



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

22 March 2025
EMA/MB/259494/2016, Rev. 7 - Adopted
Management Board

Decision of the European Medicines Agency (EMA)

On rules relating to Articles 11, 11a and 13 of the Staff Regulations concerning the handling of declared interests of staff members of the European Medicines Agency and candidates before recruitment

THE MANAGEMENT BOARD

HAVING REGARD TO Regulation (EC) No 726/2004 laying down European Union procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency, hereinafter “the Agency”, in particular Article 75 thereof;

HAVING REGARD TO Regulation (EU) 2022/123 on a reinforced role for the European Medicines Agency in crisis preparedness and management for medicinal products and medical devices, in particular Articles 15(8) and 32 thereof;

HAVING REGARD TO Regulation (EU) 2017/745 on medical devices and Regulation (EU) 2017/746 on in vitro diagnostic medical devices, in particular Article 107 thereof;

HAVING REGARD TO Regulation No 31 (EEC), 11 (EAEC), laying down the Staff Regulations of Officials and the Conditions of Employment of Other Servants (CEOS) of the European Economic Community and the European Atomic Energy Community, hereinafter the “Staff Regulations” and in particular to Articles 11, 11a and 13 of the Staff Regulations, and Articles 11 and 81 of the CEOS;

HAVING REGARD TO Regulation (EU, Euratom) 2024/2509 of 23 September 2024 on the financial rules applicable to the general budget of the Union, in particular Articles 36(2) and (7) and Article 61 thereof;

HAVING REGARD TO the Agency’s Internal Control Framework adopted by the Management Board, in particular Principles 1 and 3;

HAVING REGARD TO the opinion of the Agency’s Staff Committee,

WHEREAS

(1) The above referred provisions impose on the Agency’s staff members a set of obligations to guarantee the highest level of impartiality, integrity and independence in carrying out their duties;



(2) Independence and high standards of professional conduct by all those involved in the activities of the European Medicines Agency (the Agency) are key principles to ensure that the Agency acts within its legal mandate and in accordance with its statement of values while protecting its reputation;

(3) Transparency and openness are essential values to uphold public confidence in the activities that the Agency performs, notably considering the mandate vested in the Agency to protect and promote public health;

(4) It is in the interest of the Agency, and of its staff members, to identify, declare and manage promptly any private interests competing with the tasks and responsibilities vested in the Agency. Therefore, a system of declarations of interests and their evaluation should be established in order to support the adoption by the Agency of informed and proportionate mitigating measures;

(5) Considering the confidential nature of the information that the Agency handles, and the tasks that it performs regarding, in particular, the scientific assessment of medicinal products for human and veterinary use, these rules establish a transparent framework defining a priori a set of interests that cannot be held or that should be subject to restrictions.

(6) These rules introduce further simplification regarding the categorisation of staff members based on the nature of the duties that they perform, i.e., scientific or regulatory duties, or administrative or technical (non-scientific) duties, to which different mitigating measures would apply;

(7) These rules align with the revised policies on the handling of competing interests of scientific committee members and experts (Policy 0044) and of Management Board members (Policy 0058) as recently adopted by the Management Board. Notably, Policy 0044 was revised to implement recent judgements by the Court of Justice of the European Union in joined cases C-6/21 and C-16/21 P and in case C-291/22 P.

(8) Overall, these rules maintain the risk-based approach that has always defined the Agency's handling of competing interests of staff members, by means of balancing the assurances that must be given to citizens and stakeholders of an absence of competing interests with the needs of the Agency to attract talent with the appropriate competencies and expertise;

(9) The Agency shall continue implementing measures and controls in its processes and systems that prevent or mitigate the risks arising from potential competing interests, not only by prohibiting certain conflicting practices, but also by considering roles and responsibilities to reduce undue influence and reinforcing collegial decision-making.

