EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Code of conduct of the European Medicines Agency

An agency of the European Union

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Message from the Executive Director

Emer Cooke, Executive Director, European Medicines Agency

The European Medicines Agency (EMA) is committed to delivering for public and animal health with the highest levels of integrity and impartiality. Our work is guided by a comprehensive code of conduct that aims to uphold the ethical standards and reinforces our dedication to trust, transparency and independence in everything that we do.

This code serves as a cornerstone for all individuals working at or with EMA, ensuring that every action and decision is guided by integrity and respect for one another. It outlines clear guidelines for managing possible competing interests, emphasising the importance of declaring such interests to enable their adequate management. Furthermore, it underscores the duty of confidentiality and discretion, safeguarding sensitive information and upholding the trust placed in our Agency.

I rely on each one of you who works for or alongside the Agency to read, understand and comply with this code of conduct, and to recognise the significance of its principles, which should provide guidance for the decisions we make and actions we take every day.

Introduction

Everyone working at or with the European Medicines Agency (EMA, herein also referred to as 'the Agency') – whether managers, staff, contractors or members of the Management Board or scientific committees – must uphold the highest standards of ethical behaviour.

This code of conduct provides a clear and comprehensive guide to help you understand your obligations and how you should apply professional ethical standards in your daily work and interactions. Where applicable, legal or relevant references such as regulations, implementing provisions, executive decisions and policies are mentioned.

Since its establishment, EMA has tried to ensure that it maintains the highest professional standards of integrity, transparency and independence. The EMA code of conduct was initially adopted in 1999 and has been regularly revised to reflect changes in relevant rules. Since the last revision in 2016, the Agency has implemented several new rules related to ethical behaviour. To enhance awareness and clarity, a complete rewriting of the code of conduct was necessary.

This new code of conduct consists of three main chapters, in line with legal provisions applicable to different roles:

- The first chapter covers the common ethical principles applicable to **all individuals working at and with EMA**, irrespective of their contractual status or relationship with the Agency.
- The second chapter focuses on specific provisions applicable to **Management Board members, scientific committee members and experts.**
- The third chapter covers the specific provisions applicable to **EMA staff members** (temporary and contract agents) and, where relevant, to other categories of staff (seconded national experts, trainees, interims, visiting experts and collaborating experts).

The EMA code of conduct is based on two major pieces of legislation:

- The Staff Regulations (SR) of Officials and the Conditions of Employment of Other Servants (CEOS) of the European Economic Community and the European Atomic Energy Community[1] lay down the basic principles governing relations between the EU institutions and their staff. Of particular importance regarding staff ethics and conduct is Title II of the SR, which deals with the rights and obligations of staff members. The Staff Regulations are complemented by additional decisions and guidance in specific domains, as well as by the Financial Regulation[2].
- Regulation (EC) No 726/2004 laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency[3] sets out the requirements for the Members of the Management Board, members of the committees, rapporteurs and experts with respect to direct and indirect interest in its Article 63 (2) and with respect to confidentiality and discretion in Article 76. In addition, Articles 30 and 32 of Regulation (EU) 2022/123 on a reinforced role for the European Medicines Agency in crisis preparedness and management for medicinal products and medical devices provide further legal basis for transparency and conflicts of interests in the domain of medicinal products and medical devices.

This Code of Conduct does not replace, but shall be read and interpreted in conjunction with all relevant legislative texts, policies, and other documents referred to therein.

1 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.

2 Financial Regulation applicable to the budget of the European Medicines Agency from 1 July 2019.

3 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.

Common ethical principles

Impartiality, integrity and independence

Confidentiality

Objectivity

Respect

Non-discrimination

Prevention of harassment

Although different regulatory frameworks and rules apply to staff members, seconded national experts, trainees, collaborating and visiting experts, interims, contractors, members of the Management Board and scientific committees or experts, all are expected to adhere to common ethical principles, reflecting the Agency's dedication to ethical excellence in all its operations and interactions.

Impartiality, integrity and independence

You must be unbiased in any advice or decision you are asked to give or make. Your conduct, advice and decision-making should be determined by the need to serve the common good and the public interest, and never by any other interests, in particular those that may compromise or appear to affect your impartiality in relation to the subject of the activity you are involved in at EMA.

