



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

01 March 2023
EMA/259494/2016, Rev. 5
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”,

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,

HAVING REGARD TO Regulation (EU) 2017/745 on medical devices and Regulation (EU) 2017/746 on in vitro diagnostic medical devices,

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

HAVING REGARD TO the Code of Conduct of the Agency adopted by its Management Board,

HAVING REGARD TO the Agency’s Internal Control Framework adopted by the Management Board,

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

WHEREAS Article 75 of Regulation (EC) No 726/2004 requires that staff of the Agency is subject to the rules and regulations applicable to officials and other staff of the European Union;

WHEREAS the provisions of Article 11 of the Staff Regulations that apply by analogy to the Agency require it, before recruiting a staff member, to examine any personal interest such as to impair his independence or any other conflict of interest;

WHEREAS the provisions of Article 11 of the Staff Regulations that apply by analogy to the Agency also apply by analogy to staff members returning from leave on personal grounds;

WHEREAS the provisions of Article 11a of the Staff Regulations that apply by analogy to the Agency require that members of staff shall not, in the performance of their duties, deal with a matter in which,

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



directly or indirectly, they have any personal interest such as to impair their independence, and, in particular, family and financial interests;

WHEREAS the provisions of Article 11a of the Staff Regulations that apply by analogy to the Agency require that any member of staff of the Agency to whom it falls, in the performance of his duties, to deal with a matter referred to above shall immediately inform the Executive Director, as the Contracting Authority, who shall take any appropriate measure, and may in particular relieve the member of staff from responsibility in this matter;

WHEREAS the provisions of Article 11a of the Staff Regulations that apply by analogy to the Agency require that a member of staff of the Agency may neither keep nor acquire, directly or indirectly, in undertakings which are subject to the authority of the Agency or which have dealings with the Agency, any interest of such kind or magnitude as might impair his independence in the performance of his duties;

WHEREAS Article 13 of the Staff Regulations which applies by analogy to the Agency requires that if the spouse of a member of staff of the Agency is in gainful employment, the member of staff shall inform the Executive Director, and should the nature of the employment prove to be incompatible with that of the member of staff and if the member of staff is unable to give an undertaking that it will cease within a specified period, the Executive Director shall, after consulting the Joint Committee, decide whether the member of staff shall continue in his post or be transferred to another post;

WHEREAS Article 63(2) of Regulation (EC) No 726/2004 requires that members of the Management Board, members of the committees, rapporteurs and experts shall not have financial or other interests in the pharmaceutical industry which could affect their impartiality, that they shall undertake to act in the public interest and in an independent manner, that they shall make an annual declaration of their financial interests, and that all indirect interests which could relate to this industry shall be entered in a register held by the Agency which is accessible to the public;

WHEREAS Article 63(2) of Regulation (EC) No 726/2004 requires that the Code of Conduct provides for the implementation of this Article;

WHEREAS the provisions of Article 63(2) of Regulation (EC) No 726/2004 have been implemented in the Code of Conduct, which apply by analogy to all staff of the Agency;

WHEREAS the Code of Conduct lays down guidance on competing interests wherein it provides definitions of interests and the form, manner and frequency for making a declaration of interest;

WHEREAS principle 1 of the Agency's Internal Control Framework requires that management and staff are aware of and share appropriate ethical and organisational values and uphold these through their own behaviour and decision-making;

WHEREAS principle 3 of the Agency's Internal Control Framework- requires that the Agency's operational structure supports effective decision-making by suitable delegation of powers, and risks associated with sensitive functions are managed through mitigating controls and ultimately staff mobility;

WHEREAS a risk-based approach should be taken in balancing the assurances that must be given to citizens and stakeholders of an absence of competing interests with the needs of the Agency for staff members having the appropriate competencies and expertise;

WHEREAS the Agency has implemented measures and controls in its processes and systems that prevent or mitigate the risk arising from potential competing interests, including prohibiting certain conflicting practices, separating roles and responsibilities to reduce undue influence, and reinforcing collegial decision-making;

HAS DECIDED:

Article 1: General provisions

1. These rules shall apply to all staff members¹ of the Agency.
2. Articles 1, 2, 3 and 9 and the Annex of these rules shall apply to staff members and candidates prior to recruitment.
3. For the purposes of these rules any reference to:
 - Candidate shall mean a person to whom the Agency has issued a letter of intention regarding prospective employment.
 - Employment by the Agency shall mean employment under the Staff Regulations and the Conditions of Employment of Other Servants (CEOS).
 - Staff members of the Agency shall mean temporary agents and contract staff.
 - Reporting Officer shall mean the staff member charged with preparation of the appraisal report of the staff member.
 - Unpaid leave shall mean leave without salary granted to staff members under Articles 17, 52 or 91 of the CEOS.
4. The definitions listed in section 2 of the Annex to these rules apply to these rules and to the annex.
5. The definitions listed in this Article do not address all possible scenarios. The Agency shall evaluate on a case-by-case basis any other scenarios not covered by these definitions.
6. Any reference in these rules to a person of the male sex shall be deemed also to constitute a reference to a person of the female sex, and vice-versa, unless the context clearly indicates otherwise.
7. The Annex to these rules may be amended by the Management Board on a proposal of the Executive Director.

Article 2: Declaration of interests

1. A candidate shall abide by these rules in completing and submitting his declaration of interests.
2. A staff member, including one returning to the Agency from unpaid leave, shall complete and submit his declaration of interests.
3. The form and means for completing a declaration of interests may be paper or electronic.
4. Completed declarations of interests of staff members shall be made available on paper or electronically in a database for internal consultation by all staff members. Declarations of interests of candidates are only available for consultation by the EMA staff members involved in the functional processing under these rules and they shall treat such information with due confidentiality.
5. Staff member declarations of interests shall be retained on paper or electronically by the Agency for a period of 15 years from the date of the staff member leaving the Agency. A declaration of interests by a candidate who takes up employment at the Agency is retained on the same basis as for staff members. A declaration of interests by a candidate who does not take up employment at the Agency is destroyed within a month of the candidate notifying the Agency that he will not take up the offer of employment or of the Agency not proceeding with the employment offer.

¹ These rules apply by analogy to National Experts on Secondment, Trainees, Interims, and Visiting and Collaborating Experts of the European Medicines Agency.

6. The completed staff member declarations of interests are public information and shall be made available on request to the general public. Managers' declarations are published on the Agency's website. Candidate declarations are public information only if the candidate is recruited whereupon they shall be made available on request to the general public.
7. The processing of personal data for the purpose of the assessment of the declared interests 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.

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, within 1 week of being notified and so as not to unduly delay recruitment, the declaration of interests completed by the candidate and, assign him to one of the interest levels specified in the Annex to these rules, taking into consideration the definitions and criteria specified in the Annex.
2. The interest level assigned by the prospective reporting officer, the nature of any declared interests that are not allowed under these rules and restrictions put in place by the Agency or action required of the candidate to dispose of such interests prior to start of employment shall constitute the duly reasoned opinion of the Contracting Authority on the candidate's declared interests. This opinion shall be duly communicated by the Contracting Authority to the candidate prior to recruitment.

Article 4: Evaluation of declaration of interests of staff members

1. On initial employment of a staff member, the reporting officer shall reassess, within 1 month or prior to assignment of first duties, whichever applies first, an updated declaration of interests completed by the staff member and, in the event of any changes, reassign the staff member to a different interest level.
2. On completion of a spontaneous or annual declaration of interests by a staff member the reporting officer shall reassess the declared interests and, in the event of any changes, reassign the staff member to a different interest level.
3. On receipt of an updated declaration of interests from a staff member planning to return from unpaid leave, the prospective reporting officer shall assess, within 1 week of being notified and so as not to unduly delay return from unpaid leave, the declaration of interests completed by the staff member and, in the event of any changes, reassign the staff member to a different interest level.
4. The interest level assigned to the staff member planning to return from unpaid leave, the nature of any declared interests that are not allowed under these rules and restrictions put in place by the Agency and action to be taken by the staff member to dispose of such interests prior to return to service shall constitute the duly reasoned opinion of the Contracting Authority on the staff member's declared interests. This opinion shall be duly communicated by the Contracting Authority to the staff member, prior to return to service.