HAS DECIDED:

Article 1 - General provisions

1. This Decision applies to the handling of interests of staff members and candidates, in accordance with Articles 11 and 11a of the Staff Regulations, where those interests could impair their independence or give rise to a conflict with the tasks and responsibilities of the Agency. This Decision also applies to the handling of interests arising from the gainful employment of spouses of staff members, in accordance with Article 13 of the Staff Regulations, where the nature of the employment could prove to be incompatible with the duties of the staff member.

2. This Decision applies to the staff members¹ employed by the Agency. It also applies to candidates to whom the Agency has issued a letter of intention regarding prospective employment.
3. For the purposes of this Decision, the following definitions shall apply:
 - 3.1. Staff members shall mean temporary agents engaged by the Agency under Article 2(f) of the Staff Regulations and the Conditions of Employment of Other Servants (CEOS), and contract agents engaged by the Agency under Article 3(a) of the CEOS.
 - 3.2. Employment by the Agency shall mean employment under the Staff Regulations and the Conditions of Employment of Other Servants (CEOS).
 - 3.3. Reporting officer or prospective reporting officer shall mean the staff member's direct superior.
 - 3.4. Unpaid leave shall mean leave without salary granted to staff members under Articles 17, 52 or 91 of the CEOS.
 - 3.5. A competing interest exists whenever an individual has an interest that may affect or be reasonably perceived to affect their impartiality and independence in relation to the duties that they perform at the Agency;
 - 3.6. A current interest shall mean an interest that exists at the time of submission of a declaration of interest. An engagement/contract with a company of a recurring nature is considered a current interest.
 - 3.7. A past interest shall mean an interest held during the period of three years, i.e., entirely during that period or only for a part of it, immediately prior to the submission of a declaration of interests and that is no longer a current interest because it is not held anymore.
 - 3.8. Scientific or regulatory duties shall mean duties and responsibilities directly related to medicinal products or medical devices.
 - 3.9. Administrative or technical (non-scientific) duties shall mean all other duties not falling within the category of scientific or regulatory duties.

Article 2 – Obligation to submit a declaration of interests

1. Staff members shall be independent, impartial, objective and loyal to the Agency and the EU. They shall not hold interests that are not allowed, as specified in the Annex to these rules, during their employment with the Agency.
2. Staff members shall submit a declaration of interests upon start of their employment at the Agency. They shall also submit an updated declaration of interests immediately following a change of contract, internal transfer or a change of circumstances, e.g. when they acquire a new interest. In addition, they shall update their declaration of interests annually.
3. A staff member who passively acquires interests during the course of their employment with the Agency, for example by way of inheritance, shall submit a declaration of interests and immediately inform their reporting officer. They shall dispose of any interests that are not allowed within six months from their acquisition and will be restricted accordingly until such interests are disposed of.

¹ [These rules apply by analogy to National Experts on Secondment, Trainees, Interims, Visiting and Collaborating Experts in accordance with ED decision EMA/20311/2025.](#)

4. Staff members returning to the Agency from unpaid leave shall submit a declaration of interests prior to their reinstatement at the Agency. They shall dispose of interests that are not allowed prior to their start date.
5. Candidates to whom the Agency has issued a letter of intention of prospective employment shall submit a declaration of interests.
6. Declarations of interests shall be submitted in paper or in electronic format.
7. Completed declarations of interests of staff members shall be made available on paper or electronically for internal consultation by all staff members upon a justified request. Declarations of interests of candidates shall only be available for internal consultation by staff members involved in the functional processing under these rules.
8. Declarations of interests of staff members are considered public documents as they relate to the proper performance of the Agency's tasks. They may be made available to external parties following a written, justified request to the Agency in compliance with the rules of Article 9 of Regulation (EU) 2018/1725. Managers' declarations of interests shall be published on the Agency's website. Declarations of interests of candidates are considered public documents only if the candidate is recruited whereupon they shall follow the same rules as for declarations of interests of staff members.