Confidentiality

You must not disclose in any way any information or documents you handle in the performance of your duties at EMA, particularly those subject to the obligation of professional secrecy, as these have not been made public, are not in the public domain or you have no appropriate authority to do so. These shall also not be used for any purpose other than that in connection with your activity at EMA. You are bound to this obligation of professional secrecy even after your duties at EMA have ceased.

Objectivity

You must ensure that any conclusions you draw are balanced and based on a thorough analysis of the facts, evidence and related legal provisions. Your

conclusions should not be affected by personal bias or made while you are under external pressure related to any type of influence, interest or harassment.

Respect

You must treat everyone with respect and fairness, regardless of your or their position. You shall always maintain a professional and appropriate tone in both written and verbal communication. In the workplace, mutual respect and tolerance of differences are essential ingredients for fostering good working relationships.

Non-discrimination

Any discrimination based on any ground, including but not limited to sex, race, colour, ethnic or social origin, genetic features, language, religion or belief, political or any other opinion, membership of a national minority, property, birth, disability including neurodivergence, age or sexual orientation is strictly prohibited.

Prevention of harassment

You shall refrain from any form of psychological or sexual harassment where:

"'Psychological harassment"' refers to any improper conduct that takes place over a period, is repetitive or systematic and involves physical behaviour, spoken or written language, gestures or other acts that are intentional and that may undermine the personality, dignity or physical or psychological integrity of any person.

"'Sexual harassment' means conduct relating to sex that is unwanted by the person to whom it is directed, and that has the purpose or effect of offending that person or creating an intimidating, hostile, offensive or disturbing environment. Sexual harassment shall be treated as discrimination based on gender.

Provisions for members of the Management Board and experts of scientific committees

The provisions in this section apply to members and alternates of EMA's Management Board[4] and members and experts of the Agency's scientific committees, working parties and other groups (e.g. scientific advisory groups, ad hoc expert groups) as well as other bodies (e.g. Emergency Task Force (ETF), Medicines Shortages Steering Group (MSSG), Medical Devices Shortages Steering Group (MDSSG), etc.).

These are all hereafter referred to as 'members and experts', unless otherwise specified.

Competing interests

Essential references: Article 63(2) of Regulation 726/2004; Policy 0044 on the handling of competing interest of scientific committees' members and experts; Policy 0058 on the handling of competing interests of Management Board members.

You shall not have financial or other interests in the pharmaceutical industry that could affect your impartiality. Policy 0044[5] and Policy 0058[6] also address the handling of interests in the medical device industry and other relevant sectors.

To participate in the Agency's activities, you will be required to provide information on your interests in a declaration of interests (DoI), which is accessible to the public.

You must:

- make a declaration of interests **upon initial nomination** as a member or expert;
- **update** your declaration of interests annually;
- **submit an updated declaration** as soon as there is a change in any competing interest.

What should you declare?

The policies define the types of interest to be declared (e.g. current or past employment, consultancy or strategic advisory role in a pharmaceutical company). Some interests are incompatible with the participation in any of the Agency's activities, whereas for others, involvement is possible but subject to certain restrictions.

Based on the information in your declaration, an assessment will be carried out and, if necessary, relevant restrictions will be applied in accordance with the respective policies, taking into account several factors such as the nature of the declared interest, the timeframe during which such interest occurred and the type of activity in which you are involved at EMA.

4 Management Board members in this document also refers to official observers from Norway, Iceland and Liechtenstein.
5 Policy 0058: Handling of competing interests of Management Board members
6 Policy 0044: Handling of competing interests of scientific committees' members and experts

Professional secrecy – confidentiality and discretionn

Essential references: Article 76 of Regulation 726/2004.

As a member or expert, you are bound to confidentiality with regard to confidential documents and information of the Agency you deal with when exercising your mandate and with regard to any non-public deliberations. You are also bound by the duty of confidentiality even after your duties have ceased.

The above is without prejudice to the sharing of documents with persons assisting you in your duties for the Agency, provided that those persons are subject to an equivalent duty of confidentiality. You must take all necessary measures to ensure that the persons having access to your information also respect the above obligations to which they are subject.

In accordance with the legal framework concerning investigations conducted by the European Public Prosecutor's Office and the European Anti-Fraud Office, and in application of EMA's anti-fraud strategy[7], the release of information in response to a request from or in the course of an investigation by those Offices shall not constitute a breach of the duty of confidentiality.

Breach of trust procedure

Essential references: EMA breach of trust procedure on declarations of competing interests for Management Board members; EMA breach of trust procedure for competing interests of and disclosure of confidential information by scientific committees' members and experts.

