EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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Administration

The European Medicines Agency Code of Conduct

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In the Appendix:
List of relevant documents and provisions
Template letter for Refusal of Gifts

1. Introduction, role and purpose of EMA Code of Conduct

1.1. Background

Since its establishment, the European Medicines Agency (hereafter called 'the EMA or 'the Agency') has endeavoured to ensure that it maintains the highest professional standards of integrity, transparency and independence. The EMA Code of Conduct was first adopted in 1999 with a revised version adopted on 16 December 2004. As the Agency adopted new rules on competing interests for members of the Management Board, members of Scientific Committees and experts and staff in 2012 and 2015, the Code was reviewed and updated to reflect current needs and the new rules in place.

The Code of Conduct sets out the practice for members of the Agency's Management Board, Scientific Committees, rapporteurs, experts and staff on direct and indirect interests, and the necessity to declare them in order to avoid and manage potential competing interests. This Code of Conduct applies to the members of the Agency's Management Board and Scientific Committees, rapporteurs, experts and staff. In respect of members of the Management Board, Scientific Committees, rapporteurs and experts Article 63 of Regulation (EC) No 726/2004[1] addresses financial or other interests in the pharmaceutical industry that could affect their impartiality, requires that they undertake to act in the public interest and in an independent manner, that an annual declaration of financial interests shall be made and that this Code shall provide for the issue of acceptance of gifts. In addition, Article 76 covers the question of confidentiality and discretion.

The Code of Conduct is applied in good faith and in the spirit and interests of the whole medicines regulatory network. The Code of Conduct and its active application supports the proper functioning of the Agency in the performance of its role and responsibilities.

1.2. The role of the EMA

The mission of the European Medicines Agency is to foster scientific excellence in the evaluation and supervision of medicines, for the benefit of public and animal health. The Agency is the European Union (EU) body responsible for coordinating the existing scientific resources put at its disposal by Member States for the evaluation, supervision and pharmacovigilance of medicinal products. It provides the Member States and the institutions of the EU the best-possible scientific advice on any question relating to the evaluation of the quality, safety and efficacy of medicinal products for human or veterinary use referred to it in accordance with the provisions of EU legislation relating to medicinal products.

The EMA's responsibilities and role in the scientific evaluation and pharmacovigilance of medicinal products for human and veterinary use have a significant impact on the protection and promotion of human and animal health. The outcome is important for patients, the public, health care professionals and pharmaceutical research. Integrity and high standards of professional conduct by members of the Management Board and Scientific Committees, rapporteurs, experts and staff are crucial for the independence of the EMA, and for its reputation vis-à-vis the public regarding its execution of European Union policy in the field of public health.

EMA staff members are EU civil servants, working for the public health of EU citizens. The members of the Management Board and the Scientific Committees, rapporteurs and experts are all working to carry out the roles and responsibilities of the Agency in the interest of European public and animal health.

[1] Regulation (EC) No 726/2004 of the European Parliament and of the Council, 31 March 2004, OJ L136

The fiduciary role of the EMA demands, from all of these parties, a high standard of professional conduct and these high standards are necessary for the EMA to effectively fulfil its role.

Given the special and specific nature of the work undertaken by the EMA, additional guidance clarifies several points of critical importance to members of the Management Board and Scientific Committees, rapporteurs, experts and the Agency's staff.

The EMA Code of Conduct includes in particular, Guidance on Competing Interests, Guidance on Confidentiality and Discretion, and Guidance on Invitations and Gifts.

1.3. EMA statement of principle on the Code of Conduct

The European Medicines Agency, its staff, members of the Management Board and Scientific Committees, rapporteurs and experts are working with its stakeholders for the protection of public and animal health. The EMA applies the principles in its governing legislation, the EU Staff Regulations (applicable to staff), the guidelines on gifts and hospitality for staff of the European Commission and the following public service principles for the EU civil service drawn up by the European Ombudsman.

- Commitment to the EU and its citizens
- Integrity
- Objectivity
- Respect for others
- Transparency

We also recognise the unique nature of the Agency's activities and, EMA staff have adopted the following statement of principles:

We strongly believe that in order to ensure the success of the EMA mission we need to:

- Assure the highest personal standards of integrity, honesty and independence
- Foster the spirit of loyalty and commitment to the goals of the EMA
- Assure impartiality and discretion to applicants
- Develop public confidence in the transparency of or the Agency's processes.

