmaceutical industry and in particular on medicinal products, as well as for medical device related activities on competing interests in medical device companies and notified bodies. The policy also implements the specific requirement from Article 22 of the ATMP Regulation[8] 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.

In addition, in accordance with Article 63.2 of Regulation (EC) No 726/2004, scientific committees and Emergency Task Force (ETF) members and experts who participate in meetings or working groups of the Agency are also required to declare at each meeting any specific interests which could be considered to be prejudicial to their independence with respect to the items on the agenda. The same requirement applies to the meetings of the Medicines Shortages Steering Group (MSSG) and Medical Devices Shortages Steering Group (MDSSG) in accordance with Article 32.5 of Regulation (EU) 2022/123.

The scope of this policy does not relate to staff and experts at national level participating in the (evaluation) work (with respect to the evaluation, supervision and maintenance of medicinal products, the consultation on medical devices or the crisis preparedness and management for medicinal products and medical devices) for services provided to the Agency. This scope is in line with the MoU[9] concluded between the NCAs and the Agency.

The scope of this policy does not include 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

[8] Article 22 of Regulation (EC) No 1394/2007 of the European Parliament and of the Council of 13 November 2007 on advanced therapy medicinal products and amending Directive 2001/83/EC and Regulation (EC) No 726/2004.
[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 (EMA/150487/2010).
[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)

- CHMP: Committee for Medicinal Products for Human Use
- CME: Continuing Medical Education
- COMP: Committee for Orphan Medicinal Products
- CPD: Continuing Professional Development
- CRO: Contract Research Organisation
- CV: Curriculum Vitae
- CVMP: Committee for Medicinal Products for Veterinary Use
- 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
- MAH: Marketing Authorisation Holder
- MDSSG: Medical Devices Shortages Steering Group – Executive Steering Group on Shortages of Medical Devices
- MoU: Memorandum of Understanding
- 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** shall mean: any legal or natural person whose focus is to research, develop, manufacture, maintain, market and/or distribute medicinal products. For the purpose of this policy, the definition 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.

  In this regard 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.

Independent researchers and research organisations including universities, hospitals and learned societies[11], are excluded from the scope of the present definition. However, any unit, department, section or entity within such organisation, that manufacturers medicinal products, including ATMPs under hospital exemption, or is a marketing authorisation applicant/holder, shall be considered as a pharmaceutical company for the purpose of this policy. Staff members of such units, sections, departments or entities are considered to be equivalent to staff members of a pharmaceutical company. Other parts of the organisation to which the unit, section, department or entity belongs can be excluded from this definition of a pharmaceutical company.

- **Medical device company** shall mean: any legal or natural person whose focus is to research, develop, manufacture, maintain, market and/or distribute medical devices (Regulation (EU) 2017/745) or *in vitro* diagnostic medical devices (Regulation (EU) 2017/746). For the purpose of this policy, the definition 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.

  In this regard 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 company for the purposes of this policy.

  Independent researchers and research organisations including universities, hospitals and learned societies[11] are excluded from the scope of the present definition. However, any unit, department, section or entity within such organisation, that develops or manufactures medical devices, shall be considered as a medical device company for the purpose of this policy. Staff members of such units, sections, departments or entities are considered to be equivalent to staff members of a medical device company. Other parts of the organisation to which the unit, section, department or entity belongs can be excluded from this definition of a medical device company.

- **Biotechnology sector** shall mean: 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;

[11] The term "independent researcher and research organisations" covers facilities, resources and services that are used by the research communities to conduct research and foster innovation in their fields as well as public or private non-profit organisations/legal entities whose primary mission is to pursue research.
The term "universities" covers public or private higher education establishments awarding academic degrees.
The term "hospital" includes 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.

- Manufactures of critical starting materials for ATMPs, e.g. viral vector manufacturers.

For the purpose of this policy, the definition 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.

In this regard 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) for ATMPs, fall under the definition of 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 biotechnology sector), (ii) are controlled by or (iii) are under common control of the biotechnology sector, shall be considered as biotechnology sector for the purposes of this policy.

Independent researchers and research organisations including universities, hospitals and learned societies[11] are excluded from the scope of the present definition. However, any unit, department, section or entity within such organisation, that performs the above defined activities of the biotechnology sector, shall be considered as biotechnology sector for the purpose of this policy. Staff members of such units, sections, departments or entities are considered to be involved in the biotechnology sector. Other parts of the organisation to which the unit, section, department or entity belongs can be excluded from this definition of biotechnology sector.

- **Repurposing of a medicinal product** shall mean: the process of identifying a new therapeutic use for an existing medicinal product – out of regulatory protection – outside its existing authorised indication(s).
- **Champion for the repurposing of a medicinal product** shall mean: a non-profit stakeholder gathering or generating evidence, including seeking scientific advice as the main regulatory tool, for the repurposing of a medicinal product, that can be e.g. a patient organisation, academic institution, collaborative groups or European Reference Networks.
  A champion is typically (a) able to coordinate and/or foster the research programme up until the point of full engagement by a pharmaceutical company, (b) initially responsible for liaising and leading the interactions with regulatory authorities and pharmaceutical companies/other stakeholders, (c) transparent regarding interactions with relevant pharmaceutical company(ies) and (d) in charge of filing the initial request for scientific/regulatory advice on the basis of the available data.

3.2.2. Direct versus indirect interests

Taking into account the aforementioned EU legislation applicable to the Agency in the field of declarations of interests, the two categories of interests, i.e. direct and indirect interests in a pharmaceutical company, a medical device company or the biotechnology sector, are defined as follows.