The EMA breach of trust procedure[8,9] addresses any incomplete or incorrect declarations of interests (DoIs), as well as the disclosure of confidential information by members of the Management Board or experts of scientific committees. Failure to accurately complete the DoI or the unauthorised disclosure of confidential information may be considered sufficient proof of breach of trust towards the Agency. Consequently, the Agency may take appropriate actions, including the exclusion of the individual concerned from its activities.

7 EMA Anti-fraud strategy

8 EMA breach of trust procedure for competing interests of and disclosure of confidential information by Management Board members

9 EMA breach of trust procedure for competing interests of and disclosure of confidential information by scientific committees' members and experts

Gifts and hospitality

Essential references: Article 63(2) of Regulation (EC) No 726/2004.

Members and experts are advised to be very careful about accepting gifts or hospitality offered to them in the course of their official duties on behalf of EMA.

A gift is understood to mean a sum of money; any physical object; the possibility to participate for free in events that are either open to the public or private in nature and that would only be accessible in return for payment and represent a certain value (e.g. complimentary tickets for sports events, concerts, theatre plays, conferences, etc); any other advantage with a pecuniary value (e.g. transport costs).

Hospitality is defined as an offer of food, drink, accommodation and/or entertainment from any source outside the Agency.

You should actively discourage any interested party from offering gifts or favours, and particularly those from the pharmaceutical or medical device industries.

Any gift from the pharmaceutical or medical device industries, as well as any gift entailing a sum of money, regardless of the amount and the source, must always be refused. You should also not accept gifts or hospitality from third parties (persons, authorities or organisations) that are involved in or are seeking official action by the Agency, especially in a sensitive area in which the person is, has been or will likely be active in the foreseeable future. Any situation where the acceptance of a gift or hospitality may lead to a real, potential or perceived conflict of interests should be absolutely avoided.

Hospitality offered at events where leisure is associated or predominant, e.g. sports, concerts, holidays or weekends, may not be accepted from any source whose work is related to the Agency.

Small gifts of nominal value (below EUR 50) from other sources may be accepted where the nature of the gift allows it to be shared openly with colleagues, e.g. chocolates, cake or flowers. Similarly, traditional gifts of nominal or symbolic value (below EUR 50) from other regulators or institutions may also be accepted.

In a diplomatic or courtesy context, where refusing a gift that is not of a symbolic or low nominal value would cause offence, it may be accepted but should be declared to the EMA (Management Board or relevant scientific committee secretariat). A gift with a value likely to exceed EUR 150 should always be refused. You should not accumulate gifts (even below EUR 50 and independently of the source), as this can be a source of conflict of interests.

Hospitality (travel, accommodation) offered in the context of attendance at a conference or event authorised by EMA is acceptable, provided that the expenses are reasonable (meaning where the price category is appropriate, e.g. no luxury hotels).

Invitations to meals or refreshments of a nominal or low value may be accepted from a regulatory body or a not-for-profit organisation. As a rule, invitations from the pharmaceutical or medical device industries or their suppliers are not acceptable. Exceptionally, meals with little or moderate value may be acceptable on single occasions.

Gifts or hospitality received outside your role at EMA do not, in principle, fall under the provisions of this code. However, even in such cases, acceptance can be perceived as compromising your independence. For this reason, when you are in doubt as to whether to accept gifts or hospitality, you may contact EMA for guidance based on existing good practices.

Publications on EMA's work

Essential references: Policy 0015 on publications by EMA staff and EMA Scientific Committee members on EMA's work.

Policy 0015[10] sets out EMA's approach and requirements to ensure that scientific publications on EMA's work maintain high standards of quality, rigour and consistency.

EMA aims to ensure that all publications on EMA's role, activities and remit prepared by EMA staff as well as by members of EMA scientific committees and other bodies:

- ccontribute to the timely dissemination to the scientific community of the work done by the Agency and EU medicines regulatory network, to increase their scientific knowledge of medicines and related relevant Agency activities and priorities;
- are consistent with EMA's role and remit or, if not, that EMA is made aware in advance of the view(s) expressed by the author(s);
- are consistent with, or take due account of, EMA's official position or, if not, that EMA is made aware in advance of the view(s) expressed by the author(s);
- disclose potential conflicts of interests regarding the content of the publication;
- are of high quality;
- respect the need for confidentiality, protection of personal data and the EMA code of conduct;
- are not liable to prejudice seriously the legitimate interests of EMA or the European Union.