The EMA Code of Conduct takes into account the experience of the EU network of regulatory agencies and all its partner organisations. As such it reflects principles that are built into our culture and the way we work, so as to ensure for the EMA independence, respect from our partners and recognition and trust by the public.

While the EMA Code of Conduct will continue to guide EMA staff, the Management Board, Scientific Committees, rapporteurs and experts, the document will need to be revisited as new lessons are learnt and new situations faced.

2. EMA Guidance on Competing Interests

2.1. Legal basis

Article 63 (2) of Regulation (EC) No 726/2004 lays down provisions which require 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. They shall undertake to act in the public interest and in an independent manner, and shall make an annual declaration of their financial interests. All indirect interests which could relate to this industry shall be entered into a register held by the Agency which is accessible to the public, on request, at the Agency's offices."
>
> "The Agency's code of conduct shall provide for the implementation of this Article with particular reference to the acceptance of gifts."

The provisions of the Regulations and rules applicable to officials and other servants of the European Union (the 'Staff Regulation'), Articles 11, 11a, 12, 13, apply to all EMA staff '.

The other rules that apply to competing interests in the context of the EMA are:

- European Medicines Agency policy on the handling of competing interests of Management Board members, Policy 0058
- European Medicines Agency policy on the handling of declarations of interest of Scientific Committees' members and experts, Policy 0044
- Decision on rules relating to Articles 11, 11a and 13 of the Staff Regulations concerning the handling of declared interests of employees of the European Medicines Agency and candidates before recruitment
- For Scientific Committee members, rapporteurs and experts: European Medicines Agency breach of trust procedure on declarations of interests for scientific committees' members and experts
- For Management Board members: European Medicines Agency breach of trust procedure on declarations of competing interests for Management Board members.

2.2. Who should declare?

- All members of the Management Board and Scientific Committee, rapporteurs and experts including official observers[2].
- Official observers (Norway, Iceland and Liechtenstein) to the Management Board are treated as full members for the purposes of the Declaration of Interests.
- All EMA staff. The EMA rules on handling declared interests of staff applies by analogy to all visiting staff (e.g. national experts on secondment, trainees, interims, conference hostesses or visiting experts).

Whilst Regulation (EC) No 726/2004 specifically refers to interests held in the pharmaceutical industry, members of EMA staff are bound under the Staff Regulations by the obligation to act with integrity and loyalty. This chapter offers additional guidance on identifying interests that could present conflicts.

2.3. What to declare?

Each individual is responsible for the declaration of his or her interests. The individual must declare all interests that could be prejudicial to their independence, whether of direct or indirect nature.

[2] The Rules of Procedure of the Scientific Committees allow for possible participation of observers to their meetings, subject to prior agreement and conditions of participation as appropriate. Further details in this regard may be found in the relevant Rules of Procedure.

2.3.1. What are direct and indirect interests?

An individual may have private financial interests, personal relationships or affiliations that could compromise official decisions in which they are involved. Interests can be direct or indirect depending on their likely or potential impact on the individual's behaviour at a given point in time. Personal relationships or affiliations could compromise official decisions in which an individual is involved. Where a competing interest arises due to direct or indirect interests the person's involvement will have to be negated or restricted so that the competing interest is mitigated.

Direct interests: Interests of personal benefit to the individual at any point in time, likely to influence or give the appearance of influencing his/her behaviour. It follows from Article 63(2) of Regulation (EC) No 726/2004 that the holding of direct interests is in principle incompatible with being a member of Management Board or Scientific Committee, a rapporteur or expert and, by analogy, an EMA staff member. In order to remain in office, the individual concerned would have to take appropriate action to suppress the competing interest.

Indirect interests: Other interests that may have some influence over the individual's behaviour and therefore have to be neutralised.

Article 63(2) of Regulation (EC) No 726/2004 does not prohibit the holding of indirect interests and these are subject to public declaration. Indirect interests should be scrutinised so that precautions can be taken in order to ensure impartiality of decision taking. Appropriate actions could include precluding the individual from certain functions or tasks (e.g. rapporteur, expert, project manager) or requiring abstention from part of the relevant proceedings or voting in the meetings of the scientific committees and/or other scientific bodies.