Article 5: Principles for identification and mitigation of competing interests for scientific or regulatory duties

1. When a staff member performs scientific, regulatory or support duties directly related to medicinal products or medical devices, the reporting officer shall take into consideration the criteria for the identification of risks and the allowed interests specified in the Annex to these rules prior to assigning responsibilities relating to a specific medicinal product or medical device to that staff member.

2. Where the declared interests, if any, of the staff member do not present a potential competing interest with respect to the specific medicinal product or medical device, the reporting officer may decide to assign responsibilities for that medicinal product or medical device to the staff member.
3. Where the declared interests, if any, of the staff member present a potential competing interest with respect to the specific medicinal product or medical device, the reporting officer shall consider assigning other staff members with a lower interest level or no risk.
4. Where a staff member has been reassigned to a different interest level as required by Article 4(2), the reporting officer shall apply the provisions of paragraphs 1, 2 and 3 of this Article.
5. Detailed instructions for determining assignment of responsibilities for medicinal products or medical devices may be elaborated and documented, where necessary, to ensure consistent application of these rules. A risk-based approach may be adopted in order to ensure checks for potential competing interests are focused on staff members with higher interest levels.
6. The reporting officer shall document the decision of the check of competing interests and the reason for assigning a staff member's responsibilities related to a specific medicinal product or medical device, where applicable.
7. Documented records shall be filed and retained for a period of 15 years from the date of the staff member leaving the Agency.

Article 6: Principles for identification and mitigation of competing interests for administrative or technical (non-scientific) duties

1. When a staff member performs administrative or technical (non-scientific) duties, the reporting officer shall take into consideration the criteria for the identification of risks and the allowed interests specified in the Annex to these rules prior to assigning responsibilities for a specific procedure or duty to that staff member.
2. Where the declared interests, if any, of the staff member do not present a potential competing interest with respect to the procedure or duty, the reporting officer may decide to assign responsibilities for that specific procedure or duty to the staff member.
3. Where the declared interests, if any, of the staff member present a potential competing interest with respect to the specific procedure or duty, the reporting officer shall consider assigning other staff members with a lower interest level or no risk.
4. Where a staff member has been reassigned to a different interest level as required by Article 4(2), the reporting officer shall apply the provisions of paragraphs 1, 2 and 3 of this Article.
5. Detailed instructions for determining participation in specific procedures or duties may be elaborated and documented, where necessary, to ensure consistent application of these rules. A risk-based approach may be adopted in order to ensure checks for potential competing interests are focused on staff members with higher interest levels.
6. The reporting officer shall document the decision of the check of competing interests and the reason for assigning a staff member to the specific procedure or duty, where applicable.
7. Documented records shall be filed and retained for a period of 15 years from the date of the staff member leaving the Agency.

Article 7: Allowed interests

1. The allowed interests specified in the Annex to these rules are based on the principles for identification and mitigation of competing interests, specified in the aforementioned Annex, in relation to a staff member's specific medicinal product or medical device-related scientific or regulatory duties or to a staff member's non-medicinal product or non-medical device-related administrative or technical duties that are directly related to a specific procedure or duty.

Article 8: Other provisions

1. A staff member shall not hold direct interests that are not allowed, as specified in the Annex to these rules during his employment with the Agency. Consequently, such not allowed direct interests shall be disposed of prior to the start of employment with the Agency or the return from unpaid leave.
2. A staff member who passively acquires during the course of his employment with the Agency direct interests that are not allowed, for example by way of an inheritance, shall complete a declaration of interests in line with Article 2 and immediately inform his reporting officer. The staff member shall dispose of the direct interests that are not allowed within six months from acquisition of title to such interests. The staff member will be restricted accordingly until such interests are disposed of.
3. A staff member who changes his duties within the Agency is required to verify the need to update his declaration of interests. On receipt of an updated declaration of interests, the new reporting officer shall assess and, if necessary, reassign the staff member to a different interest level.