All scientific publications by members or experts on EMA's work must follow a peer-review process coordinated by the Agency's scientific publications team. The policy also covers aspects related to authorship and affiliations, as well as transfer of copyright.

Representing the Agency at external events or in professional bodies

Essential references: Policy 0029 on representing the Agency at external events or in professional bodies.

EMA receives many invitations to contribute to different fora and to attend external events such as conferences and workshops. This policy harmonises the Agency's approach to these requests and aims to provide consistency of responses and facilitate a rapid reply.

Policy 0029[11] addresses the handling of requests for participation at external events by EMA staff, members of scientific committees, members of working parties, scientific advisory groups and other bodies (i.e. ETF, MSSG and MDSSG, etc.), members of the EMA Management Board and experts from the European medicines regulatory network. The policy also addresses membership of professional bodies.

The policy includes guidance regarding acceptability of invitations depending on the nature of the requester. Exceptions are indicated.

10 Policy 0015: Publications by EMA staff and EMA scientific committee members on EMA's work
11 Policy 0029: Representing the Agency at external events or in professional bodies

EMA staff ethics and conduct

EMA staff play a crucial role in shaping the organisational culture and fostering an environment that upholds the highest ethical standards.

To maintain EMA's independence and credibility, staff members are subject to specific requirements that affect the exercise of their duties and can have implications on their private lives. Therefore, staff are required to proactively request authorisations or provide notifications in various situations, such as conflicts of interests, gifts, outside activities, spouse's employment and publications or speeches on EU-related matters.

As part of Agency-wide exercises, a set of behaviours deemed essential was discussed and agreed by EMA staff. The outcome was articulated in five value statements that define EMA's staff identity and aspirations.

- **We deliver for human and animal health with integrity and impartiality.**
- **We achieve common goals together, through cooperation and mutual trust.**
- **We embrace diversity and treat everyone with fairness, respect and solidarity.**
- **We listen to our stakeholders and communicate transparently and proactively.**
- **We strive for excellence through continuous development and innovation.**

Specific provisions referred to in this section apply to EMA's staff members (temporary agents and contract agents) who are subject to the Staff Regulations and CEOS. However, other staff working for EMA (non-statutory staff), such as seconded national experts (SNEs), trainees, persons employed under private law contracts (interims and contractors), visiting experts and collaborating experts, should refer to this section in addition to the specific rules regarding their specific engagement situation[12,13,14]. Where a provision is not applicable to a specific category of non-statutory staff, this is explicitly mentioned.

How to act and follow rules

Essential references: Articles 12, 12a 21 and 21a of SR; EMA decision on the policy preventing psychological and sexual harassment, Article 7.1(c) and (j) of the SNE rules; Article 15.2. of the traineeship rules.

You have an obligation to "assist and tender advice" to your superiors and you are responsible for the performance of the duties assigned to you. You must follow instructions unless they are manifestly illegal or constitute a breach of the relevant safety standards (simple disagreements or differences of opinion are not considered illegal or a breach of safety standards).

If your manager instructs you to do something that you consider to be irregular or likely to give rise to serious difficulties, you should ask for the instruction to be confirmed in writing, and then, if necessary, by their immediate superior. If the latter confirms the instructions in writing, you should carry them out, unless they are manifestly illegal or in breach of safety standards.

You should avoid any actions or behaviour (including psychological and sexual harassment[15]) that could harm your or the Agency's reputation. This includes your conduct in and outside of the workplace.

12 Decision of the Executive Director on rules governing the secondment of national experts to the EMA
13 Decision of the Executive Director on rules governing the traineeship programme at the EMA
14 Policy 0083: Visiting and collaborating experts involved in the activities of the European Medicines Agency
15 EMA decision on the policy preventing psychological and sexual harassment

Examples

You start exhibiting inappropriate behaviour towards your manager. You begin using unprofessional language in both verbal and written communications and you openly challenge decisions made by your superiors, also questioning the priority of certain tasks. Additionally, you refuse to carry out specific assignments or perform them late, and you frequently miss scheduled meetings. This behaviour not only disrupts the workflow but also undermines the authority of your hierarchy.

You start using aggressive language in both verbal and written communications. You begin accusing your colleagues of incompetence and adopt a harsh, inappropriate tone when communicating with your manager, colleagues or external partners. This behaviour creates a hostile work environment, damages professional relationships, and can severely impact team morale and productivity.