- Direct interests are:
  - Employment
  - Consultancy
  - Strategic advisory role

- Financial interests
- Involvement of the expert in the repurposing of a medicinal product

- Indirect interests are:
  - Principal investigator
  - Involvement of the expert's organisation in the repurposing of a medicinal product
  - Investigator
  - Grant or other funding to the expert's organisation/institution
  - Close family member direct interest.

Each of these interests is further defined below. However, it should be emphasised that some of the definitions cannot address all the various scenarios which may exist. Additional guidance is included in the document "Procedural guidance on inclusion of declared interests in the European Medicines Agency's electronic declaration of interests form (for scientific committees' members and experts)" (EMA/627294/2014).

3.2.2.1. Direct interests

- **Employment with a pharmaceutical company, a medical device company or the biotechnology sector** shall mean: any form of occupation, part-time or full-time, paid or unpaid, in a pharmaceutical company, a medical device company or the biotechnology sector.
- **Consultancy to a pharmaceutical company, a medical device company or the biotechnology sector** shall mean: any activity where the concerned expert provides advice (including training on a one to one basis or involvement in the repurposing of a medicinal product) to a pharmaceutical company, a medical device company or the biotechnology sector regardless of contractual arrangements or any form of remuneration.

  It should be noted that (scientific) advice provided by the NCA of a Member State is not considered a consultancy activity.
- **Strategic advisory role for a pharmaceutical company, a medical device company or the biotechnology sector** shall mean: any activity where the expert is participating (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 a pharmaceutical company, a medical device company or the biotechnology sector, either in terms of general strategy or product related strategy, regardless of contractual arrangements or any form of remuneration.

  It should be noted that:
  - Data monitoring committees (composed of independent external experts reviewing unblinded clinical trial or clinical investigation data independently of the sponsor/pharmaceutical company or the medical device company) fall outside the scope of this definition. Experts participating in these fora are considered in the same way as principal investigators (for definition of principal investigator see below).
  - Involvement of an expert in research work for a pharmaceutical company, a medical device company or the biotechnology sector is considered an indirect interest.

- **Financial interests in a pharmaceutical company, a medical device company or the biotechnology sector** shall mean any economic stake in a pharmaceutical company, a medical device company or a biotechnology sector including:
  - Holding of stocks and shares, stock options, stock warrants, equities, bonds, ownership or partnership interest in the capital of such pharmaceutical company, a medical device company or the biotechnology sector. 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 concerned sector) and they are independently managed (i.e. the individual has no influence on their financial management).
  - Compensation, fees, honoraria, salaries, grant or other funding (including rents, sponsorships and fellowships) paid by a pharmaceutical company, a medical device company or the biotechnology sector to the expert in a personal capacity.
    Payment for or reimbursement of expenses incurred with the research work or reimbursement of reasonable expenses directly related to a conference/seminar attendance (i.e. accommodation and travel costs) are not considered as financial interests.
  - Intellectual property rights including patents, trademarks, know-how and/or copyrights relating to a medicinal product, to a medical devices or to the biotechnology sector owned by the individual or of which the individual is directly a beneficiary.
- **Involvement of the expert in the repurposing of a medicinal product shall mean:** an expert whose organisation is acting as a champion in the repurposing of a medicinal product or whose organisation is collaborating with the champion of the repurposing of a medicinal product, and whom as an individual is involved in the repurposing.

3.2.2.2. Indirect interests

- **Principal investigator** shall mean: an investigator with the responsibility for the coordination of investigators at different centres participating in a multicentre pharmaceutical or medical device company instigated/sponsored clinical trial, clinical investigation or performance study or the leading investigator of a monocentre pharmaceutical or medical device company instigated/sponsored clinical trial, clinical investigation or performance study, or the coordinating (principal) investigator signing the clinical study report[12].
- **Investigator** shall mean: an investigator involved in a pharmaceutical or medical device company instigated/sponsored clinical trial, clinical investigation or performance study at a specific trial site which can be the responsible lead investigator of the trial, investigation or study at that specific site or a member of the clinical trial, clinical investigation or performance study team who performs critical trial, investigation or study related procedures and makes important trial, investigation or study related decisions.
- **Grant or other funding to the expert's organisation/institution** shall mean: any funding received from a pharmaceutical company, a medical device company or the biotechnology sector by the organisation/institution to which the expert belongs, or for which he/she performs any kind of activity, and which is used to support any activity of the expert whether or not it is related to research work.

[12] This definition does not include a national coordinating investigator in a multinational trial.

- **Involvement of the expert's organisation in the repurposing of a medicinal product** shall mean: an expert whose organisation is acting as a champion in the repurposing of a medicinal product or whose organisation is collaborating with the champion of the repurposing, and whom as an individual is not involved in the repurposing themselves.
- **Close family members** (interests) shall mean (interests held by): first-line members of the family of the expert (i.e. a spouse or a partner, children and parents). Partner shall mean: a natural person with whom the expert is registered as having a stable non-marital partner legally recognised by an EU member state or any competent authority of a member state, acknowledging their status as non-marital partners.

3.2.3. Other definitions

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

- **Rival product for a medicinal product** shall mean: a medicinal product that targets a similar patient population with the same clinical objective (i.e. to treat, prevent or diagnose a particular condition), and constituting a potential commercial competition.
- **Expert witness** shall mean: an expert whose role is limited to testify and give specialist advice on a specific issue by providing information and replying to any questions only. Such expert witness can be invited to participate at scientific committee, working party, SAG or *ad hoc* expert group, ETF, MSSG or MDSSG meetings.