Article 9: Entry into force

These rules relating to Articles 11, 11a and 13 of the Staff Regulations shall enter into force on the date of their adoption. This version supersedes EMA document EMA/259494/2016 revision 4 of 1/10/2020.

Done at Amsterdam, 1ST March 2023.

[Signature on file]

Lorraine Nolan

Chair, EMA Management Board

Annex

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

A staff member or a candidate will be assigned by his reporting officer or prospective reporting officer to one of the following interest levels on the basis of the outcome of the assessment of his declared 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

Direct versus indirect interests

Taking into account the activities of the Agency, two categories of interests are possible, i.e. direct and indirect interests.

- **Direct interests in a pharmaceutical or medical device company are:**
 - Employment
 - Consultancy
 - Strategic advisory role
 - Financial interests
- **Indirect interests in a pharmaceutical or medical device company are:**
 - Principal investigator
 - Investigator
 - Grant or other funding to an organisation/institution where the staff member was/is involved
 - Close family member's direct interest

Direct interests

- **Employment with a pharmaceutical or medical device company** shall mean: any form of occupation, part-time or full-time, paid or unpaid, in a pharmaceutical or medical device company.
- **Consultancy to a pharmaceutical or medical device company** shall mean: any activity where the concerned staff member has provided advice (including training on a one to one basis) to a pharmaceutical or medical device company regardless of contractual arrangements or any form of remuneration.
- **Strategic advisory role for a pharmaceutical or medical device company** shall mean: any activity where the staff member has participated (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 or medical device company, 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 or medical device company) fall outside the scope of this definition. Individuals participating in these fora are considered in the same way as principal investigators (for definition of principal investigator see below).
- Involvement of an individual in research work for a pharmaceutical or medical device company is considered an indirect interest.
- **Financial interests** shall mean any economic stake in a pharmaceutical or medical device company including:
 - Holding of stocks and shares, stock options, stock warrants, equities, bonds, ownership or partnership interest in the capital of such pharmaceutical or medical device 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, salaries, grant or other funding (including rents, sponsorships and fellowships) paid by a pharmaceutical or medical device company to the staff member 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 financial interests.
 - Intellectual property rights including patents, trademarks, know-how and/or copyrights relating to a medicinal product or a medical device owned by the individual or of which the individual is directly a beneficiary.

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 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 report².
- **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 who 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.

² This definition does not include a national coordinating investigator in a multinational trial.

- **Grant or other funding to an organisation/institution** shall mean: 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 to support any activity of the individual whether or not it is related to research work.
- **Close family members** (interests) shall mean (interests held by): first-line members of the family of the staff member (i.e. a spouse or a partner, children and parents). Partner shall mean: a natural person with whom the staff member or candidate before recruitment 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.

Other definitions

- **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 decision, 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 contract basis.

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

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

Independent researchers and research organisations including universities, hospitals and learned societies³, are excluded from the scope of the present definition. However, any unit, department, section or entity within such organisation, that manufactures 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 Decision. 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 implementing provisions, 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.

³ 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.

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 implementing provisions.

Independent researchers and research organisations including universities, hospitals and learned societies 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 these implementing provisions. 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.

3. Determining involvement in Agency activities in case of interests declared in a pharmaceutical or medical device company

In order to determine involvement of a staff member with either a scientific/regulatory or an administrative/technical duty in the Agency's activities on the basis of the declared interests in a pharmaceutical or medical device company, a risk-based approach shall be applied.

General principles:

- Involvement in the Agency's activities is determined taking into account:
 - the nature of the declared interest,
 - the timeframe during which such interest occurred,
 - the staff member's specific role and responsibilities (this includes the following aspects: the nature of the staff member's duties, the nature of the staff member's input to the Agency's activities and the degree of influence that may be exerted on the final scientific or regulatory opinion or decision).
- In order to achieve the best possible balance between managing competing interests of the staff member versus the specific role and responsibilities of the staff member, the following methodology is applied:
 - First the nature of the declared interest will be looked at, before determining the length of time any restrictions will apply.
 - Secondly, the nature of the staff member's duties, the nature of the staff member's input to the Agency's activities and the degree of influence.
- 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, for a period of 5 years. However, staff members may always declare any interests beyond those periods limited in time (i.e. current, or within the past 3

or 5 years). They may also always restrict on their own initiative their involvement in the Agency's activities as a result of this declaration of an interest.