Your conduct, both professional and private, should uphold the standards of the European civil service. Should your actions bring EMA into disrepute, it could result in consequences.

Conflicts of interests

Essential references: Article 11a of SR; Article 61 of the Financial Regulation; EMA decision on handling of declared interests of staff members and candidates before recruitment; Article 7.1(d) and (e) of the SNE rules; Article 15.2. of the traineeship rules.

You must avoid any individual personal interests (including family or financial interests) that could compromise impartiality in your judgement, decisions or actions, to maintain EMA's independence, credibility, and financial interests. Preventing such situations from arising in the first place is crucial. Anyone can find themselves in a conflict-of-interests situation despite taking all precautions, and if this happens, it is essential to know how to react.

In this regard, everyone who has been offered employment or currently works for the Agency is required to complete a declaration of interests form to assess and mitigate any potential or real conflict of interests. In particular, you must declare financial or other interests in the pharmaceutical or medical devices industries that could affect your impartiality.

This is extended to other industries that relate to your work and that may also affect your impartiality, e.g. if you work in IT, procurement or administration.

When should you make a declaration on competing interests?

- Before you start your employment (as a selected candidate), so that EMA can assess any possible conflict of interests (this is always done as part of your onboarding process).
- As soon as you take up your duties (initial employment or change of activity/role).
- Every year, as part of the annual renewal exercise.
- Whenever there are changes in your circumstances that may cause a potential conflict of interests (e.g. you inherit shares in the pharmaceutical industry or a member of your close family changes employment).

The decision[16] on handling declared interests of staff and candidates before recruitment referenced above provides extensive definitions of what may constitute an interest that needs to be declared.

16 EMA Decision on rules relating to Articles 11, 11a and 13 of the Staff Regulations concerning the handling of declared interests

Example

I have been offered a position at EMA and I have declared that I hold shares in a pharmaceutical company. Can I keep them if I don't deal with products myself?

No, having financial interests in a pharmaceutical company is incompatible with employment at EMA. Following your declaration, you will be informed about the requirement to sell the shares prior to the start of your contract.

Declaring other conflicts of interests

You may not, during the performance of your duties, deal with any matter in which you have a direct or indirect personal interest that may compromise your independence and, by extension, EMA's reputation.

Such situations can arise when:

- there is some link between your work and your private interests, or those of your family or partner[17];
- you find yourself in a situation that could reasonably lead to allegations being made of bias or partiality, in light of your personal interests.

Examples of such situations can arise when, for example, there is a direct or indirect hierarchical link between family members (including partners), close personal ties with candidates in a selection procedure, professional or personal ties with companies bidding in procurement procedures, etc.

Example

My father is the CEO of an IT company with which the Agency has signed a contract. I have been offered the possibility to become the authorising officer for that contract, which would be very good for my development. Do I need to declare it?

Yes. This would be a clear conflict of interests given your role as authorising officer and the role of your father in the IT company. You must declare this relationship, and, in this instance, the Executive Director will need to delegate the authorising officer role to another colleague.

In the specific situation where family members (including partners) have a direct or indirect reporting relationship, the Agency will reassign one of them to a different role to ensure impartiality and avoid any perceived or real conflict of interests.

If you find yourself in any such situation or are unsure whether your circumstances could give rise to concerns over a conflict of interests, you should first discuss it with your line manager or seek advice from relevant EMA HR service.

17 A partner means: a natural person with whom the staff member is registered as having a stable non-marital partnership legally recognised by an EU Member State or any competent authority of a Member State, acknowledging their status as non-marital partners.

Example

You are a manager and you start a romantic relationship with one of your direct reports. As your relationship progresses, you find yourself spending more time together both inside and outside of work. Colleagues begin to notice that you are giving more favourable assignments and opportunities for professional development to this person. Despite your best efforts to remain impartial, the perception of bias grows among your team.

This situation could lead to allegations of favouritism and undermine the trust and morale within the workplace, highlighting the potential conflicts that can arise from personal relationships in a professional setting.

Gainful employment of your spouse

Essential references: Article 13 of SR.

You must inform EMA if your spouse is "in gainful employment[18]", i.e. is doing paid work. This is to prevent any appearance of a conflict of interests that could arise because of your respective professional activities. In this respect, unmarried but legally recognised partners are regarded as spouses. If there is any change in your spouse's professional situation, or your own, you must also declare this to EMA using the relevant (online) spouse occupation form, which will inform on any issue of conflict of interests.

