HPRA
An tÚdarás Rialála Táirgí Sláinte
Health Products Regulatory Authority

Health Products Regulatory Authority
Conflicts of Interest Policy

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CONTENTS

1 SCOPE

This policy document applies to members of the Authority, its committees, the statutory advisory committees, subcommittees and working parties, experts and staff.

In the context of this document, 'Authority, committees, external experts and staff' is taken to include all of the above groups.

2 INTRODUCTION

Given the nature of the HPRA's regulatory functions, particular care and transparency is necessary in relation to potential conflicts of interest in relation to the industries regulated by the HPRA. Persons connected with the HPRA's business must not misuse their position or information acquired in the course of their duties to further their private interests or those of others, and should not receive benefits of any kind from a third party which might reasonably be seen to compromise their personal judgement or integrity. This document provides detailed guidance on the requirements in relation to conflicts of interest.

3 LEGAL AND OTHER REQUIREMENTS

3.1 Legal requirements

The rules on conflicts of interest, which apply to members of the Authority, committees, external experts and staff, are derived from the following legislative sources:

- Irish Medicines Board Acts, 1995 and 2006
- Ethics in Public Office Act, 1995 and 2001
- Directive 2001/83/EC
- Regulation (EU) No 536/2014 on clinical trials of medicinal products for human use

The primary and most important of these is the Irish Medicines Board Acts, which state in Section 24(1) that:

'Where the Chief Executive, a member of the Board, an employee of the Board, a member of a committee or of a subcommittee established under section 9, a consultant, adviser or other person engaged by the Board, has a pecuniary or other beneficial interest in, or material to, any matter which falls to be considered by the Board, a committee or a subcommittee, he or she shall comply with the following requirements –

(a) he or she shall disclose to the Board, committee or subcommittee, as the case may be, the nature of his or her interest in advance of any consideration of the matter,
(b) he or she shall neither influence nor seek to influence a decision in relation to the matter,
(c) he or she shall take no part in any consideration of the matter,

(d) if he or she is the Chief Executive of the Board, a member of the Board, an employee of the Board or a member of a committee or subcommittee established under section 9, he or she shall withdraw from the meeting for so long as the matter is being discussed or considered by the Board, committee or subcommittee and shall not vote or otherwise act as such Chief Executive or member in relation to the matter.'

The Irish Medicines Board Acts refer to either a 'pecuniary or other beneficial interest'; in general, although not exclusively, these terms imply a financial or other beneficial interest which, while not specifically a financial interest, could lead to financial gain. The HPRA's code of conduct (MGT-P0025) reflects the contents of the Irish Medicines Board Acts and provides for annual declarations in respect of conflicts of interest.

The Ethics in Public Office Acts require declarations in relation to interests held by specified persons.

Part 1 of Article 126(b) of Directive 2001/83/EC (as set out in Appendix 1) outlines the requirement to guarantee independence and transparency by ensuring that competent authority staff members, rapporteurs and experts involved in the authorisation and surveillance of medicinal products have no financial or other interests that could affect their impartiality; and the requirement for such persons to make an annual declaration of their financial interests.

Article 9(1) of Regulation (EU) No 536/2014 requires Member States to ensure that persons validating and assessing clinical trial applications do not have conflicts of interests, are independent of the sponsor, of the clinical trial site and the investigators involved and of persons financing the clinical trial, as well as free of any other undue influence.

The Authority and advisory committees are appointed by the Minister for Health, with, in the case of the Advisory Committee for Veterinary Medicines, the consent of the Minister for Agriculture, Food and the Marine. It is expected and indeed desirable that some experts appointed to the Authority or committees or as staff members will have worked in industries that the HPRA regulates. In cases where a member of the Authority, committees, external experts or staff has a beneficial interest in any matter to be considered by the HPRA, then the requirements of Section 24 of the Irish Medicines Board Acts must be followed.

Appendix 1 lists relevant statutory and other obligations.

3.2 State body requirements

This policy reflects the requirements outlined in the Code of Practice for the Governance of State Bodies published by the Department of Public Expenditure and Reform. The Code of Practice states that the Boards of state bodies should have procedures in place to monitor and manage potential conflicts of interest of Board members and management. In addition, under the Code of Practice appropriate polices are to be in place to ensure that members and staff

take decisions objectively and that steps are taken to avoid or deal with any potential conflicts of interest, whether actual or perceived.