Article 3 - Evaluation of declaration of interests of candidates

1. On receipt of a candidate's declaration of interests, the prospective reporting officer shall assess it, within one week of being notified so as not to unduly delay recruitment and assign the candidate to one of the interest levels specified in the Annex, considering the definitions and criteria therein.
2. The decision concerning the interest level assigned by the prospective reporting officer, the interests that are not allowed and the restrictions necessary to address the identified competing interest shall be duly documented and communicated to the candidate. The right to be heard of the candidate shall be respected prior to the adoption of a decision.

Article 4 - Evaluation of declaration of interests of staff members

1. A staff member shall submit a completed declaration of interests within one week upon commencing employment at the Agency. The reporting officer shall assess it within one month thereafter or prior to assignment of first duties, whichever applies first, assign an interest level and where required, apply the relevant restrictions in accordance with the Annex to these rules.

The same procedure shall apply where the staff member submits an updated declaration of interests, either due to a change of circumstances or during the annual update of declarations of interests.

2. On receipt of a declaration of interests from a staff member planning to return from unpaid leave, the prospective reporting officer shall assess, within one week of being notified so as not to unduly delay return from unpaid leave, their declaration of interests and assign the staff member to an interest level, and if required, document the restrictions that will apply upon reinstatement.
3. A staff member who changes duties within the Agency is required to verify the need to update their declaration of interests. On receipt of an updated declaration of interests, the new reporting officer

shall assess and assign the staff member to an interest level and, where required, apply the relevant restrictions in accordance with the Annex to these rules.

4. The decision concerning the interest level assigned, the interests that are not allowed to be held and the restrictions necessary to address the identified competing interest shall be duly documented and communicated to the staff member. The right to be heard of staff members shall be respected prior to the adoption of a decision.

Article 5 - Principles for the identification and mitigation of interests of staff members performing scientific or regulatory duties

1. Involvement of a staff member in the Agency's activities is determined taking into account the nature of the declared interest, its timeframe and the scientific or regulatory duties to be performed.

In particular, and before assigning any responsibilities for a specific task or duty relating to medicinal products or medical devices to the concerned staff member, the reporting officer shall take into consideration the interest level assigned as specified in the Annex.

2. The reporting officer shall consider that certain interests might be incompatible with the participation of the concerned staff member in any of the Agency's activities, whereas other interests may give rise to restrictions. Some restrictions shall be applicable during a cooling-off period of three years following termination of the interest.
3. When a staff member declares a competing interest with respect to a specific task or duty relating to medicinal products or medical devices, the reporting officer shall consider assigning other colleague with no competing interests with respect to that specific task or duty.

Article 6 - Principles for the identification and mitigation of competing interests of staff members performing administrative or technical (non-scientific) duties

1. Involvement of a staff member in the Agency's activities is determined taking into account the nature of the declared interest, its timeframe and the administrative or technical (non-scientific) duties to be performed.

In particular, staff members performing administrative or technical (non-scientific) duties shall also declare interests in entities providing services to the Agency (e.g. IT, facilities, administration, catering) where relevant.

2. Before assigning any responsibilities for any specific task or responsibility, the reporting officer shall consider the interest level assigned as per the Annex as well as interests declared in other areas providing services to the Agency.
3. The reporting officer shall consider that certain interests might be incompatible with the participation of the concerned staff member in any of the Agency's activities, whereas other interests may give rise to restrictions. Some restrictions shall be applicable during a cooling-off period of three years following termination of the interest.
4. When a staff member declares a competing interest with respect to a specific task or duty, the reporting officer shall consider assigning other colleague with no competing interests to that specific task or duty.