If the nature of your spouse's employment is considered incompatible with yours and you are unable to give an undertaking that your spouse's activity will cease within a specified period, the Executive Director may decide to transfer you to another post, after consulting the Joint Committee.

Please note that declarations under Article 13 are different from the declarations you need to make to EMA's HR services that may affect your allowances, health insurance for your spouse, etc.

This provision does not apply to SNEs, trainees, interims or collaborating/visiting experts.

Outside activities during active service or leave on personal grounds

Essential references: Article 12b of SR; MB decision of 4 October 2018 adopting Commission rules on outside activities and assignments by analogy; Article 7.1(b) of the SNE rules; Article 15.2. of the traineeship rules.

If you wish to engage in an outside activity going beyond what can be considered a hobby, paid or unpaid, you must request prior authorisation at least 2 months before the start of such activity.

At a practical level, such an outside activity should not:

- be so time consuming that it could negatively impact your work at EMA or constitute a job in itself;
- give rise to any possible appearance of a conflict of interests or risk bringing EMA into disrepute.

The activity will also be prohibited when the remuneration of that activity, by itself or combined with the remuneration of other permitted activities, exceeds the ceiling of EUR 10,000 net per calendar year.

18 Further information for staff members on the intranet.

There is no need to seek prior permission for unpaid activities that meet these cumulative conditions:

- they are unpaid or do not generate revenues;
- they are not pursued in a professional capacity nor performed for a commercial entity;
- they are performed outside agreed working hours;
- they do not compromise your impartiality or objectivity;
- they do not have a negative impact on the reputation of the Agency.

Example

In my spare time I provide pilates lessons once a week in a senior citizens' home. I do not get any payment; this is a voluntary activity. However, I am also thinking of offering my services to a gym, for which I would charge a fee. Do I need to declare it?

While your pilates activity in the senior citizens' home is unpaid and carried out outside of work you do not need to declare it. However, if it becomes a commercial activity for which you charge a fee to a gym, you will need to request prior authorisation before the start and, if granted, the limit of EUR 10,000 net income per year for all your outside activities will apply.

Gifts, awards and public roles

Essential references: Articles 11, 12 and 15 of SR; Article 7.1(a) of the SNE rules; Article 15.2. of the traineeship rules

You shall not apply for, receive or accept from any source any advantage, direct or indirect (e.g. as a gift or in the form of hospitality) that is connected in any way to your role at EMA. This includes advantages for performing or failing to perform something in your official capacity, or for showing favouritism to an individual or to an organisation.

A gift is understood to mean a sum of money; any physical object; the possibility to participate for free in events that are either open to the public or private in nature and that would only be accessible in return for payment and represent a certain value (e.g. complimentary tickets for sports events, concerts, theatre, conferences, etc); any other advantage with a pecuniary value (e.g. transport costs).

Hospitality is defined as an offer of food, drink, accommodation and/or entertainment from any source outside the Agency.

You should actively discourage any interested party from offering gifts or favours, and particularly those from the pharmaceutical or medical device industries.

Any gift from the pharmaceutical or medical device industries, as well as any gift entailing a sum of money, regardless of the amount and the source, must always be refused. You should also not accept gifts or hospitality from third parties (persons, authorities or organisations) that are involved in or are seeking official action by the Agency, especially in a sensitive area in which the person is, has been or will likely be active in the foreseeable future. Any situation where the acceptance of a gift or hospitality may lead to a real, potential or perceived conflict of interests should be absolutely avoided.

Hospitality offered at events where leisure is associated or predominant, e.g. sports, concerts, holidays or weekends, may not be accepted from any source whose work is related to the Agency.

Small gifts of a nominal value (below EUR 50) from other sources may be accepted where the nature of the gift allows it to be shared openly with colleagues, e.g. chocolates, cake or flowers. Similarly, traditional gifts of a nominal or symbolic value (below EUR 50), e.g. diaries, calendars, small desk items, an invitation for coffee, etc.), offered by other regulators or institutions may also be accepted.

In a diplomatic or courtesy context, where refusing a gift that is not of a symbolic or low nominal value would cause offence, it may be accepted; however, you must apply for permission by sending an email to the Executive Director and respective HR service[19]. A gift with a value likely to exceed EUR 150 should always be refused. You should not accumulate gifts (even below EUR 50 and regardless of the source), as this can be a source of conflict of interests.