3.3 Authority requirements

In addition to complying with legislative requirements, and, where applicable, requirements of the Code of Practice, Authority members, committees, external experts and staff have an obligation under this HPRA policy to declare any matter that could affect their impartiality or that could reasonably be perceived as affecting their impartiality.

Where a conflict of interest is established, the person must follow the rules laid down in the Irish Medicines Board Acts as if there were a financial or beneficial interest. If in doubt, a committee member can consult the chairperson of the committee who will determine whether such a conflict exists; staff should consult their manager.

In order to avoid any conflicts of interest or the perception of conflicts, the HPRA has decided that staff may not hold any direct financial interest in any industry regulated by the HPRA. Any financial interests in these industries must be disposed of before commencing employment with the HPRA, though employee share options may be kept until the date of exercise – the work the employee may do will be limited during this time. Neither may staff be employed, carry out any consultancy or paid work of any kind or act as a director or partner in any regulated industry.

Scientific staff and those who provide scientific expertise to the HPRA may also contribute to committees and working parties at the European Medicines Agency, and are required to comply with the agency's requirements on declarations of interest.

4 DEFINITIONS

4.1 Industry or organisations regulated by the HPRA

Any company, organisation, partnerships or individual involved in the research and development, importation, manufacture, sale or supply of medicinal products for human or veterinary use, medical devices, blood, tissues and cells, organs, animals used for scientific purposes, cosmetics and certain aspects of substances controlled under the Misuse of Drugs Act. Trade associations representing companies involved in such activities and sponsors, funders and sites involved in clinical trials or clinical investigations are also included.

4.2 Close family members

First-line members of the family of the member of the Authority, committee, external expert or staff (i.e. a spouse, partner, children and parents).

5 INTERESTS TO BE DECLARED

5.1 General points

Where a financial interest is involved, a declaration that the value is above or below €20,000 is required but the actual amount does not need to be declared. Financial securities should be valued using their market price at the date of declaration. For investment funds, the current value should be used if known, otherwise the value at last valuation by the fund management institution. For other interests, advice on valuation should be sought if required from the Director with responsibility for financial affairs. For companies where the valuation is unknown (i.e. privately owned) the percentage shareholding should be disclosed.

Each year members of the Authority, committees, external experts and staff are asked to confirm whether there have been any changes to their interests. However, it is important to note that the onus is on the person to report changes immediately after they happen rather than waiting to be asked to update their declaration of interests.

Where the declaration relates to a close family member, the name of the family member does not have to be declared.

Any person who is involved in or who may influence the award of a contract by the HPRA must disclose any direct or indirect interest which could be perceived to compromise the integrity of the award process.

Individuals are only required to declare interests of which they are or should be aware.

In case of doubt as to whether an interest should be declared in line with this policy, the person should always make a declaration, either in the declaration of interest form (if aware of the interest) or when the particular matter is under assessment. The person may also seek the guidance of the chairperson (Authority and committee members), manager (staff and experts) or the Scientific Affairs Manager.

Where an Authority member is in doubt as to whether he or she has an obligation under the Ethics in Public Office Acts 1995 and 2001, he or she should seek advice from the Standards in Public Office Commission.

5.2 Direct financial interests

Direct financial interests held by the person or a close family member in a sector or organisation regulated by the HPRA include:

- Equity securities, e.g. stocks, shareholdings
- Debt securities, e.g. bonds, debentures
- Hybrid securities, e.g. preference shares
- Derivatives, e.g. futures, options

- Partnership interests
- Patent interests
- Business/trade with the company, e.g. a supplier to the company
- Compensation, fees, honoraria, grants or other funding paid to the person in a personal capacity other than payment for or reimbursement of expenses incurred with research work or reimbursement of reasonable expenses directly related to attendance at a conference or seminar (i.e. accommodation and travel costs)

Direct financial interests in any other industry sector (e.g. IT, management consultancy, travel, training) or an organisation must also be declared if they relate to a person's activities in the HPRA and they are involved in any decisions on contracts between the HPRA and companies in that sector.

Diversified stocks or shareholdings (i.e. not exclusively based on sectors regulated by the HPRA) over which the person or their close family member has no control need not be declared, e.g. holdings in a managed investment fund or similar, where the choice of companies to invest in is at the total discretion of the fund manager. However, if the stocks or shareholdings are not diversified or if the person or a close family member is able to instruct the fund manager as to the composition of the fund, then the holding must be declared.

Accrued pension rights from employment in any industry company do not need to be declared.