2.3.2. What is an interest?

The definition of what is an interest is set out in the specific EMA policies. The definitions are interpreted as referring also to non-pharmaceutical companies or industry where applicable. All parties have the individual responsibility to consult the policies as required for their personal circumstances and to act in accordance with the applicable EMA policies.

2.3.3. What restrictions apply?

For members of the Management Board or Scientific Committees, rapporteurs and experts as well as EMA staff involvement in the Agency's activities is subject to the availability of a signed declaration of interests form and an assessment of the declared interests.

The restrictions that will apply in terms of the individual's activities in the context of the EMA's role and responsibilities will depend on the specific individual's competing interest and their particular role. The details of the relevant restrictions are set out in the EMA policy documents.

2.4. When to declare?

The declaration of interest forms reflect the applicable rules and provide more guidance to all parties concerned on how to complete and update them.

2.4.1. Initial declaration

Upon nomination as a member of the Management Board or Scientific Committee, rapporteur or expert or appointment as EMA staff member, each individual is required to fill out a declaration of interests form on paper or using the relevant electronic database, as instructed by the Agency.

In the case of a Scientific Committee member, expert or EMA staff member, an interest level is assigned to the individual on the basis of the declared interests. Depending on the interest level mitigating action may be taken including exclusion of the individual from certain activities for a period of time until such time that the competing interest no longer applies.

2.4.2. Spontaneous declarations

Under Article 63(2) of Regulation (EC) 726/2004 if during meetings or working groups and, as specified in the EMA experts policy, during assessment or advisory work, a potential competing interest becomes apparent to a member of the Management Board or Scientific Committees, rapporteur or expert, then, it must be declared to the chairperson immediately who will notify the Secretariat and appropriate action agreed to. These declarations shall be made available to the public.

Moreover, members of the Management Board or Scientific Committees, rapporteurs or experts must update their declarations of interests as soon as their interests change.

If at any time, in the course of their duties, EMA staff members become aware of any potential competing interest they must immediately inform their Reporting Officer who will determine any appropriate action. In addition, staff members should update their declarations of interests as soon as their interests change and notify their Reporting Officer.

2.4.3. Update of declaration

Under Article 63(2) of Regulation (EC) No 726/2004 members of the Management Board and Scientific Committees, rapporteurs and experts must declare their interests at least annually or as soon as their interests change and at the beginning of the official mandate of the Management Board. As part of the experts database, electronic updates are available to facilitate exchange of information.

Staff members must likewise update their declarations annually using the designated database.

2.4.4. Operational aspects and public availability of declarations

Tasks of EMA Secretariat

The EMA Secretariat, under the direct responsibility of the Head of Division concerned, undertakes the following:

- Remind all parties concerned of their obligation to declare their interests;
- Assess and monitor regularly declarations and make preliminary appraisal of compatibility of interests declared with general or specific office or duties of the individuals concerned;
- Initiate and facilitate dialogue within the appropriate forum (e.g. committee or working party).

In accordance with Article 63(2) of Regulation (EC) No 726/2004, the EMA Secretariat ensures under the responsibility of the Head of Administration and Corporate Management, in respect of EMA staff only, the availability of all declarations and updates for public consultation. All declarations of staff are public within the EMA and the annual declarations of the Executive Director, other Directors, Heads of

Division, Department, Office and Service are all published on the EMA external web site. The Agency may elect to publish declarations of interest of all staff public in the future.

For Management Board members, all Scientific Committee members and experts declarations and updates are available for public consultation through the Agency's public website under 'About us/Who we are/Management Board/ Members' (or the following link) for the public declaration of interests of the Management Board Members, and under 'About us/How we work/European medicines regulatory network/European Experts' (or the following link) for the public declaration of interests of all committee, working party members and experts.