- Current direct and indirect interests in a pharmaceutical company (i.e. current employment with a pharmaceutical company, current financial interests in a pharmaceutical company, current consultancy to a pharmaceutical company, current strategic advisory role for a pharmaceutical company, current principal investigator, current investigator, current grant or funding to an organisation/institution) are incompatible with employment, secondment, expert visits/collaborations, traineeship or provision of services by temporary workers at the Agency.
- For direct interests in a pharmaceutical company such as employment, consultancy and strategic advisory role, the interest is considered over following a 3-year cooling-off period but involvement during the cooling-off period is restricted for the staff member concerned, with regards to any product(s) from the declared company or any activity(ies) involving the declared company. However, a leading role during previous employment with a pharmaceutical company is only considered over following a 5-year cooling-off period with restricted involvement for scientific and regulatory managers, on two possible levels:
 - Either an executive role within a pharmaceutical company, resulting in non-involvement for any medicinal product for which that pharmaceutical company is the applicant or marketing authorisation holder for a period of five years.
 - Or a lead role in the development of a medicinal product, resulting in non-involvement for that medicinal product for a period of five years.
- For indirect interests in a pharmaceutical company such as principal investigator and investigator, the interest is considered over following a 3-year cooling-off period but involvement during the cooling-off period is restricted for the staff member concerned, with regards to the declared product or any activity involving the declared product.
- Current direct and indirect interests in a medical device company (i.e. current employment with a medical device company, current consultancy to a medical device company, current strategic advisory role for a medical device company, current principal investigator, current investigator, current grant or funding to an organisation/institution) are incompatible with employment, secondment, expert visits/collaborations, traineeship or provision of services by temporary workers at the Agency.
- Current financial interests in a medical device company are not incompatible with employment, secondment, expert visits/collaborations, traineeship or provision of services by temporary workers at the Agency, however, this may result in restrictions applied for the individual concerned, with regards to involvement in procedures concerning medical devices linked to the declared medical device company.
- Previous employment with a medical device company, previous consultancy to a medical device company, previous strategic advisory role for a medical device company, previous principal investigator or investigator within the past 3 years (or in some cases within the past 5 years) needs to be declared, however, no restrictions will be applied with regards to the declared medical device company.
- For certain direct and indirect interests in a pharmaceutical or medical device company (i.e. financial interests in a pharmaceutical or a medical device company, grant or other funding to an organisation/institution) 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. Therefore, previous financial interests in a pharmaceutical or medical device company and previous grant or

other funding to an organisation/institution do not need to be declared. However, past intellectual property rights related to medicinal products or medical devices or uses of such medicinal products or medical devices, including patent ownership and patent applications need to be declared covering the period up to five years preceding the start of employment at the Agency, for transparency reasons.

- Close family members are not prohibited from holding direct interests in a pharmaceutical or medical device company. However, current direct interests related to close family members (i.e., current employment, current consultancy, current strategic advisory role, and current financial interests) need to be declared and will result in restrictions for the staff member concerned, with regards to any medicinal product(s) or medical device(s) from the declared company(ies) or any activity(ies) involving the declared company(ies). It is also assumed that the declared interest is considered over when such interest is no longer present, resulting in full involvement in the Agency's activities. Therefore, previous direct interests related to close family members do not need to be declared.
- 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.
- Staff members are required to 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, other than a pharmaceutical or medical device company, held within the past 3 years. Such interests should not in principle result in mitigating measures but should always be declared for transparency reasons. However, in exceptional cases such interests may result in restrictions, to be decided on a case-by-case basis.
- Furthermore, if a staff member intends to engage in an occupational activity (whether gainful or not, such as employment) following departure from the Agency, the individual shall immediately inform Administration and his reporting officer in accordance with Article 16 of the Staff Regulations. This requirement to inform the Agency of an intention to engage in an occupational activity applies for a period of two years after leaving the service. This should be done in advance of accepting any employment offer. If the occupational activity is related to the work carried out during the last three years of service and could lead to a conflict with the legitimate interests of the Agency, the Agency after consulting the Joint Committee, may either forbid the staff member from undertaking it or give its approval subject to any conditions it sees fit. The Agency shall inform the staff member within 30 working days of receiving the information. Further information can be found on EMA related documents⁴.