Where the interest derives from a patent, the name of the substance, product or process concerned by the patent must be declared.

5.3 Indirect financial interests

Indirect financial interests held by the person or a close family member in a sector or organisation regulated by the HPRA include:

- Non-paid consultancy work
- Payment to a department or organisation for which the person or a close family member is responsible but which is not received personally, e.g. fellowships, sponsorships, grants, commissions, non-financial supports or benefits

Where the interest relates to a specific substance or product, the name of the substance or product must be declared.

5.4 Industry funding of organisations or institutions

In general, it is recognised that industry funding of organisations (such as university/teaching hospitals) is paid to, and is for the benefit of, the organisation and is not a payment to a particular expert. In addition, the funding is often general in nature rather than product-specific.

The following guidelines apply to declarations of industry funding by Authority and committee members and other external experts:

- Authority members, committee members and experts should declare all current industry funding received by an organisation or institution which is used to support any of the member's or expert's activities (for example, research).
- The purpose of the funding and its relevance to their personal activities within the organisation or institution should be declared. It should also be stated whether the funding is general in nature or relates to a specific product.
- In the event that the funding relates to a specific product, the member or expert should consider themselves conflicted in relation to the product to which the funding relates and any direct competitor products and exclude themselves from any meeting, for that part of the meeting when such products are discussed.
- In the event that the total value of the funding is equal to or greater than €20,000, they should consider themselves conflicted in relation to the company and its products.
- In the event that the total value of the funding is less than €20,000, a declaration should be made but it may not result in a conflict depending on the circumstances (for example, if the funding related to the purchase of equipment for use by multiple researchers within the institution).

5.5 Employment

Details of current or past paid or unpaid work by the person or a close family member in or for any sector or organisation that the HPRA regulates, in any capacity including but not limited to:

- Employee
- Consultant
- Partner
- Clinical investigator
- Member of a steering committee
- Member of a scientific or advisory committee
- Non-executive director

If the person or a close family member was involved in the development of a particular substance, medicinal product, medical device or healthcare product, the name of the substance or product must be declared and a description of the nature of their involvement must be provided.

5.6 Clinical trial interests

The majority of experts on the advisory committees and subcommittees come from academia and the leading teaching hospitals and all are leaders in their area of expertise. It is recognised that, to provide the level of expertise that the HPRA requires, (sub)committee members will have a significant background in research of which clinical trials often play a key part. Consequently, many of our (sub)committee members are experienced in carrying out clinical trials and bring this valuable expertise to our assessment process. It is also recognised that almost all the universities and hospitals actively seek industry sponsorship for their research programmes. It therefore follows that many of our experts will be involved in research programmes funded

directly or indirectly by industry, may act as investigators or sponsors (so-called academic trials) on trials approved by the HPRA and may sit on ethics committees that approve certain aspects of the trials.
It is important to the HPRA and to the quality of the assessment process that such people give their services to the HPRA and we are particularly privileged that this service is given without payment. We consider that both the public interest and public health are served from their dedication and contribution to the HPRA. As a matter of good governance it is incumbent on us to manage any actual, potential or perceived conflict of interest that may arise.

Members of the Clinical Trials Subcommittee or Advisory Committee on Human Medicines providing advice on a trial to be approved by the HPRA:

- Committee members must declare any involvement with sponsors, funders, investigators or sites performing clinical trials in their declarations of interest form which will result in restrictions being put in place relating to any related clinical trials.
- The HPRA will not circulate any assessment papers to committee members who have a potential conflict in relation to a clinical trial.
- Members will declare at the start of the meeting if they have any interest related to clinical trials listed for discussion and absent themselves from that part of the meeting (and similarly from all subsequent meetings) when the trial is being discussed. This will be recorded in the minutes of the meeting.
- Members will inform the meeting chairperson where similar trials involving a competitor product are to be discussed. The meeting chairperson will consider whether any conflict of interest is likely to arise and will advise accordingly. This will be recorded in the minutes of the meeting.
- Documents sent to the HPRA Leadership Team for approval will note that potential conflicts of interests have been declared by a member of the committee(s) and will indicate that he/she has complied with the requirements above.
- Should a significant issue arise with an ongoing trial where the matter is referred to a committee, in circumstances where a committee member has a potential conflict of interest relating to that trial, the committee member will declare their interest at the start of the meeting and absent themselves from the relevant part of the meeting (and similarly from all subsequent meetings where the trial is being discussed). The chairperson may, at his or her discretion, decide that the issue is so significant that the committee member may be asked not to attend the committee until the matter is resolved.