Article 7 – Processing of personal data

1. The processing of personal data contained in the declarations of interests of staff members shall be conducted in accordance with the provisions of Regulation (EU) 2018/1725 on the protection of natural persons with regard to the processing of personal data by the Union institutions, bodies, offices and agencies and on the free movement of such data.²
2. The purpose of processing personal data of staff members is to ensure the proper management of their competing interests by the Agency. The legal basis for the processing of personal data is Articles 11, 11a and 13 of the Staff Regulations and Article 11 of the Conditions of Employment of Other Servants, and Articles 36(2) and (7) and Article 61 of Regulation (EU, Euratom) 2024/2509 of 23 September 2024 on the financial rules applicable to the general budget of the Union.
3. The declarations of interests of staff members and seconded national experts are kept for a period of 15 years from their date of departure from the Agency. The declarations of interests of trainees, interims, visiting and collaborating experts are kept for a period for 2 years from their date of departure from the Agency. The declaration of interests of candidates who take up employment at the Agency shall be kept for the same period of time except where they do not take up employment, in which case they will be destroyed within a month of the candidate notifying the Agency that they will not take up the offer of employment or the Agency withdrawing its employment offer.
4. Staff members have the right to access, rectify, erase, restrict and object to the processing of personal data contained in their declarations of interests in accordance with Regulation (EU) 2018/1725. They may contact the Agency's data controller to exercise their rights. They may lodge a complaint with the Agency's Data Protection Officer or with the European Data Protection Supervisor (EDPS).
5. A privacy statement shall be published with detailed information on the processing of personal data in the declarations of interests of staff members.

Article 8 - Entry into force

This Decision shall enter into force on 1 May 2025 and supersedes EMA document EMA/259494/2016 revision 5 of 6/02/2023.

Done at Amsterdam,

[signature on file]

Lorraine Nolan

Chair, EMA Management Board

² Regulation (EU) 2018/1725 of the European Parliament and of the Council of 23 October 2018 on the protection of natural persons with regard to the processing of personal data by the Union institutions, bodies, offices and agencies and on the free movement of such data, and repealing Regulation (EC) No 45/2001 and Decision No 1247/2002/EC (Text with EEA relevance.) OJ L 295, 21.11.2018, p. 39–98

Annex

1. Interest levels to which staff members and candidates are assigned

A staff member or a candidate will be assigned by their reporting officer or prospective reporting officer to one of the following interest levels following the assessment of their declaration of interests.

- Interest level 3: If the staff member or candidate has declared direct interests.
- Interest level 2: If the staff member or candidate has declared indirect interests.
- Interest level 1: If the staff member or candidate has not declared any direct or indirect interests.

2. Definitions

2.1. General definitions

For the purpose of these rules, the following definitions shall apply:

- **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 these rules.

- **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 these rules.

- **Research organisation:** any entity, including but not limited to public or private non-profit organisations, universities, hospitals or learned societies³, 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 unit⁴ within a research organisation that develops or manufactures medicinal products (including ATMPs under the hospital exemption⁵) or medical devices⁶ 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 these rules. Other parts of the organisation to which the unit belongs are not considered as a pharmaceutical or medical device company for the purpose of these rules.

2.2. Direct versus indirect interests

Taking into account the activities of the Agency, two categories of interests are defined: direct and indirect interests in a pharmaceutical company or a medical device company (hereafter referred to as interests in 'a company' unless otherwise specified) or in a research organisation. These interests are further defined below for the purpose of these rules.

2.2.1. Direct interests

- **Employment with a company:** any form of occupation, part-time or full-time, paid or unpaid, in a pharmaceutical or medical device company.
- **Consultancy or strategic advisory role to a company:** any activity where the concerned staff member has provided 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.
- **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 does not need to be declared provided that they are diversified (i.e. not exclusively based on the pharmaceutical or medical device sector) 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 concerned staff member in a personal capacity.
- Intellectual property rights including patents, trademarks, know-how and/or copyrights relating to a medicinal product or a medical devices or uses of such medicinal products or medical devices owned by the individual or of which the individual is directly a beneficiary or an applicant.

³ 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.

⁴ The term unit may also refer to a section, department or entity, as defined within the specific research organisation.

⁵ 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 these rules..

⁶ 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 these rules.