4. Policy statement

The following aspects are addressed in this policy:

- Objectives of the policy
- Principles of the policy
- Preparatory steps for the operation of the policy
- Practical operation of the policy

4.1. Objectives of the policy

The main objective of the policy is to ensure that the members and the experts participating in the Agency's scientific committees' and other bodies' activities have no interests in pharmaceutical companies, medical device companies and/or the biotechnology sector which could affect their impartiality, as per the requirements of EU legislation. This objective has to 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, of utmost importance to strive for the optimal balance between the cooling-off period for the declared interests versus maintaining the experts' knowledge.

In order to achieve this objective and to strike the aforementioned balance the focus will first be on the nature of the declared interest before determining the length of time any restrictions will apply.

4.2. Principles of the policy

The policy focuses on 3 pillars, i.e.:

- robustness,
- efficiency, and
- transparency of the process for the handling of competing interests of scientific committees' and the Agency's other bodies' members and experts.

4.2.1. Achieving a robust process

The following principles apply:

4.2.1.1. Declared interests

Direct interests versus indirect interests versus no interests declared

In terms of declarations of interests 3 interest levels can be identified:

- "direct interests declared" (i.e. interest level 3);
- "indirect interests declared" (i.e. interest level 2);
- "no interests declared" (i.e. interest level 1).

The primary focus is on direct interests leading to the most pronounced restrictions in involvement in the Agency's activities.

Indirect interests will be addressed through mitigating actions to reach the best possible balance between limiting the involvement in the Agency's activities and the need for the availability of the best (specialist) scientific expertise.

Looking at the nature of the declared interest, three categories have been identified:

- Category 1: leading role during previous employment or involvement in repurposing of a medicinal product which results in non-involvement during the term of the mandate of the committee or other body member or expert. This applies to:
  - Executive role[13] within a pharmaceutical company, resulting in non-involvement in committee, ETF or MSSG-related activities during the term of the mandate for any medicinal product for which the pharmaceutical company is the Applicant or MAH, irrespective if such involvement relates to a decision-making or an advisory body;

    Executive role within a medical device company resulting in non-involvement in MDSSG-related activities during the term of the mandate for any medicinal device from the medical device company, irrespective if such involvement relates to a decision-making or an advisory body.
  - Lead role[13] in the development of a medicinal product, resulting in non-involvement in committee, ETF or MSSG-related activities during the term of the mandate for the medicinal product, irrespective if such involvement relates to a decision-making or advisory body;

    Lead role in the development of a medical device, resulting in non-involvement in MDSSG-related activities during the term of the mandate for any medicinal device from the medical device company, irrespective if such involvement relates to a decision-making or an advisory body.

[13] Further information is provided in the aforementioned "Procedural guidance on inclusion of declared interests in the European Medicines Agency's electronic declaration of interests form (for scientific committees' members and experts)" (EMA/627294/2014).

- The involvement of an expert in the repurposing of a medicinal product whose organisation is acting as a champion in the repurposing.

- Category 2: for certain declared interests, as specified below, it is assumed that the declared interest is considered over when such interest is no longer present, resulting in full involvement in the Agency's activities:
  - Financial interests in a pharmaceutical company, a medical device company or the biotechnology sector
  - Grant or other funding from a pharmaceutical company, a medical device company or the biotechnology sector to the expert's organisation/institution
  - Interests related to close family members in a pharmaceutical company, a medical device company or the biotechnology sector
  - Employment, consultancy, strategic advisory role, principal investigator or investigator in a pharmaceutical company in case of MDSSG-related activities
  - Employment, consultancy, strategic advisory role, principal investigator or investigator in a medical device company in case of committee, ETF or MSSG-related activities and in case of CAT membership.
  - Employment, consultancy, strategic advisory role, principal investigator or investigator in the biotechnology sector in case of CAT membership.
- Category 3: for the remaining declared interests, not listed in categories 1 and 2, it is assumed that the declared interest is considered over following a 3-year cooling-off period. Mitigating measures will vary depending on whether the involvement of the expert relates to a committee, ETF, MSSG or MDSSG or to a decision-making or an advisory body, and will depend as well on the role of the expert (chairperson, rapporteur or equivalent leading/co-ordinating role, formally appointed peer reviewer).

Other declarable interests

- For transparency purposes, other interests should be declared, such as:
  - Involvement in academic trials or investigations and in publicly funded research/development initiatives
  - Membership of an ethics committee
  - If colleagues in their organisation/institution provide consultancy advice to pharmaceutical companies or medical device companies
  - Participation in European societies/research foundations/strategy boards/treatment groups/focus groups, which may be funded in full or in part from unrestricted grants from pharmaceutical companies or medical device companies (not from one single company), with or without involvement of industry participants and which may provide general advice (on development programmes, clinical study design, strategy, etc.) to several companies (not one particular company) in a specific therapeutic area
  - Expert opinion or testimony in judicial proceedings against or by a pharmaceutical company or a medical device company relating to a medicinal product or medical device
  - Participation as a patient in a clinical trial or clinical investigation

This will not result in the Agency restricting involvement in its activities unless a specific interest is identified.