Members of the Clinical Trials Subcommittee or Advisory Committee on Human Medicines who are a member of the ethics committee which has approved the trial:

- Members should declare that they were a member of the ethics committee that approved the trial and absent themselves from any discussion in relation to the trial.

The above rules should also be considered where it is proposed to seek advice from an expert who is not a member of the Clinical Trials Subcommittee or Advisory Committee on Human Medicines in relation to any clinical trial application.

5.7 Other interests, matters or connections

Any other direct or indirect interest or matter or connection relating to the person or a close family member in any sector or organisation that the HPRA regulates must be declared. A list of possible other interests is given below but the list is not exhaustive.

- The person has made positive or negative public statements about a particular company or product or class of products or about a competitor's product or class of products.
- The person or their department has undertaken research on a particular product or class of product and, although not funded by industry, has taken a particular line regarding the product, e.g. its quality or safety.
- The person participates in, or is connected with, a charity or pressure group that would have an interest in the outcome of the advice or decision.
- The person has a family member who suffers from an illness which might benefit from treatment if a product under discussion were approved.
- The person has a family member who has suffered a severe reaction or other problem as a result of treatment with a product under discussion.
- The person has someone who is closely connected to them, e.g. sibling or close friend, whose work or other interests are closely associated with any industry that the HPRA regulates and which could reasonably be perceived as affecting the person's impartiality.
- The person has received gifts or hospitality from any industry that the HPRA regulates (see below also).

6 EVALUATION OF CONFLICT OF INTERESTS

6.1 Evaluation process

Declarations of interest by members of the Authority, committees and external experts are evaluated by the Chief Executive (Authority members) or relevant HPRA director (committee members) and the Scientific Affairs Manager, who also assesses the declarations of interest by staff in conjunction with department management teams.

Where a question arises as to whether or not an interest declared by an Authority member is a material interest, the chairperson should determine whether the provisions of the Code of Practice for the Governance of State Bodies apply and whether the interest represents a conflict in line with this policy.

6.2 Evaluation criteria

The assessment of conflicts of interest takes into account the following:

1 Persons who have worked as employees, as well as non-executive directors and partners, for a company or organisation should be considered to have a conflict of interest for a minimum period of three years after their work with the company or

organisation ended. For employees, this three year period may be extended to up to five years following an assessment of the following criteria:

- Seniority of the person
- Role they carried out
- Length of time with the company
- Any existing involvement with the company
- Level of contact that they may have had with the company
- Relationships that they may have with persons in the company
- Where a company merges with, or is taken over by another company, any conflict relates only to the sites and products of the original company

Persons who have worked as employees, as well as non-executive directors and partners, for a company or organisation more than five years previously will generally not be considered to have a conflict of interest, but it will be a matter for the individual and the chairperson or their manager (as appropriate) to confirm that this position is correct.

2 Persons who have acted as consultants, investigators or as members of a steering committee or a scientific or advisory committee should be considered to have a conflict of interest with respect to the company or product as appropriate for a period of three years after that role ended. After three years they will generally not be considered to have a conflict of interest but it will be a matter for the individual and the chairperson or their manager (as appropriate) to confirm that this position is correct.

3 Persons who have held direct and specific responsibility for the development of a specific product under discussion/decision should always be considered to have a conflict of interest with respect to that product. They may also be considered to have a conflict of interest in relation to competitor products in situations where there are only a very small number (one to two) of competitor products. In situations where there are a larger number of competitor products, the existing extent of competition would adequately dilute potential interests.

Examples of roles involving specific responsibility for product development would include:

- Clinical programme/project manager
- Product manager/specialist
- Programme leader/manager
- Project leader/manager

Indirect support roles such as performing quality control tests on products under development as well as commercial products would not necessarily be considered to constitute specific responsibility for product development and will be considered on a case-by-case basis.

Where a person has developed expertise in a specific class of products while working in industry, this will not normally give rise to a conflict of interest, subject to the specifics in an individual case which should be reviewed by the manager or chairperson as appropriate.

It will be a matter for the chairperson or manager (as appropriate), having consulted with the person, to determine whether a conflict exists. Where more than one interest is declared, all interests will be evaluated and the most restrictive approach addressing all declared interests will be applied.