2.4.5. Obligations of individuals concerned

Members of the Management Board and Scientific Committees, rapporteurs and experts (Article 63(2) of Regulation (EC) No 726/2004) and staff members (Article 11a of the Staff Regulations) have a primary obligation to disclose at any time the existence of possible competing interests that may place the impartiality of EMA at risk. The individual should state, in particular, the type and nature of interests, specifying whether they are general or relate to a specific activity, e.g. a product, tender, recruitment etc. Failure to fill in the declaration of interests in a complete and/or correct manner may be considered as a prima facie breach of trust towards the EMA. In the case of Scientific Committee members, rapporteurs and experts, it may lead to the exclusion of the concerned person from EMA activities and to the initiation of the Breach of Trust procedure.

The applicable policies on breach of trust are:

- For Scientific Committee members, rapporteurs and experts: European Medicines Agency breach of trust procedure on declarations of interests for scientific committees' members and experts
- For Management Board members: European Medicines Agency breach of trust procedure on declarations of competing interests for Management Board members

The relevant procedures and sanctions for EMA staff are contained in the Staff Regulations.

2.4.6. Meeting proceedings

Article 63(2) of Regulation (EC) No 726/2004 lays down provisions which require that

> 'Members of the Management Board, members of the committees, rapporteurs and experts who participate in meetings or working groups of the Agency shall declare, at each meeting, any specific interest which could be considered to be prejudicial to their independence with respect to the items on the agenda. These declarations shall be made available to the public.'

Individuals have the primary responsibility to spontaneously declare any new or changed competing interests at all times further to their existing declaration.

Chairpersons of all meetings shall at the start of each meeting ask the attendees to identify and state any competing interests, and at least every 6 months, where applicable, remind members and experts of their obligation to update their declarations.

Particular precautions should be taken in the case of ad-hoc expert groups or other situations where competing interests are likely, in which case a systematic reminder shall always be made at the beginning of every such meeting.

Reminders and discussions should be recorded in minutes of meetings together with detailed statements on competing interests.

On the basis of the type and nature of interests noted, chairpersons and EMA secretariat shall apply the EMA policies in place.

3. EMA Guidance on Confidentiality and Discretion

3.1. Introduction

The EMA is a public body of the European Union. It has been entrusted with the important duty of protection of public and animal health and the evaluation of medicinal products (both human and veterinary) on behalf of consumers, patients and the pharmaceutical industry. Members of the Management Board, members of Scientific Committees, rapporteurs, experts and EMA staff members must treat information on the Agency's work with the utmost discretion and confidentiality.

The EMA faces potentially conflicting obligations, requiring it to weigh the duty to protect public and animal health, transparency and granting public access to documents[3], with the need to respect confidentiality of information that the Agency holds, where appropriate as legally required. Under Article 73 of Regulation (EC) No 726/2004, Regulation (EC) No 1049/2001 of the European Parliament and of the Council of 30 May 2001 regarding public access to European Parliament, Council and Commission documents shall apply to documents held by the Agency.

A significant amount of information is available through the EMA website (http://www.ema.europa.eu). This access to information, however, is balanced by the rules of professional secrecy for EMA staff and other concerned persons and the obligation to respect European and international laws on the protection of commercially confidential data in the pharmaceutical sector.

3.2. Duty of confidentiality

Article 76 of Regulation (EC) No 726/2004 sets out a duty of confidentiality for members of the Management Board and Scientific Committees, rapporteurs, experts and EMA staff. The protection of personal data and respect of confidential information is an essential part of the relationship between the EMA, European institutions, Member States, pharmaceutical companies and patients. The EMA recognises that its staff, members of Scientific Committees, rapporteurs and experts have access to confidential information.

Article 17 of the Regulations and Rules applicable to officials and other servants of the European Union (Staff Regulations) binds staff members to a general duty of confidentiality and a duty to exercise the greatest discretion even after leaving the service of the EMA. Interim staff, national experts on secondment, visiting experts, and persons participating in a work experience programme (trainees) are all required to sign a confidentiality undertaking.

EMA staff and other concerned persons are advised to exercise care when answering questions so as not to supply information to third parties regarding specific products where this information is not public. Discretion should be exercised when discussing professional work with third parties, including family and friends, and with colleagues or third parties in a public place, e.g. EMA restaurant, public transport. The provenance of the party putting a question should always be ascertained and questions should be put in writing where possible. Common sense must be applied regarding indirect questions seeking to obtain information. EMA staff should follow the procedure laid down in SOP/EMA/0019, Handling of requests for access to information.