- Attendance at courses and conferences funded by pharmaceutical or medical device companies or for CAT members and alternates funded by the biotechnology sector (including attendance at accredited courses or conferences with respect to continuing development of experts CPD/CME acquisition) do not need to be declared. However, where the expert receives payment from the funding company or sector going beyond reimbursement of reasonable expenses (i.e. accommodation and travel costs) directly related to a conference/seminar attendance or participation, this needs to be declared as a financial interest and this will be incompatible with involvement in the Agency's activities.

4.2.1.2. Restricting involvement in the Agency's activities

Levels of restriction and timeframes

- Involvement of the individual in the Agency's activities is restricted taking into account 3 factors: the nature of the declared interest, the timeframe during which such interest occurred, as well as the type of activity. The following methodology applies: first the nature of the declared interest within the frame of the specific Agency activity will be looked at, before determining the length of time any restrictions will apply.
- 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 (whether initial or updated), at any time point during the term of the mandate of a member or at the time of involvement of an individual in a specific Agency activity.
- As a general rule, current employment with a pharmaceutical company or, current financial interests in a pharmaceutical company, or current involvement of an expert in the repurposing of a medicinal product where his organisation is acting as a champion, are incompatible with involvement in the Agency's activities. Current employment or current financial interests in a medical device company are incompatible with involvement in MDSSG-related activities. Current employment or current financial interests in a medical device company where the medical device is used or to be used in combined ATMPs or in the biotechnology sector are incompatible with CAT membership.
- One exception to this general rule relates to the concept of expert witness. Current financial interests are compatible with this concept in order to maintain access to specific scientific expertise.
- The requirements for membership of decision-making bodies (e.g. scientific committees) are stricter than for advisory bodies (e.g. SAGs and *ad hoc* expert groups).
- The requirements are also stricter for chairpersons/vice-chairpersons of the committees, ETF, MSSG and MDSSG compared to the chairpersons/vice-chairpersons of other fora (e.g. working parties) and compared to the members of the committees, ETF, MSSG and MDSSG and the other fora. Likewise, the requirements are stricter for rapporteurs (or equivalent leading/co-ordinating role) and formally appointed peer reviewers compared to the other members of the scientific fora.
- For CAT members and alternates, additional requirements apply for interests in the biotechnology sector or medical device companies where the medical device is used or to be used in combined ATMPs, where the requirements are stricter for direct interests than for indirect interests.

- Requirements for an expert involved in the repurposing of a medicinal product are stricter than for an expert not involved in the repurposing, but whose organisation is acting as the champion for the repurposing of a medicinal product or is collaborating with a champion for the repurposing.
- The timeframe to be considered depending on the declared direct or indirect interest is either current, or within the past 3 years, or in certain cases, as stated before, for a longer period (see section 4.2.1.1. for further details). As already mentioned before, the nature of the declared interest will be considered first before deciding on the duration of any restrictions. However, individuals can always declare any interests beyond those periods limited in time (i.e. current, or within the past 3 years). They can always also restrict, on their own initiative, their involvement in the Agency's activities as a result of the declaration of an interest.
- For committee, ETF and MSSG-related activities, no restrictions apply for past (within the past 3 years or for a longer period) interests in a medical device company.
- For MDSSG-related activities, no restrictions apply for past (within the past 3 years or for a longer period) interests in a pharmaceutical company.
- Scientific committee and other body members belonging to an organisation which submits regulatory applications to the Agency, e.g. scientific advice applications or paediatric investigation plans, are restricted from involvement in all committee activities related to the applications from that organisation.
- 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. 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[14].

Specific case of rival products

For the specific case of rival products for medicinal products a two-tier approach is applied:

- The concept of rival products relates to those situations where there are only a very small number (1 to 2) of rival products. The same would apply for the brand leader when a generic product is under consideration.
- For broad indications, since many products are authorised for the same indication, the existing volume of competition dilutes adequately potential interests.

In situations characterised by only a very small number of rival products as specified above, consequences will relate to the (vice)-chairpersons of the scientific committees and the working

[14] 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" (EMA/267183/2015).

parties, as well as the rapporteurs or other members in a leading/ co-ordinating role, or formally appointed peer reviewers.

4.2.2. Achieving an efficient process

The following should enable the establishment of an efficient process:

- As regards the handling of competing interests a 2-step procedure applies: following receipt of the DoI an interest level is automatically assigned according to the aforementioned interest levels. 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 which apply to participation in the various activities of the Agency.
- For scientific committees' and the Agency's other bodies' members a proactive approach is applied as regards the possible identification of the need for restrictions in involvement in the Agency's activities through mandatory pre-screening by the Agency of the declared interests prior to any formal nomination by the Nominating Authority[15]. The Agency will provide feedback to the Nominating Authority on the outcome of the pre-screening for subsequent consideration by the Nominating Authority when launching the formal nomination process. Likewise, the possibility of pre-screening of any expert prior to involvement in the Agency's activities is offered to the Nominating Authority.
- A proactive approach is also applied with respect to the search for alternative experts in the field, making the best use of the established relationships with academia and learned societies. In addition, for the establishment of a new SAG or the renewal of the mandate of an existing SAG a public call for expression of interests is launched by the Agency.

4.2.3. Achieving a transparent process

Transparency is achieved through:

- Publication on the Agency's website of the minutes of the scientific committees', MSSG and MDSSG meetings, including – where relevant – restricted involvement of the chairs, members and experts.
- Publication of the DoIs with all direct and/or indirect interests in a pharmaceutical company, a medical device company and the biotechnology sector and the CVs on the Agency's website of all scientific committees', ETF, MSSG and MDSSG members and experts, whilst ensuring that personal data legislation is adhered to, as well as publication of the assigned interest levels.