6.3 Evaluation outcome

If a conflict of interest is established for an Authority or committee member, the chairperson of the Authority or committee is notified and the person must follow the requirements of Section 24 of the Irish Medicines Board Acts, 1995 and 2006. An agenda item on declarations of interests is included at the beginning of each meeting's agenda. Where a conflict of interest is known in advance of the meeting, the member concerned should not receive meeting papers or minutes concerning the relevant agenda item.

Staff who hold any direct financial interest must dispose of it when joining the HPRA. Staff who hold share options via employee share schemes are permitted to keep them until the date of exercise; however, this will limit the work they may do while they retain the share options. Staff members may not increase their options while employed by the HPRA and must exercise the options and dispose of them at the exercise date.

HPRA staff are prohibited from taking part in any activity relating to a previous employer in any sector or organisation regulated by the HPRA for a period of at least three years after leaving a previous employer. This period may be extended to up to five years, as indicated in point 1 in section 6.2 above.

Employees are also prohibited from ever taking part in any activity relating to a medicinal product, medical device or cosmetic where they had direct and specific responsibility for product development and may also be considered to have a conflict of interest in relation to competitor products in situations where there are only a very small number (one to two) of competitor products.

Staff holding share options may not work on any application or product from the company in which they hold options. Neither may they work on any application or product which would be in direct competition with an application or product of the company in which they hold options.

6.4 Joint inspections or audits

Where HPRA inspectors or auditors are accompanied on inspection or audit by staff from another agency of the State, of a Member State, of the European Commission or international

government agency, the HPRA relies on the policies and procedures of the other agency to ensure that no conflict of interest arises with respect to those staff.

6.5 Breaches of trust

Failure to declare all interests or failure to declare an interest which has the potential for conflict may be considered as a *prima facie* breach of trust towards the HPRA. The HPRA considers this a very serious matter as it is essential that our scientific and regulatory decision-making are independent and impartial.

In the event that the HPRA discovers or is made aware that a declaration is incomplete, clarification of the situation will be sought from the individual concerned with the objective of resolving any possible conflict. In the meantime, the person's involvement in HPRA activities will be restricted as considered appropriate pending clarification of the situation. Appropriate corrective action will be taken following due process.

7 INSIDER DEALING

The use of information gained during employment or engagement with the HPRA to benefit the private investments of the person, a close family member or a person closely connected with them is prohibited under this policy. In addition, the use of any material non-public information which is likely to affect a company's share price to trade or encourage others to trade in the company's shares is prohibited by law.

8 GIFTS

8.1 General principles

As a general principle, gifts should not be accepted if they might be seen as compromising personal or professional integrity. The actions of those employed or engaged in the activities of the HPRA must be above suspicion and not give rise to any conflict of interest, and their dealings with commercial and other interests should bear the closest possible scrutiny.

For the purposes of these provisions, the term 'gift' includes any goods, service or benefit which is given to a member of the Authority, committees, external expert or staff free of charge or at less than its commercial price. The following general guidelines provide a framework within which specific decisions in this area can be made.

8.2 General guidelines

A person may not solicit gifts, directly or indirectly. Neither may they approach any business with which they have contact through their official duties seeking sponsorship or support for

any club, association, trade union or other organisation with which they are associated in a personal capacity.

The requirements of these guidelines apply to members of the Authority, committees, and experts only in relation to their role with the HPRA. However, in accepting gifts in circumstances outside this role, they should be mindful of the general principles outlined above.

Gifts to a spouse or child of a member of the Authority, committees, experts and staff should be treated in the same way as gifts to the individuals employed or engaged in the activities of the HPRA if they are given by virtue of the individual's involvement in the HPRA.

The following may be accepted and retained:
- Branded items such as pens, paper, folders, diaries, bags and lanyards (for name tags) These may be provided by conference or meeting organisers or during events organised by other industry associated organisations/companies. Such items may be used for the duration of the conference, meeting or event and may be retained but must not be used during any subsequent meetings, conferences or events that an individual is attending as part of their role with the HPRA and where attendees other than HPRA staff may be present.
- Conventional personal gifts, such as flowers, fruit or confectionary, in appropriate circumstances
- Gifts of modest value, such as confectionary for distribution among a section or department
- Gifts from someone in a company or organisation the HPRA regulates with whom the staff member has formed a personal friendship, provided that the gift is a personal gift and not provided or paid for by the company
- Gifts from a company or organisation the HPRA regulates where it is the custom in the country concerned to give such gifts and where to decline may cause offence

Particular care should be taken in relation to gifts from donors who stand to derive a personal or commercial benefit from their relationship with the HPRA.
The following may not be accepted:
- Gifts of a more significant value
- Cash, cash vouchers or cash equivalents regardless of the amount
- Special facilities or discounts on private purchases from suppliers with whom they have official dealings (however, benefits under frequent travel schemes may be retained by individual staff members in recognition of the fact that official travel is disruptive to personal and family life)
- Subsidies for HPRA social events

8.3 Reporting

Staff must report all offers of gifts, other than promotional gifts, to their manager, and must return any items received which are in breach of this policy, explaining that receipt is not permitted under this policy. Any gift that is perishable and cannot be returned should be

disposed of or, at the discretion of the manager, may be shared among a group of staff or given to charity.