As soon as the staff member informs his reporting officer of his intention to take up employment following departure from the Agency, the reporting officer shall immediately reassess the new declared interests and may reassign the staff member to a different interest level. The reporting officer subsequently applies any necessary restrictions (similar rules apply for future employment as those for employment within the past 3 years) to the staff member on his existing activities and for the period until he leaves the Agency.

⁴ [Joint Committee General Opinion n. 13/2013 of 17/10/2013](#); [Joint Committee General Opinion No 27/2020 on criteria and restrictions for Senior Staff](#); [Executive Decision on transparency for senior staff](#); [Best practice guide for staff leaving the Agency](#).

The table below summarises the restrictions that are applied to staff members for declared interests in a pharmaceutical company based on their roles and responsibilities.

Declared interests in a pharmaceutical company		Involvement of staff members in scientific or regulatory duties			Involvement of staff members in administrative or technical (non-scientific) duties	
Declared interest	Time since declared interest ended (in years)	A	B	C	Y	Z
Employee (executive role or lead role in development of medicinal product)	Current interest	X	X	X	X	X
	0 to 3	XC/XP	XC	F	F	F
	3 to 5	XC/XP	F	F	F	F
Employee (cross company role other than executive role, or medicinal product involvement other than lead role in development of medicinal product)	Current interest	X	X	X	X	X
	0 to 3	XC	XC	F	F	F
Consultancy to company	Current interest	X	X	X	X	X
	0 to 3	XC	XC	F	F	F
Strategic advisory role for company	Current interest	X	X	X	X	X
	0 to 3	XC	XC	F	F	F
Financial Interests	Current interest	X	X	X	X	X
	0 to 3	F	F	F	F	F
Principal investigator	Current interest	X	X	X	X	X
	0 to 3	XP	XP	F	F	F
Investigator	Current interest	X	X	X	X	X
	0 to 3	XP	XP	F	F	F
Grant/other funding to organisation/institution	Current interest	X	X	X	X	X
	0 to 3	F	F	F	F	F
Close family member	Current interest	XC	XC	F	F	F
	0 to 3	F	F	F	F	F

A: Executive Director; Deputy Executive Director; Chief Medical Officer; scientific and regulatory managers

B: Scientific, regulatory, and other administrators involved in product-specific activities

C: Scientific/regulatory assistants; scientific, regulatory and other administrators involved in non product-specific activities

Y: Executive Director; Deputy Executive Director; non-scientific/regulatory managers and administrators

Z: Non-scientific/regulatory assistants

Outcome restriction level	Impact of the outcome
X	No involvement in activity allowed.
XC	No involvement with respect to medicinal products from the relevant company.
XC/XP	No involvement with respect to either medicinal products from the relevant company (XC) or in procedures involving the relevant medicinal product (XP).
XP	No involvement with respect to procedures involving the relevant medicinal product.
F	Full involvement in activity allowed.

The table below summarises the restrictions that are applied to staff members for declared interests in a medical device company based on their roles and responsibilities.

Declared interest in a medical device company		Involvement of staff members in scientific or regulatory duties			Involvement of staff members in administrative or technical (non-scientific) duties	
	Time since declared interest ended (in years)	A	B	C	Y	Z
Employee (executive role or lead role in development of medical device)	Current interest	X	X	X	X	X
	0 to 3	F	F	F	F	F
	3 to 5	F	F	F	F	F
Employee (cross company role other than executive role, or medical device involvement other than lead role in development of medical device)	Current interest	X	X	X	X	X
	0 to 3	F	F	F	F	F
Consultancy to company	Current interest	X	X	X	X	X
	0 to 3	F	F	F	F	F
Strategic advisory role for company	Current interest	X	X	X	X	X
	0 to 3	F	F	F	F	F
Financial interests	Current interest	XC	XC	F	F	F
	0 to 3	F	F	F	F	F
Principal investigator	Current interest	X	X	X	X	X
	0 to 3	F	F	F	F	F
Investigator	Current interest	X	X	X	X	X
	0 to 3	F	F	F	F	F
Grant/other funding to organisation/institution	Current interest	X	X	X	X	X
	0 to 3	F	F	F	F	F
Close family member	Current interest	XC	XC	F	F	F
	0 to 3	F	F	F	F	F