- *Payment for or reimbursement of reasonable expenses directly related to a conference/seminar attendance (i.e. accommodation, meals and travel costs) are not considered financial interests unless these go beyond reimbursement of reasonable expenses.*
- **Involvement or affiliation in a research organisation.** This includes employment or collaboration with a research organisation.

This excludes lectures or teaching activities undertaken in the context of outside activities that may be requested by staff members under the relevant implementing provisions.⁷

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 an organisation/institution:** any funding received from a pharmaceutical or medical device company by an organisation/institution to which the individual belongs to, or for which he performs any kind of activity, and which is used specifically to support any activity of the individual whether or not it is related to research work.
- **Close family members interests:** direct interests in a company held by first-line members of the family of the staff member (i.e. a spouse or a partner, children and parents). Partner is a natural person with whom the staff member or candidate are registered as having a stable non-marital partner legally recognised by a Member State or any competent authority of a Member State, acknowledging their status as non-marital partners.

3. Determining involvement in Agency activities in case of interests declared in a company or in a research organisation

3.1. Interests in pharmaceutical or medical device companies

Current interests

With the exception of close family member interests, staff members are not allowed to have current interests in a company.

Restrictions will be applied to staff members involved in scientific or regulatory duties who declare a current close family member interest.

Membership of a patient organisation is not an interest to be declared. However, involvement of a staff member in EMA activities as a patient or a patient representative is not permitted.

Past interests

Staff members involved in scientific or regulatory duties are subject to restrictions during a 3-year cooling-off period after the interest has ended in case of past employment or consultancy/strategic advisory role in a pharmaceutical company and (principal) investigator role for a pharmaceutical

⁷ Decision of the Management Board of 4 October 2018 on the application by analogy of Commission decision on outside activities and assignments and occupational activities after leaving the service of 29 June 2018.

company. During this cooling-off period, restrictions apply to the performance of tasks or duties relating either to the medicinal product(s) or pharmaceutical company concerned, as applicable.

No restrictions are applied to staff members involved in administrative or technical (non-scientific) duties.

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

Staff members should declare previous positions (either a managerial role or other influential roles) in a governing body (irrespective if such position is paid or not) of a professional organisation with an interest in the field of pharmaceuticals or medical devices, held within the past 3 years. In exceptional cases such interests may result in restrictions, to be decided on a case-by-case basis.

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

3.2. Interests in research organisations

Current interests

Current involvement or affiliation (through employment or participation in a strategic advisory or supervisory board) in a research organisation is incompatible with employment at the Agency.

Past interests

Staff members involved in scientific or regulatory duties are subject to restrictions in case of past involvement or affiliation in a research organisation during a 3-year cooling-off period after the interest has ended. During this cooling-off period, restrictions apply to the performance of tasks or duties relating to applications and procedures with the research organisation concerned.

No restrictions are applied to staff members involved in administrative or technical (non-scientific) duties.

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

4. Determining involvement in Agency activities in relation to staff members with administrative or technical duties in case of declared interests in areas possibly providing services to the Agency (other than pharmaceutical, or medical device companies)

The definitions in section 2 shall be interpreted as referring also to non-pharmaceutical or medical device companies, where applicable.

Staff members with administrative or technical (non-scientific) duties are also required to declare interests from companies or entities in areas possibly providing services to the Agency (e.g. in the areas of IT, facilities, administration, catering) if their activities relate directly to those services. On the basis of the declared interests, a risk-based approach shall be applied and may result in mitigating measures: input to the Agency's activities as well as the degree of influence that may be exerted on the final administrative or technical proposal, opinion or decision, are considered.

Current interests

Staff members are not allowed to have a current employment, consultancy/strategic advisory role or financial interests in an entity related to their duties.

In case of close family members' current direct interests declared in entities in the same working area, the staff member concerned cannot be involved in decision-making with respect to services provided by the declared entity.

Past interests

Restrictions are applied to staff members' involvement in decision-making with respect to services provided by the declared entity in case of past employment or consultancy/strategic advisory role during a 3-year cooling-off period after the interest has ended. In particular, reporting officers may apply restrictions taking into consideration any delegation as authorising officer.