Members of the Authority and committees must report all offers of gifts, other than promotional gifts, which have been offered to them in their role as persons engaged in the activities of the HPRA, to the relevant chairperson. Experts should report offers to the HPRA manager by whom they have been engaged.

8.4 Gifts from the HPRA

The HPRA does not normally provide gifts to any company or organisation it regulates, or to its suppliers. If, in exceptional circumstances, it is proposed to do so, approval from the relevant director must be obtained in advance. It must be made clear in making the gift that no reciprocation is to be made; however, it is recognised that, in certain countries, small gifts are exchanged as a token of welcome and respect.

As part of the European or international network, gifts can, for example, be given to fellow regulators as part of the European presidency or similar events.

The HPRA can, in appropriate circumstances, gift money to charity and may recognise significant staff or Authority events with a modest gift.

9 HOSPITALITY

9.1 General principles

As a general principle, hospitality that might be seen as compromising personal or professional integrity should not be accepted. The actions of members of the Authority, committees, external experts and staff must be above suspicion and not give rise to any conflict of interest, and their dealings with commercial and other interests should bear the closest possible scrutiny. It is accepted that staff should not be put in a position where they cannot accept what are regarded as normal courtesies in business relationships or where it is the custom in the country concerned to provide hospitality and where to decline may cause offence. That being said, in their contacts with outside organisations or persons, every care must be taken by staff to ensure that their acceptance of hospitality does not influence them, and could not reasonably be seen to influence them, in discharging their official functions.

The requirements of these guidelines apply to members of the Authority, its committees, and experts only in relation to their role with the HPRA. However, in accepting hospitality in circumstances outside this role, they should be mindful of the general principles outlined above.

For the purposes of these provisions, 'hospitality' is defined as meals, drinks, social functions, travel, accommodation or entertainment. The following general guidelines provide a framework within which specific decisions in this area can be made.

9.2 General guidelines

No objection would normally be taken to the acceptance of what is regarded as routine hospitality, the most obvious example being a business lunch. What may be regarded as 'routine' for this purpose will depend on a number of factors such as the value of the hospitality offered, the frequency of offers, whether there is an element of reciprocity and the circumstances in which it is offered (for example, whether it is offered by a company to all its customers or is directed at specific customers or potential customers). Certain types of hospitality (for example, involving travelling abroad or holiday weekends) are not regarded as routine and should always be refused.

All offers of hospitality from commercial interests which have had or might have contractual relations with the HPRA are particularly sensitive, especially where staff are directly involved in negotiating contracts. All such offers must be reported by the staff member to his/her manager for direction.

Acceptance of entertainment is only allowed in exceptional circumstances. Approval will not be given to the acceptance of tickets to cultural or sporting events, entertainment where the host is not present, use of company property such as holiday homes, or extensions of business trips for personal purposes.

9.3 Declaration and reporting

Staff members must declare all hospitality offers other than routine hospitality. They should not accept offers of hospitality which go beyond the routine practices referred to above, except where acceptance of such an offer can be clearly shown to be in the interest of the HPRA and has been approved by the manager of the staff member.

Members of the Authority and committees must report all offers of hospitality, other than routine, which have been offered to them in their role as persons engaged in the activities of the HPRA, to the relevant chairperson. Experts should report offers to the HPRA manager by whom they have been engaged.

9.4 Hospitality provided by the HPRA

Hospitality provided by the HPRA to companies, suppliers and external auditors, such as business meals and drinks, is provided at a modest level, usually during normal working hours. Entertainment is not provided, and the provision of alcohol is limited and reasonable.

10 EXTERNAL PRESENTATION AND PUBLICATIONS

10.1 Invitations

The HPRA organises information days and workshops and provides continuously-updated advice on its website. Therefore acceptance of invitations to give speeches, lectures or publications are subject to the availability of HPRA staff and HPRA priorities.