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. Preparatory steps for the operation of the policy

Before any work can be undertaken by the Agency on the checking of declarations of interests, scientific committees' and the Agency's other bodies' members and experts need to be first nominated as a European expert after which they need to be included in the Agency's Experts Management tool.

[15] 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.

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. Nomination process for scientific committees', MSSG and MDSSG members

Scientific committees' members[16, 17] (and, where relevant, alternates), as well as MSSG and MDSSG members, are nominated by Member States for a term of three years, which may be renewed[18]. 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 by reason of their role and experience in the Agency's activities relating to medicinal products for human and veterinary use and medical devices, as appropriate, and shall represent their Competent Authorities.

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 a description of 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 expertise 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 at the level of the Agency (meeting attendance, scientific evaluation, 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 and confidentiality undertaking form, and
- CV.

The Nominating Authority has to ensure, in close collaboration with the nominated member/expert, that all relevant information necessary for the Agency's review has been made 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 patients and healthcare professionals organisations' representatives and for other experts not covered by nominations by the Member States but identified by the Agency.

[16] It should be noted that some scientific committees' members are nominated by the European Commission.
[17] It should be noted that at the level of some scientific committees (CHMP, CVMP and HMPC), the committee may decide to appoint co-opted members.
[18] In case of the PRAC, the mandate may be prolonged once and thereafter renewed.

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].

4.4. Practical operation of the policy

The consequences of the application of the principles laid down in this policy in terms of the allowable interests are summarised in annex 1 "Scientific committees' and the Agency's other bodies' members and experts allowed involvement in medicinal product or medical device related matters based on declared interests in a pharmaceutical company or a medical device company" and in annex 2 "CAT members and alternates allowed involvement in medicinal product related matters based on declared interests in the biotechnology sector or medical device companies where the medical device is used or to be used in combined ATMPs".

In order to check 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. In addition, a Breach of Trust Procedure is available in case of observed failure by a scientific committee member or expert to fill in the DoI in a complete and/or correct manner.[20]

5. Related documents

- Regulation (EC) No 726/2004 of the European Parliament and of the Council of 31 March 2004 laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency.
- Regulation (EU) 2019/6 of the European Parliament and of the Council of 11 December 2018 on veterinary medicinal products and repealing Directive 2001/82/EC.
- Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices.
- Regulation (EU) 2017/746 of the European Parliament and of the Council of 5 April 2017 on in vitro diagnostic medical devices.
- Regulation (EU) 2022/123 of the European Parliament and of the Council of 25 January 2022 on a reinforced role for the European Medicines Agency in crisis preparedness and management for medicinal products and medical devices.
- 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).

6. 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 IVD procedures as set out in Regulations (EU)

[19] https://www.ema.europa.eu/en/about-us/how-we-work/european-medicines-regulatory-network/european-experts

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

2017/745 and 2017/746, as well as from its extended mandate in accordance with Regulation (EU) 2022/123.

Amsterdam, 15 December 2022

Emer Cooke
Executive Director

Annex 1

Scientific committees' and the Agency's other bodies' members and experts allowed involvement in medicinal product or medical device related matters based on declared interests in a pharmaceutical company or a medical device company

Declared interest in a pharmaceutical company	Time since declared interest ended (in years)	Scientific committee / ETF / MSSG (Co-)(Vice-)Chair	Working party / MSSG Working Party (Vice-)Chair	Scientific committee / ETF / MSSG / Working party / MSSG Working Party member	Scientific committee / ETF / MSSG / Working party / MSSG Working Party expert	SAG/ad-hoc expert group (Vice-)Chair	SAG/ad-hoc expert group member/expert	Inspection	Expert Witness
Employee (executive role)	Current interest	X	X	X	X	X	X	X	X
	0 to 3	X	RC	XC-XRpC	XC	RC	DC	XI	Q
	> 3	RC	RC	XC-XRpC	XC	RC	DC	XI	Q
Employee (lead role in development of medicinal product)	Current interest	X	X	X	X	X	X	X	X
	0 to 3	X	RR	XP-XRpR	XP	RP	DP	XI	Q
	> 3	RP	RP	XP-XRpP	XP	RP	DP	XI	Q
Involvement in the repurposing of a medicinal product where the expert's organisation is the champion of the repurposing	Current interest	X	X	X	X	X	X	X	X
	0 to 3	X	RP	XP-XRpP	XP	RP	DP	XI	Q
	> 3	RP	RP	XP-XRpP	XP	RP	DP	XI	Q
Employee (cross medicinal products/general role other than executive role)	Current interest	X	X	X	X	X	X	X	X
	0 to 3	X	RC	XC-XRpC	XC	RC	DC	XI	Q
Employee (individual medicinal product involvement other than lead role in development of	Current interest	X	X	X	X	X	X	X	X
	0 to 3	X	RR	XP-XRpR	XP	RP	DP	XI	Q
Consultancy to company (cross medicinal products/general)	Current interest	X	X	X	X	X	X	X	Q
	0 to 3	X	RC	XC-XRpC	XC	RC	DC	XI	Q
Consultancy to company (individual medicinal product)	Current interest	X	X	X	X	RP	XP	X	Q
	0 to 3	X	RR	XP-XRpR	XP	RP	DP	XI	Q
Involvement in the repurposing of a medicinal product where the expert's organisation is collaborating with the champion of the repurposing	Current interest	X	X	X	X	RP	XP	X	Q
	0 to 3	X	RP	XP-XRpP	XP	RP	DP	XI	Q
Strategic advisory role for company (cross medicinal products/general)	Current interest	X	X	X	X	X	X	X	Q
	0 to 3	X	RC	XC-XRpC	XC	RC	DC	XI	Q
Strategic advisory role for company (individual medicinal product)	Current interest	X	X	X	X	RP	XP	X	Q
	0 to 3	X	RR	XP-XRpR	XP	RP	DP	XI	Q
Financial interests	Current interest	X	X	X	X	X	X	X	Q
	0 to 3	F	F	F	F	F	F	F	Q
Principal investigator	Current interest	X	RR	XP-XRpR	XP	RP	DP	XI	Q
	0 to 3	X	RR	XP-XRpR	XP	F	F	XI	Q
Involvement of the expert's organisation in the repurposing of a medicinal product, where the expert themself is not involved in the repurposing	Current interest	X	RP	XP-XRpP	XP	RP	XP	XI	Q
	0 to 3	X	RP	XP-XRpP	XP	RP	DP	XI	Q
Investigator	Current interest	X	RR	DP-XRpR	DP	F	F	XI	Q
	0 to 3	X	RR	DP-XRpR	DP	F	F	XI	Q
Grant/other funding to organisation/institution	Current interest	RC	RC	XRpC	F	F	F	XI	Q
	0 to 3	F	F	F	F	F	F	F	Q
Close family member	Current interest	RC	RC	DC-XRpC	F	F	F	XI	Q
	0 to 3	F	F	F	F	F	F	F	Q