Hospitality (travel, accommodation) offered in the context of attendance at a conference or event authorised by EMA is acceptable, provided that the expenses are reasonable (meaning where the price category is appropriate, e.g. no luxury hotels).

Invitations to meals or refreshments of a nominal or low value may be accepted from a regulatory body or a not-for-profit organisation. As a rule, invitations from pharmaceutical or medical device industries or suppliers are not acceptable. Exceptionally, meals with little or moderate value may be acceptable on single occasions.

Example

A pharmaceutical company has sent an art book (small gifts of a nominal value below EUR 50) to your service following the positive opinion for one of their products. What should you do?

Given that the gift comes from the pharmaceutical industry, you must refuse it. This can be done via a letter to the sender. If returning the gift is too costly, the book can be donated to a charity and you can inform the sender accordingly.

Bearing in mind the overriding principle of independence, you should not accept an **honour or decoration** from any government or other source without prior permission from the Executive Director. There is an exception for services rendered before your appointment at EMA or during special leave for military or other national service and in respect of such services. Your request to receive an honour or decoration should be sent to the relevant HR service via email.

19 Consult the staff support contact points on the EMA intranet.

If you wish to stand for public office, for example as a candidate in municipal, regional, national or European elections, you must first inform the Executive Director and the relevant HR service.

The Executive Director will decide whether, in the period leading up to the date of the election or appointment, you:

- must take leave on personal grounds;
- must take annual leave;
- may be authorised to work part-time; or
- may continue to work with no change to your hours.

If elected or appointed to a position, you must also inform the Executive Director and relevant HR service immediately.

This provision does not apply to SNEs, trainees, interims collaborating experts or visiting experts. However, if you decide to stand for public office, you still need to notify the relevant HR service immediately. EMA will assess if there is a need to terminate your SNE placement, traineeship, collaborating/ visiting expert agreement or interim placement.

Freedom of expression, publications, conferences and speeches

Essential references: Articles 12 and 17a of SR; Policy 0015 on publications by EMA staff and EMA scientific committee members on EMA's work; Policy 0029 on representing the Agency at external events or in professional bodies; Article 7.1(g) of the SNE rules; Article 15.2 of the traineeship rules; EMA's social media guidelines.

You have the **right to freedom of expression** "with due respect to the principles of loyalty and impartiality."

When it comes to your professional activity, this is subject to the following two criteria:

- you must show restraint and caution in expressing opinions, especially when these obviously diverge from well-known policies of EMA; such opinions or any others regarding EU policies must be expressed with moderation and under your sole responsibility (i.e. with a disclaimer);
- you are also subject to the rules concerning non-disclosure of information and the confidentiality requirement.

You can use **social media**[20] when you work for EMA, but you do so **in your own personal capacity**. Please keep in mind that you should act responsibly and with decorum at all times when engaging on social media. You should refrain from any actions or statements that might negatively impact your position or EMA's. The core principles of circumspection, confidentiality, objectivity, impartiality and loyalty to the European Union should always guide your social media activities.

20 Social Media guidance available on the intranet.

Policy 0015[21] sets out EMA's approach and requirements to ensure that publications by EMA staff maintain high standards of quality, rigour and consistency. This includes scientific, regulatory, legal and non-scientific publications related to EMA activities, as well as to EU matters.

EMA aims to ensure that all publications on EMA's role, activities and remit, prepared by EMA staff, as well as by members of EMA scientific committees or other bodies:

- contribute to the timely dissemination to the scientific community of the work done by the Agency and the EU medicines regulatory network, to increase their scientific knowledge of medicines and related relevant Agency activities and priorities;
- are consistent with EMA's role and remit or, if not, that EMA is made aware in advance of the view(s) expressed by the author(s);
- are consistent with, or take due account of, EMA's official position or, if not, that EMA is made aware in advance of the view(s) expressed by the author(s);
- disclose potential conflicts of interests regarding the content of the publication;
- are of high quality;
- respect the need for confidentiality, protection of personal data and the EMA code of conduct;
- are not liable to prejudice seriously the legitimate interests of EMA or the EU;
- and, specific to EMA staff members, are in accordance with Article 17a of the Staff Regulations.