Staff wishing to publish a text, give a speech or lecture on a subject relating to the work of the HPRA and/or knowledge and experience gained from working at the HPRA must obtain permission in advance from their manager or director. Work relating to the HPRA is defined as the protection of public health through the regulation of medicines, medical devices and other healthcare products.

In permitting staff to make an external presentation or publication, the manager will take into account the benefits to the HPRA: organisation profile, communication of HPRA policies and requirements, reputation, and the source of the invitation. In principle, invitations from EU organisations or not-for-profit associations or congresses are acceptable. Invitations from other congresses or meetings organised by for-profit organisations or individual companies or associations in any sector or organisation regulated by the HPRA will only be accepted if approved by the relevant staff member's director. Such approval will be granted if the director considers that there is a benefit to the HPRA in the speech being made. Permission will not be granted if networking or gaining influence is assumed to be the major objective of the organiser when issuing the invitation to speak or publish.

Where it is not possible to clear a presentation or statement in advance, e.g. answers to questions in a panel discussion, it is advisable to give a disclaimer (e.g. that the views presented are those of the individual and may not be understood or quoted as to be made on behalf of the HPRA or to reflect the position of the HPRA).

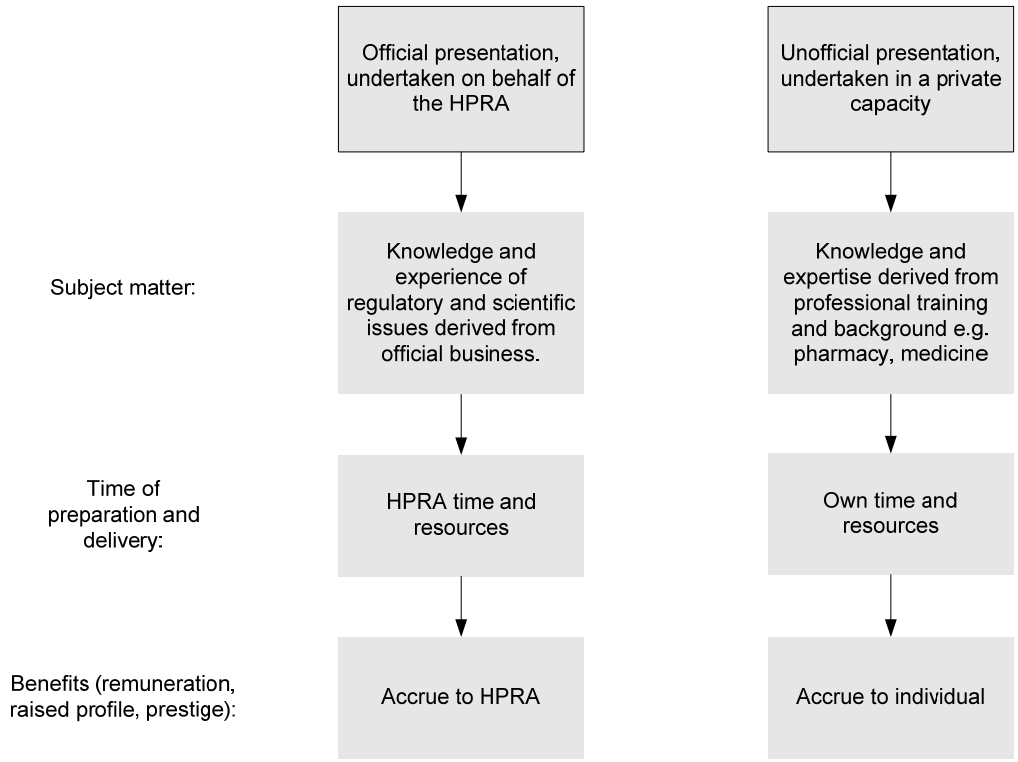
If permission is refused for an invitation to speak, publish or to participate at a meeting, conference or to represent the HPRA, it is not acceptable to attend during a weekend or by taking leave.

Lectures, talks, publications on matters not relating to HPRA work but drawing on staff's knowledge and experience from their professional training and development, e.g. pharmacy, medicine, toxicology, law or information technology, may be undertaken in a private capacity. In these cases, no references to the HPRA should be made. The presentation or publication should avoid any conflict with the work of the HPRA and nothing should be said or published that would be against the interests of the HPRA. If the presentation or publication relates to healthcare or health systems, the manager should be informed in advance.