Where there is doubt about the provision of information, EMA staff members should seek guidance from their Head of Service, Office, Department or Division.

[3] The European Medicines Agency Policy on access to documents (related to medicinal products for human and veterinary use), Policy 0043 (EMA/110196/2006), effective from 1 December 2010.

As a general policy, on matters related to the Agency or the medicines regulatory network, staff members should not speak directly to journalists and the wider media without informing the Agency's Press Office in advance.

3.3. Continuing duty of confidentiality

Under Article 76 of Regulation (EC) No 726/2004, members of the Management Board, Scientific Committees and working parties, experts and staff have a life-long duty of confidentiality even after they have ceased their relationship with the EMA. This covers all information of the kind covered by the obligation of professional secrecy.

Staff members are required to behave with integrity and discretion after leaving the Agency. For a period of two years following departure from the Agency staff have to apply under Article 16 of the Staff Regulations for authorisation in advance of engaging in paid or unpaid activities. In addition, in line with the Staff Regulations and current commercial practices, the EMA is entitled to impose restrictions on employment after members of staff leave the Agency. Ex EMA staff should not exploit their relationship with former colleagues to obtain professional advantage or information of a specific or regulatory nature for personal advantage. EMA shall apply a distance policy to former staff to ensure that its interests are protected and that such problems do not arise.

Staff leaving the EMA are able to use the skills acquired in the course of their employment at the EMA so long as such use is, for a period of two years, not in conflict with the legitimate interests of the service and does not interfere with their obligation of confidentiality. This is, in particular, intended to prevent breaches of confidentiality that would be detrimental to the public interest, interests of the Agency or EU Institutions, Member States, applicants or holders of marketing authorisations. The provisions of Article 16 of the Staff Regulations have been extended to apply by analogy to interim staff, national experts on secondment, visiting experts, and persons participating in a work experience programme (trainees).

3.4. Public right of access

There also exists a public right of access to documents that is enforced through Regulation (EC) No 1049/2001 and the decision of the Management Board on rules for the implementation of Regulation (EC) No 1049/2001. These rules set out the procedure for access to documents, the classification of documents as public, EU restricted or EU confidential, and the reasons for which access to documents may be denied by the EMA. Documents classified as EU restricted or EU confidential may not be released to the public.

Once a document or information has been made public, the duty of confidentiality ceases only to the extent of the information released into the public domain.

3.5. Cooperation with the European Anti-Fraud Office (OLAF) or Commission Internal Audit Service, or national or European Courts

In accordance with European Parliament and Council Regulation (EC) No 1073/1999 concerning investigations conducted by the Office and the Executive Director's decision of 1 June 1999 concerning cooperation with the Office (EDIR/007/1999), staff and experts are required to cooperate fully with the European Anti-Fraud Office. The release of information in response to a request from or in the course of an investigation by the Office shall not constitute a breach of confidentiality.

Information provided to the European Court of Auditors or the Commission's Internal Audit Service in the course of its duties, national or European Courts shall not constitute a breach of confidentiality.

4. EMA Guidance on Invitations and Gifts

4.1. Introduction

Article 63(2) of Regulation (EC) No 726/2004 and Article 11(2) of the Staff Regulations provide for procedures relating to gifts. Members of the Management Board and Scientific Committees, rapporteurs, experts and staff should seek permission before accepting any honour, decoration, favour, gift or payment of any kind whatever, except for services rendered prior to appointment to the EMA or during special leave for military or other national service and related to that service. The European Commission's guideline on gifts and hospitality or invitations for Commission staff members (Administrative Notice 07-2012) has been reflected in this chapter.

In principle, invitations or hospitality are to be treated like gifts, since an invitation might influence one because it is of value (whether or not of a monetary value), or give the impression to the world that the EMA is partisan or being influenced or open to influence.

Members of the Management Board and Scientific Committees, rapporteurs, experts and staff are advised to be very careful about accepting gifts or hospitality or invitations offered to them in the course of their official duties on behalf of the EMA. As a rule, they should discourage gifts of anything more than nominal or symbolic value. Traditional gifts of nominal or symbolic value offered by foreign regulators may however be accepted. Where they are unable to refuse a gift which is not of nominal value without causing offence, they must declare its acceptance, in writing, to the relevant Head of Department or Head of Division. This declaration should be retained by the relevant Head of Department or Division for a period of five years from the date of declaration.