A: Executive Director; Deputy Executive Director; Chief Medical Officer; scientific and regulatory managers
B: Scientific, regulatory, and other administrators involved in medical devices specific activities
C: Scientific/regulatory assistants; scientific, regulatory and other administrators involved in non-medical devices specific activities
Y: Executive Director; Deputy Executive Director; Chief Medical Officer; non-scientific/regulatory managers and administrators
Z: Non-scientific/regulatory assistants

Outcome restriction level	Impact of the outcome
X	No involvement in activity allowed.
XC	No involvement with respect to medical devices from the relevant company.
XC/XP	No involvement with respect to either medical devices from the relevant company (XC) or in procedures involving the relevant medical device (XP).
XP	No involvement with respect to procedures involving the relevant medical device.
F	Full involvement in activity allowed.

4. Determining involvement in Agency activities in relation to staff members with administrative or technical duties in case of declared personal interests other than interests in a pharmaceutical or medical device company

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 duties are required to declare personal interests in areas possibly providing services to the Agency (e.g. in the areas of IT, facilities, administration, catering) if they work in that area. Such interests will result in mitigating measures proportionate to the nature of the interest(s) declared.

In order to determine involvement of a staff member with an administrative/technical duty in the Agency's activities, on the basis of the declared interests, other than interests in a pharmaceutical or medical device company, in areas possibly providing services to the Agency, a risk-based approach shall be applied.

General principles:

- Involvement in the Agency activities is determined by taking into account:
 - the nature of the declared interests,
 - the timeframe during which such interest occurred,
 - the staff member's specific role and responsibilities (this includes the following aspects: the nature of the staff member's duties, the nature of the staff member's input to the Agency's activities and the degree of influence that may be exerted on the final administrative or technical proposal, opinion or decision).
- In order to achieve the best possible balance between managing competing interests of the staff member versus the specific role and responsibilities of the staff member, the following methodology is applied:
 - Firstly the nature of the declared interest will be looked at, before determining the length of time any restrictions will apply.
 - Secondly, the nature of the staff member's duties, the nature of the staff member's input to the Agency's activities and the degree of influence.
- The timeframe to be considered depending on the declared direct or indirect interest is either current or within the past 3 years. However, staff members may always declare any interests beyond those periods limited in time. They may also always restrict on their own initiative their involvement in the Agency's activities as a result of such declaration.
- Current direct interests (i.e. current employment, current financial interests, current consultancy and current strategic advisory role) in a company related to the staff members' duties is incompatible with employment, secondment, expert visits/collaborations, traineeship or provisions of services by temporary workers at the Agency.
- For the following direct interests in a company related to the staff members' duties: employment, consultancy and strategic advisory role, the interest is considered over following a 3-year cooling-off period but involvement during the cooling-off period is restricted for the staff member concerned, with regards to any activities involving the declared company.