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

For further details on the handling of current and past interests in other entities possibly providing services to the Agency, please refer to Appendix [4](#).

5. Achieving an efficient and transparent process

Checks for competing interests of staff members should take place at least yearly, at the same time of the annual update of the declarations of interests. This will streamline the process while maintaining the robustness of the system and making it more efficient to operate. A check is also required when new staff members are recruited, staff members change duties within the Agency, when staff members return to the Agency from unpaid leave or whenever a staff member updates their declaration.

Reporting officers are responsible for assigning interest levels to staff members (as described in Article 1 of the Annex) and ensuring that there are no competing interests with respect to the declared medicinal product(s), company(ies) or research organisation(s) when assigning responsibilities for tasks or duties.

Reporting officers are immediately informed of any changes to the staff member's declaration of interests. In such cases, they shall ensure that no tasks or duties are allocated to staff members with competing interests.

Declared interests that are not listed in the Appendixes shall be taken into consideration and assessed on a case-by-case basis.

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

Declared interest in a pharmaceutical company	Time since declared interest ended	Staff members with scientific or regulatory duties	Staff members with administrative or technical (non-scientific) duties
Employee	Current	X	X
	Past (0-3 yrs)	XC	F
Consultancy/strategic advisory role	Current	X	X
	Past (0-3 yrs)	XC	F
Financial interests	Current	X	X
	Past (0-3 yrs)	F	F
(Principal) investigator	Current	X	X
	Past (0-3 yrs)	XP	F
Grant/other funding to organisation/institution	Current	X	X
	Past (0-3 yrs)	F	F
Close family member	Current	XC	F
	Past (0-3 yrs)	F	F

X= No involvement in the activity allowed.

XC = No involvement in relation to any medicinal product from the declared company.

XP = No involvement in relation to the declared medicinal product.

F = Full involvement.

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

Declared interest in a medical device company	Time since declared interest ended	Staff members with scientific or regulatory duties	Staff members with administrative or technical (non-scientific) duties
Employee	Current	X	X
	Past (0-3 yrs)	F	F
Consultancy/strategic advisory role	Current	X	X
	Past (0-3 yrs)	F	F
Financial interests	Current	X	X
	Past (0-3 yrs)	F	F
(Principal) investigator	Current	X	X
	Past (0-3 yrs)	F	F
Grant/other funding to organisation/institution	Current	X	X
	Past (0-3 yrs)	F	F
Close family member	Current	XC	F
	Past (0-3 yrs)	F	F

X= No involvement in the activity allowed.

XC = No involvement in relation to any medical device from the declared company.

F = Full involvement.

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

Declared interest in a research organisation	Time since declared interest ended	Staff members with scientific or regulatory duties	Staff members with administrative or technical (non-scientific) duties
Involvement or affiliation in a research organisation	Current ⁸	X	X
	Past (0-3 yrs)	XRo	F

X= No involvement in the activity allowed.

XRo = No involvement in relation to any application or procedure from the declared research organisation.

F = Full involvement.

⁸ This excludes lectures or teaching activities undertaken in the context of outside activities, which may be requested by staff members under the relevant implementing provisions

Appendix 4 – Handling of current and past interests in areas possibly providing services to the Agency (e.g. IT, facilities, administration, catering)

Declared interest in entities from areas possibly providing services to the Agency	Time since declared interest ended	Staff members with scientific or regulatory duties	Staff members with administrative or technical (non-scientific) duties
Employment, consultancy/strategic advisory role	Current	n/a	X
	Past (0-3 yrs)	n/a	XE
Financial interests	Current	n/a	X
	Past (0-3 yrs)	n/a	F
Close family member interest	Current	n/a	XE
	Past (0-3 yrs)	n/a	F

X= No involvement in the activity allowed.

XE = No involvement in relation to decision-making with respect to services provided by the declared entity to the Agency.

F = Full involvement.