4.2. Acceptability of gifts

The source of the gift or invitation is the defining factor for its acceptability.

4.3. Definition of Gifts

A gift is understood to mean:

- A sum of money, or
- Any physical object, or
- The possibility to participate for free in events which are open to the public or are private in nature, are only accessible in return for payment and represent a certain value (such as complimentary tickets for sports events, concerts, theatre, conferences etc), or
- Any other advantage with a pecuniary value such as transport costs.

Low value items given for purely information purposes (brochures, which are not offered directly booklets, catalogues) are not considered as gifts in this context. Indirect gifts are those which are not offered directly but to a third party that is close to the staff member.

4.4. Definition of Hospitality

This guidance deals with hospitality offers which are considered to be a type of favour. Hospitality is defined as an offer of food, drink, accommodation, and /or entertainment from any source outside the Agency.

4.5. Gifts and favours

The policy of the EMA is to actively discourage any interested party to offer gifts or favours and in particular that suppliers or the pharmaceutical industry must not offer gifts or favours. As a general rule, EMA staff or other concerned persons should not accept any direct or indirect gifts or hospitality from third parties. This is most evident where gifts are offered by persons, authorities or organisations which 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 real, potential or perceived conflict of interest should be absolutely avoided. Any gifts entailing a sum of money, regardless of the amount, must always be refused.

Small gifts of nominal value from sources outside the pharmaceutical industry may be accepted where the nature of the gift allows it to be shared openly with colleagues, e.g. chocolates, cake, flowers. Similarly traditional gifts of nominal or symbolic value offered by foreign regulators may also be accepted. Where refusing the gift would cause offence, in a diplomatic or courtesy context when the offer of a gift is of nominal or symbolic value or is addressed to a large number of persons, it may be accepted, but where the gift is not of nominal value its acceptance should be declared in writing to the relevant Head of Department or Division. This declaration should be retained by the relevant Head of Department or Division for a period of five years from the date of declaration.

Any gift addressed to a single staff member, or which is of a personal nature must be refused and/or returned, e.g. scarf, book, CD, gift card, vouchers, and must be declared to the Agency (sent to HR). A gift sent to a home address may not be accepted and must be returned and the Agency notified in writing (sent to HR). The Agency's template letter is available in the Appendix and should be used in these circumstances.

Where it is not practical to return a gift, e.g. due to high postage cost, the sender should be informed in writing by the recipient that the gift cannot be accepted and will be transmitted to charity. The gift should be sent to HR which will arrange for an anonymous donation to a charitable organisation.

Accumulation of gifts of low value is not acceptable. Accumulation may be seen as compromising the person's objectivity or may damage the Agency's public image.

Where there is any doubt regarding a gift or favour, the advice of the Head of Department or Division should be sought.

Staff members should not use items with logos of pharmaceutical companies in the course of their work.

Gifts or hospitality motivated solely by a family relationship or personal friendship, or in a context not related to the person's duties for the Agency, do not, in principle, fall under the provisions of this guidance. However, even here situations may arise when acceptance can be perceived as compromising the person's independence.

4.6. Invitations to events

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

Any invitation or event should be avoided where the price category is not appropriate, e.g. luxury hotels or very expensive restaurants.

Staff should normally pay themselves for refreshments or meals in the course of a meeting or on mission, and should not accept invitations from individual pharmaceutical companies, suppliers, etc. A spouse or partner may attend events with the staff member or other concerned persons if invited, provided they pay in full all the additional costs involved. Discretion must be exercised as to the possible impression on third parties or the public.

Advance permission should be requested where possible. If this is not possible, the invitation should be declared on the mission claim where relevant. The 'relevant authority' to ask for authorisation to accept invitations is the Head of Service or Office or, in his/her absence, the Head of Department or Division.

4.7. Invitations to refreshments, lunch, dinner etc.

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 industry or suppliers are not acceptable. Exceptionally, meals with little or moderate value may be acceptable on single occasions.