Declared interest in a pharmaceutical company	Time since declared interest ended (in years)	MDSSG (Co-)Chair	MDSSG Working party (Vice-)Chair	MDSSG / MDSSG Working party member	MDSSG / MDSSG Working party expert	Expert Witness
Employee (executive role)	Current interest	X	X	X	X	X
	0 to 3	F	F	F	F	Q
	> 3	F	F	F	F	Q
Employee (lead role in development of medicinal product)	Current interest	X	X	X	X	X
	0 to 3	F	F	F	F	Q
	> 3	F	F	F	F	Q
Involvement in the repurposing of a medicinal product where the expert's organisation is the champion of the repurposing	Current interest	X	X	X	X	X
	0 to 3	F	F	F	F	Q
	> 3	F	F	F	F	Q
Employee (cross medicinal products/general role other than executive role)	Current interest	X	X	X	X	X
	0 to 3	F	F	F	F	Q
Employee (individual medicinal product involvement other than lead role in development of	Current interest	X	X	X	X	X
	0 to 3	F	F	F	F	Q
Consultancy to company (cross medicinal products/general)	Current interest	X	X	X	X	Q
	0 to 3	F	F	F	F	Q
Consultancy to company (individual medicinal product)	Current interest	X	X	X	X	Q
	0 to 3	F	F	F	F	Q
Involvement in the repurposing of a medicinal product where the expert's organisation is collaborating with the champion of the repurposing	Current interest	X	X	X	X	Q
	0 to 3	F	F	F	F	Q
Strategic advisory role for company (cross medicinal products/general)	Current interest	X	X	X	X	Q
	0 to 3	F	F	F	F	Q
Strategic advisory role for company (individual medicinal product)	Current interest	X	X	X	X	Q
	0 to 3	F	F	F	F	Q
Financial interests	Current interest	X	X	X	X	Q
	0 to 3	F	F	F	F	Q
Principal investigator	Current interest	X	RR	XP-XRpR	XP	Q
	0 to 3	F	F	F	F	Q
Involvement of the expert's organisation in the repurposing of a medicinal product, where the expert themself is not involved in the repurposing	Current interest	X	RP	XP-XRpP	XP	Q
	0 to 3	F	F	F	F	Q
Investigator	Current interest	X	RR	DP-XRpR	DP	Q
	0 to 3	F	F	F	F	Q
Grant/other funding to organisation/institution	Current interest	RC	RC	XRpC	F	Q
	0 to 3	F	F	F	F	Q
Close family member	Current interest	RC	RC	DC-XRpC	F	Q
	0 to 3	F	F	F	F	Q

Outcome of evaluation

Please select the outcome restriction level(s) in the dropdown list below.