EMA staff need to provide advance notification of their intent to write a publication. All scientific publications must follow a peer-review process coordinated by the Agency's scientific publications team. The policy also covers aspects related to authorship and affiliations, as well as transfer of copyright.

For publications that are not related to European matters, you do not require any authorisation to publish. However, if time spent on this would qualify as an outside activity (i.e. carried out on a regular basis or there is a signed contract in place), you do need to ask for prior authorisation.

EMA receives many invitations to contribute to different fora and to **attend external events** such as conferences or workshops. EMA's Policy 0029[22] harmonises the Agency's approach to these requests, and aims to provide consistency of responses and facilitate a rapid reply.

It addresses the handling of requests for participation at external events by EMA staff, members of scientific committees, working parties, scientific advisory groups and other bodies (i.e. ETF, MSSG and MDSSG), members of the EMA Management Board and experts from the European medicines regulatory network.

21 Policy 0015: Publications by EMA staff and EMA scientific committee members on EMA's work

22 Policy 0029 :Representing the Agency at external events or in professional bodies

Obligations after leaving the service

Essential references: Article 16 of SR; Implementing provisions on outside activities and occupation after leaving the Agency; Article 7.3 of the SNE rules.

During your professional life at the Agency, you will not only have acquired professional experience but may also have had access to sensitive information. This is why even after leaving the service you are still bound by certain obligations as provided in the Commission Decision[23] adopted by analogy. In particular, the duty of confidentiality continues and you must "behave with integrity and discretion".

If you are intending to engage in an occupational activity, whether paid or unpaid, within two years of leaving the service, you must inform EMA in writing. The Agency may apply necessary restrictions to protect its interests.

This does not apply if you are taking up a post in another European Union institution or body, or if the activity is part of the limited list of permissible non-remunerated activities carried out in your personal capacity and does not involve lobbying or influencing EMA staff.

This provision does not apply to trainees, interims or collaborating/visiting experts.

Reporting serious wrongdoings (whistleblowing)

Essential references: Articles 22a and 22b of SR; EMA decision laying down guidelines on whistleblowing.

You are obliged to report facts indicating possible illegal activity, including fraud or corruption, or a serious failure to comply with the professional obligations of the Agency's staff.

If you become aware of any serious wrongdoing, you should report it in writing and without delay to (either) your supervisor, the Executive Director, the Chair of the Management Board or the European Anti-Fraud Office (OLAF). You may also contact EMA's anti-fraud office by email to afo@ema.europa.eu

The Agency has a reporting system in place that inspires confidence and can help break down any 'walls of silence', protecting you from any retaliation when reporting such cases in good faith.

The EMA decision[24] laying down guidelines on whistleblowing is applicable to temporary and contract agents. However, the other categories of staff are also encouraged to make use of the arrangements set out in this document. EMA also undertakes to protect these categories of staff against retaliation if they do so in good faith.

23 Commission decision on outside activities and assignments and on occupational activities after leaving the Service
24 EMA Decision laying down guidelines on whistleblowing

Relations with the public

Essential references: Code of good administrative behaviour.

Given that stakeholder relations from an important part of the Agency's mission of serving the public interest, we, as public servants, consistently aim to represent the Agency at the highest professional level and act as ambassadors in every interaction. The code of good administrative behaviour[25] offers detailed guidelines for engaging with the public.

When interacting with the public, you[26] should be guided by the principles of openness and transparency, while behaving with discretion, as well as with courtesy, helpfulness and efficiency.

Any EU citizen or company/organisation registered in a Member State is entitled to expect a prompt response when they address queries to EMA.

EMA commits to answering enquiries from citizens in the most appropriate manner and within a reasonable timeframe. As a rule, written correspondence to the Agency shall receive an acknowledgement of receipt within a period of two weeks, except if a substantive reply can be sent within that period. In any case, a reply shall be sent no later than 2 months from the date of receipt. Answers should be in the same language as the request, provided this is one of the official EU languages.

When answering telephone calls, you should clearly identify yourself or your department and always treat the caller in a courteous and professional manner. You should return calls as promptly as possible.

Any requests for information, comments and interviews from press and media should be directed to the EMA's Media and Public Relations Office and should not be dealt by the individual member of the staff, unless authorised to do so.

25 The European Medicines Agency Code of Good Administrative Behaviour

26 EMA staff members, seconded national experts, trainees, visiting/collaborating experts and persons employed under private law contracts (interims and contractors) performing duties for EMA.

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