EMA staff on mission attending a pharmaceutical conference on behalf of EMA may attend official dinners provided that the invitation to the official dinner is extended to all participants. For EMA staff a deduction from the mission expenses will be made under the EMA mission rules. The mission order will as a rule cover all predictable offers of hospitality, based on the mission programme, notably meals, accommodation and transport. These will not be considered as hospitality offers if the programme of the mission and the participation of the EMA staff has been authorised, as they form part of the performance of the duties in the interest of the service. The acceptance of these offers will then be declared in the mission expenses claim.

4.8. Invitations to publish, give speeches or lectures

Invitations to publish or to give speeches or lectures can be seen as a gift or an indirect benefit. One must distinguish between publications, speeches or lectures in an official capacity on behalf of the Agency and private publications, speeches or lectures. For scientific committee members the applicable policy is set out in the Policy on scientific publication and representation for the EMA's scientific committees and their members. Staff must follow EMA Policy 0015 Scientific Publications by EMA staff.

When an EMA staff member is acting in an official capacity, advance clearance for the content is required by the Head of Department or Division. Staff wishing in a private capacity to publish a text, give a speech, an interview or lecture on a subject relating to the work of the EMA or the European Union must inform the EMA in advance in writing, in accordance with Article 17a of the Staff Regulations and the Agency's rules on external activities. Permission will usually be granted unless the content of the publication, speech, or lecture would seriously prejudice the legitimate interests of the EMA and/or the European Union. Attendance by EMA staff to give a speech or lecture is subject to availability and work priorities.

Permission to attend will not be granted if networking or gaining influence must be assumed to be the major objective of the organiser when issuing the invitation to speak or publish, or if the event is funded by a pharmaceutical company (declaration regarding missions).

Staff must also obtain advance permission concerning the acceptance of any payment for publications, speeches or lectures which are not directly related to their work at the EMA in accordance with the rules on external activities. Payment for publications, speeches or lectures directly relating to the activities of the EMA is normally not permitted. In exceptional circumstances payments may be accepted. Any financial payment for staff participation must be declared and sent to Administration Unit for processing action.

The source of the invitation is the defining factor for acceptability of invitations. In principle, invitations from EU organisations or associations are acceptable, in some cases as are non-profit oriented invitations from national associations or congresses. Invitations from congresses or meetings organised by individual pharmaceutical companies are not accepted. The inviting body/meeting organiser must declare that 'any travel and accommodation costs and expenses concerning the participation of the invited EMA member(s) of staff will be directly borne by the meeting organiser and will not be linked to an individual pharmaceutical company.'

Where it is not possible to clear a presentation or statement in advance, e.g. answers to questions in a panel discussion or during an interview, a disclaimer must be stated, i.e. that the views presented are those of the individual and may not be understood or quoted as being made on behalf of EMA or reflecting the position of EMA.

On some occasions, it may not be appropriate for anyone from the EMA to attend or participate in any way. Therefore, if permission is refused for an invitation to speak, publish or to participate at a meeting, conference or to represent the EMA, it is not acceptable to attend during a weekend or by taking leave.

Where for financial reasons only, the Agency cannot agree to the staff member's attendance the staff member may apply to attend as an external activity. In this case, the external activity rules and procedures apply[4].

4.9. Fees and honorariums

For invitations to speak (for which permission to attend has been granted) it is acceptable that the participation fee is waived and/or travel expenses are paid for by the inviting organisation.

However, no honorarium may normally be accepted for publications, speeches or lectures in the course of duty. Exceptionally, a payment may be accepted to defray reasonable attendance and accommodation costs.

In the special case of a private publication, provided that the publication is written using free time and advance permission has been obtained, the fee for publication (declared in advance) may be accepted by the staff member in line with the rules on external activities. The rules regarding avoidance of conflict of interest at the EMA and prevention of publication that is liable to seriously prejudice the legitimate interests of the EMA or the EU apply.

Staff members must seek permission for external activities, whether gainful or not. The issue is whether the activity would impair the staff member's independence or be detrimental to the work of

[4] Decision of the Management board, European Medicines Agency on the adoption of implementing rules for outside activities and assignments (EMA/712718/2013)

the EMA. Specific guidance on external activities of staff members is available from Human Resources (HR).

4.10. Honours or decorations

If a staff member is offered an honour or decoration, permission to accept it must have been requested in writing and obtained in advance from the Executive Director.