Outcome restriction level	Impact of the outcome
X	**No involvement in activity allowed.**
Q	**Involvement limited** to testify and give specialist advice on a specific issue by providing information and replying to any questions only.
RC	**To be replaced as chair** for the discussions, final deliberations and voting as appropriate in relation to any medicinal product from the relevant company.
RR	**To be replaced as chair** for the discussions, final deliberations and voting as appropriate in relation to the relevant medicinal product or a rival product.
RP	**To be replaced as chair** for the discussions, final deliberations and voting as appropriate in relation to the relevant medicinal product.
XC-XRpC	• **No involvement** with respect to medicinal products from the relevant company, i.e. no part in discussions, final deliberations and voting as appropriate as regards medicinal products from the relevant company **(XC)**. • **Cannot act as rapporteur, other leading/co-ordinating role or formally appointed peer reviewer** for medicinal products from the relevant company **(XRpC)**.
XC	**No involvement** with respect to medicinal products from the relevant company, i.e. no part in discussions, final deliberations and voting as appropriate as regards medicinal products from the relevant company.
DC-XRpC	• **Involvement only in discussions** with respect to medicinal products from the relevant company, i.e. no part in final deliberations and voting as appropriate as regards medicinal products from the relevant company. • **Cannot act as rapporteur, other leading/co-ordinating role or formally appointed peer reviewer** in relation to any medicinal product from the relevant company.
DC	**Involvement only in discussions** with respect to medicinal products from the relevant company, i.e. no part in final deliberations and voting as appropriate as regards medicinal products from the relevant company.
XRpC	**Cannot act as rapporteur, other leading/co-ordinating role or formally appointed peer reviewer** in relation to any medicinal product from the relevant company.
XP-XRpR	• **No involvement** with respect to procedures involving the relevant medicinal product, i.e. no part in discussions, final deliberations and voting as appropriate as regards the medicinal product **(XP)**. • **Cannot act as rapporteur, other leading/co-ordinating role or formally appointed peer reviewer** for the relevant medicinal product or a rival product **(XRpR)**.
DP-XRpR	• **Involvement only in discussions** with respect to procedures involving the relevant medicinal product, i.e. no part in final deliberations and voting as appropriate as regards the medicinal product **(DP)**. • **Cannot act as rapporteur, other leading/co-ordinating role or formally appointed peer reviewer** for the relevant medicinal product or a rival product **(XRpR)**.
XP-XRpP	• No involvement with respect to procedures involving the relevant medicinal product, i.e. no part in discussions, final deliberations and voting as appropriate as regards the medicinal product **(XP)**. • Cannot act as rapporteur, other leading/co-ordinating role or formally appointed peer reviewer for the relevant medicinal product **(XRpP)**.
XP	**No involvement** with respect to procedures involving the relevant medicinal product, i.e. no part in discussions, final deliberations and voting as appropriate as regards the medicinal product.
DP	**Involvement only in discussions** with respect to procedures involving the relevant medicinal product, i.e. no part in final deliberations and voting as appropriate as regards the medicinal product.
XI	**Cannot participate in inspections** relating to the relevant company (all medicinal products).
F	**Full involvement in activity allowed.**

Declared interest in a medical device company or notified body	Time since declared interest ended (in years)	Committee / ETF (Vice-)Chair	Committee / ETF member	Committee / ETF expert	Expert Witness	MSSG (Co-)Chair	MSSG Working party (Vice-)Chair	MSSG / MSSG Working party member	MSSG / MSSG Working party expert	Expert Witness
Employee (executive role)	Current interest	X	XC-XRpC	XC	XC	X	RC	XC-XRpC	XC	XC
	0 to 3	F	F	F	Q	F	F	F	F	Q
	> 3	F	F	F	Q	F	F	F	F	Q
Employee (lead role in development of medical device)	Current interest	X	XP-XRpP	XP	XC	X	RP	XP-XRpP	XP	XC
	0 to 3	F	F	F	Q	F	F	F	F	Q
	> 3	F	F	F	Q	F	F	F	F	Q
Employee (cross medical device/general role other than executive role)	Current interest	X	XC-XRpC	XC	XC	X	RC	XC-XRpC	XC	XC
	0 to 3	F	F	F	Q	F	F	F	F	Q
Employee (individual medical device involvement other than lead role in development of medical	Current interest	X	XP-XRpP	XP	XC	X	RP	XP-XRpP	XP	XC
	0 to 3	F	F	F	Q	F	F	F	F	Q
Consultancy to company (cross medical device/general)	Current interest	X	XC-XRpC	XC	Q	X	RC	XC-XRpC	XC	Q
	0 to 3	F	F	F	Q	F	F	F	F	Q
Consultancy to company (individual medical device)	Current interest	X	XP-XRpP	XP	Q	X	RP	XP-XRpP	XP	Q
	0 to 3	F	F	F	Q	F	F	F	F	Q
Strategic advisory role for company (cross medical device/general)	Current interest	X	XC-XRpC	XC	Q	X	RC	XC-XRpC	XC	Q
	0 to 3	F	F	F	Q	F	F	F	F	Q
Strategic advisory role for company (individual medical device)	Current interest	X	XP-XRpP	XP	Q	X	RP	XP-XRpP	XP	Q
	0 to 3	F	F	F	Q	F	F	F	F	Q
Financial interests	Current interest	X	XC-XRpC	XC	Q	X	RC	XC-XRpC	XC	Q
	0 to 3	F	F	F	Q	F	F	F	F	Q
Principal investigator	Current interest	X	XP-XRpP	XP	Q	X	RP	XP-XRpP	XP	Q
	0 to 3	F	F	F	Q	F	F	F	F	Q
Investigator	Current interest	X	DP-XRpP	DP	Q	X	RP	DP-XRpP	DP	Q
	0 to 3	F	F	F	Q	F	F	F	F	Q
Grant/other funding to organisation/institution	Current interest	RC	XRpC	F	Q	RC	RC	XRpC	F	Q
	0 to 3	F	F	F	Q	F	F	F	F	Q
Close family member	Current interest	RC	DC-XRpC	F	Q	RC	RC	DC-XRpC	F	Q
	0 to 3	F	F	F	Q	F	F	F	F	Q