- For financial interests in a company related to the staff members' duties 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. Therefore, previous financial interests in a company relating to the staff members' duties do not need to be declared.
- Close family members are not prohibited from holding direct interests in areas other than a pharmaceutical or medical device company, possibly providing services to the Agency. However, close family members' current direct interests in the same working area as the staff member need to be declared and will result in restrictions for the staff member concerned, with regards to activities with the declared company. It is also assumed that the declared interest is considered over when such interest is no longer present, resulting in full involvement in the Agency's activities. Therefore, previous interests related to close family members do not need to be declared.
- Furthermore, if a staff member intends to engage in an occupational activity (whether gainful or not, such as employment) following departure of the Agency, the individual shall immediately inform Administration and his reporting officer in accordance with Article 16 of the Staff Regulations. This requirement to inform the Agency of an intention to engage in an occupational activity applies for a period of two years after leaving the service. This should be done in advance of accepting any employment offer. If the occupational activity is related to the work carried out during the last three years of service and could lead to a conflict with the legitimate interests of the Agency, the Agency after consulting the Joint Committee, may either forbid the staff member from undertaking it or give its approval subject to any conditions it sees fit. The Agency shall inform the staff member within 30 working days of receiving the information. Further information can be found on EMA's related documents⁵.

As soon as the staff member informs his reporting officer of his intention to take up employment following departure from the Agency, the reporting officer shall immediately reassess the new declared interest and may reassign the staff member to a different interest level. The reporting officer subsequently applies any necessary restrictions (similar rules apply for future employment as those for employment within the past 3 years) to the staff member on his existing activities and for the period until he leaves the Agency.

⁵ Please see footnote 4.

The table below summarises the restrictions that are applied in case of declared personal interests, other than interests in a pharmaceutical or medical devices company.

Declared personal interests, other than interests in a pharmaceutical or medical devices company		Involvement of staff members in scientific or regulatory duties			Involvement of staff members in administrative or technical (non-scientific) duties	
Declared interest	Time since declared interest ended (in years)	A	B	C	Y	Z
Employment, consultancy or strategic advisory role in other entities possibly providing services to the EMA (e.g. IT, facilities, administration, catering)	Current interest	n/a	n/a	n/a	X	X
	0 to 3	n/a	n/a	n/a	XC-nPhC	F
Financial interest in other entities possibly providing services to the EMA (e.g. IT, facilities, administration, catering)	Current interest	n/a	n/a	n/a	X	X
	0 to 3	n/a	n/a	n/a	F	F
Close family member	Current interest	n/a	n/a	n/a	XC-nPhC	F
	0 to 3	n/a	n/a	n/a	F	F

A: Executive Director; Deputy Executive Director; Chief Medical Officer; scientific and regulatory managers
B: Scientific, regulatory and other administrators involved in product-specific activities
C: Scientific/regulatory assistants; scientific, regulatory and other administrators involved in non product-specific activities
Y: Executive Director; Deputy Executive Director; non-scientific/regulatory managers and administrators
Z: Non-scientific/regulatory assistants

Outcome restriction level	Impact of the outcome
n/a	Not applicable.
X	No involvement in activity allowed.
XC-nPhC	No involvement with respect to duties involving the relevant company (non-pharmaceutical).
F	Full involvement in activity allowed.

5. Achieving an efficient process

Checks for competing interests in relation to all categories of staff should take place yearly, at the same time of the annual update of the declarations of interests of staff members. This will streamline the process while maintaining the robustness of the system and making it more efficient to operate.

Reporting officers are responsible for assigning interest levels to staff members (as described in Article 4) and, based upon the information gathered, create an inventory of staff with competing interests together with the corresponding interests (companies or products). According to the information in the inventory, reporting officers will assign duties or allocate products ensuring that there are no competing interests that could unduly influence, i.e. staff with competing interests will be restricted for activities with companies for which they have declared direct or indirect interests, based on the principles described above.

To ensure that the information in the inventory is up-to-date at all times, reporting officers are immediately informed of any changes that are made to the staff member's declaration of interests by email (automatically sent by the EMA's declarations of interests database). In such cases, they will amend the inventory to ensure that no products or duties are allocated to staff with competing interests at any time.

In situations where two or more restrictions apply to a staff member, the reporting officer shall take the strictest restriction into consideration during the risk assessment prior to assigning duties to the staff member. Declared interests that are not listed in the tables shall be taken into consideration and assessed on a case-by-case basis.

6. Achieving a transparent process

The declarations of interests and curricula vitae of all Agency reporting officers are published on the Agency's website. The declarations of interests of all other staff members are available upon request.

The Agency processes personal data in accordance with 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. Further information is provided on the Agency's website under "Privacy statement".