Declared interest in a medical device company or notified body	Time since declared interest ended (in years)	MDSSG (Co-)Chair	MDSSG Working party (Vice-)Chair	MDSSG / MDSSG Working party member	MDSSG / MDSSG Working party expert	Expert Witness
Employee (executive role)	Current interest	X	X	X	X	X
	0 to 3	X	RC	XC-XRpC	XC	Q
	> 3	RC	RC	XC-XRpC	XC	Q
Employee (lead role in development of medical device)	Current interest	X	X	X	X	X
	0 to 3	X	RP	XP-XRpP	XP	Q
	> 3	RP	RP	XP-XRpP	XP	Q
Employee (cross medical device/general role other than executive role)	Current interest	X	X	X	X	X
	0 to 3	X	RC	XC-XRpC	XC	Q
Employee (individual medical device involvement other than lead role in development of medical	Current interest	X	X	X	X	X
	0 to 3	X	RP	XP-XRpP	XP	Q
Consultancy to company (cross medical device/general)	Current interest	X	X	X	X	Q
	0 to 3	X	RC	XC-XRpC	XC	Q
Consultancy to company (individual medical device)	Current interest	X	X	X	X	Q
	0 to 3	X	RP	XP-XRpP	XP	Q
Strategic advisory role for company (cross medical device/general)	Current interest	X	X	X	X	Q
	0 to 3	X	RC	XC-XRpC	XC	Q
Strategic advisory role for company (individual medical device)	Current interest	X	X	X	X	Q
	0 to 3	X	RP	XP-XRpP	XP	Q
Financial interests	Current interest	X	X	X	X	Q
	0 to 3	F	F	F	F	Q
Principal investigator	Current interest	X	RP	XP-XRpP	XP	Q
	0 to 3	X	RP	XP-XRpP	XP	Q
Investigator	Current interest	X	RP	DP-XRpP	DP	Q
	0 to 3	X	RP	DP-XRpP	DP	Q
Grant/other funding to organisation/institution	Current interest	RC	RC	XRpC	F	Q
	0 to 3	F	F	F	F	Q
Close family member	Current interest	RC	RC	DC-XRpC	F	Q
	0 to 3	F	F	F	F	Q

Outcome of evaluation

Please select the outcome restriction level(s) in the dropdown list below.

Outcome restriction lev	Impact of the outcome
X	**No involvement in activity allowed.**
Q	**Involvement limited** to testify and give specialist advice on a specific issue by providing information and replying to any questions only.
RC	**To be replaced as chair** for the discussions, final deliberations and voting as appropriate in relation to any medical device from the relevant company.
RP	**To be replaced as chair** for the discussions, final deliberations and voting as appropriate in relation to the relevant medical device.
XC-XRpC	• **No involvement** with respect to medical device from the relevant company, i.e. no part in discussions, final deliberations and voting as appropriate as regards medical devices from the relevant company **(XC)**. • **Cannot act as rapporteur, other leading/co-ordinating role or formally appointed peer reviewer** for medical devices from the relevant company **(XRpC)**.
XC	**No involvement** with respect to medical devices from the relevant company, i.e. no part in discussions, final deliberations and voting as appropriate as regards medical devices from the relevant company.
DC-XRpC	• **Involvement only in discussions** with respect to medical devices from the relevant company, i.e. no part in final deliberations and voting as appropriate as regards medical devices from the relevant company. • **Cannot act as rapporteur, other leading/co-ordinating role or formally appointed peer reviewer** in relation to any medical device from the relevant company.
DC	**Involvement only in discussions** with respect to medical devices from the relevant company, i.e. no part in final deliberations and voting as appropriate as regards medical devices from the relevant company.
XRpC	**Cannot act as rapporteur, other leading/co-ordinating role or formally appointed peer reviewer** in relation to any medical device from the relevant company.
XP-XRpP	• No involvement with respect to procedures involving the relevant medical device, i.e. no part in discussions, final deliberations and voting as appropriate as regards the medical device **(XP)**. • Cannot act as rapporteur, other leading/co-ordinating role or formally appointed peer reviewer for the relevant medical device **(XRpP)**.
XP	**No involvement** with respect to procedures involving the relevant medical device, i.e. no part in discussions, final deliberations and voting as appropriate as regards the medical device.
DP-XRpP	• Involvement only in discussions with respect to procedures involving the relevant medical device, i.e. no part in final deliberations and voting as appropriate as regards the medical device **(DP)**. • Cannot act as rapporteur, other leading/co-ordinating role or formally appointed peer reviewer for the relevant medical device **(XRpP)**.
DP	**Involvement only in discussions** with respect to procedures involving the relevant medical device, i.e. no part in final deliberations and voting as appropriate as regards the medical device.
F	**Full involvement in activity allowed.**

Annex 2

CAT members and alternates allowed involvement in medicinal product related matters based on declared interests in the biotechnology sector or in medical device companies where the medical device is used or to be used in combined ATMPs

Declared interest	Time since declared interest ended (in years)	Scientific committee (Vice)-Chair	Scientific committee / member
Employee (cross products/general)	Current interest	X	X
	0 to 3	X	F
Employee (individual product)	Current interest	X	X
	0 to 3	X	F
Consultancy to company (cross products/general)	Current interest	X	X
	0 to 3	X	F
Consultancy to company (individual product)	Current interest	X	X
	0 to 3	X	F
Strategic advisory role for company (cross products/general)	Current interest	X	X
	0 to 3	X	F
Strategic advisory role for company (individual product)	Current interest	X	X
	0 to 3	X	F
Financial interests	Current interest	X	X
	0 to 3	F	F
Principal investigator	Current interest	F	F
	0 to 3	F	F
Investigator	Current interest	F	F
	0 to 3	F	F
Grant/other funding to organisation/institution	Current interest	F	F
	0 to 3	F	F
Close family member	Current interest	F	F
	0 to 3	F	F

Outcome of evaluation

Outcome restriction level	Impact of the outcome
X	No involvement in activity allowed.
F	Full involvement in activity allowed.