Members of the Authority and committees should seek approval from the relevant chairperson for any lecture, speech or publication relating to the work of the HPRA.

10.2 Preparation and delivery

The graphic below summarises the differences between official presentations, undertaken on behalf of the HPRA, and unofficial presentations, undertaken in a private capacity.



The preparation of external presentations and publications undertaken on behalf of the HPRA may be done within working hours and using HPRA resources. Staff must ensure that the speech or document is consistent with the policies and practices of the HPRA. The HPRA logo must be used on any presentation, and reference to the staff member's employment in the HPRA made in any publication. The presentation or publication must be sent to the relevant manager for approval before submission to the meeting organisers or publishers.

The preparation of external presentations and publications undertaken in a private capacity must be done in the staff member's own time and using their own resources. No reference to the HPRA by name or logo may be made in the presentation, publication or any associated promotional material.

Members of the Authority and committees may use HPRA resources in the preparation of external presentations and publications relating to the HPRA's work. The presentation or publication must be sent to the relevant chairperson for approval before submission to the

meeting organisers or publishers. External presentations, publications or promotional material relating to the member's professional role and undertaken in a private capacity may not make reference to the HPRA or use the HPRA's logo.

10.3 Fees and honoraria

All fees, honoraria and expenses paid for external presentations and publications relating to HPRA work must be paid directly to the HPRA. If a small gift is presented, this may be accepted by the staff member or Authority or committee member, so long as it complies with the requirements for gifts specified in section 8 above. For lectures or talks at a meeting, it is acceptable that the participation fee is waived and/or travel expenses are paid for by the inviting organisation.

Authority and committee members and staff may accept any fees, honoraria and expenses paid for external presentations and publications undertaken in a private capacity.

11 EXTERNAL ACTIVITIES AND EMPLOYMENT

Staff may not be employed, carry out any consultancy or paid work of any kind or act as a director or partner, in any sector or organisation regulated by the HPRA. Staff members must ensure that their non-HPRA activities do not interfere with their responsibilities to the HPRA either in time or in any other regard. In particular, they should ensure that the non-HPRA activity does not impair their independence or is not detrimental to the work of the HPRA.

Staff members may not be involved with any outside organisation, whether economic, social, cultural or political, or be employed in any outside employment (including self-employment) which may in any way represent, or may be reasonably interpreted as representing, a conflict of interest with any matter relating to the functions of the HPRA other than with the written consent of the Chief Executive. Staff may not use the name or standing of the HPRA in any outside activity or employment.

Staff may not engage in outside employment without the prior written consent of the HPRA. The Director of Human Resources and Change will decide on the most appropriate person to give this consent, depending on the individual circumstances. While it is accepted that staff may have outside financial interests provided they are not in conflict with the HPRA (as outlined in this policy), it is the general stated view that full-time employees should not have significant outside commitments. In particular, paid leave such as holidays should not be used for that purpose in accordance with the Working Time Acts.

Staff may not seek to use knowledge acquired in the performance of, or as a result of, their work in the HPRA to financially benefit themselves, or others with whom they have personal, family or other ties.

Authority and committee members and other external experts may not use the name or standing of the HPRA in any outside activity or employment. They may not seek to use knowledge acquired as a result of their participation in the work in the HPRA to financially benefit themselves, or others with whom they have personal, family or other ties.

12 EXPECTATIONS OF EMPLOYMENT AND ACCEPTANCE OF FURTHER EMPLOYMENT

A conflict of interest may arise where staff intend to resign from the HPRA and take up employment with a company or organisation that the HPRA regulates or one of its suppliers. In these circumstances, the staff member must inform his/her line manager as soon as possible of their intention to take up such employment and declare this as an interest by updating their declaration of interests form. This must be done prior to accepting any employment offer and appropriate restrictions will be immediately applied.

The 'Code of Practice for the Governance of State Bodies' advises that 'the acceptance of further employment where the potential for conflict of interest arises should be restricted during a reasonable period of time after the exercise of a function in the State body has ceased.'

13 CONFIDENTIALITY AFTER RESIGNATION OR RETIREMENT

Members of the Authority, committees, external experts and staff have a life-long duty of confidentiality even after they have ceased their relationship with the HPRA. They may not use or disclose any confidential information gathered during their association with the HPRA, regardless of the length of time that has elapsed. They must also continue to uphold the reputation and good standing of the HPRA.

APPENDIX 1 RELEVANT STATUTORY AND OTHER OBLIGATIONS

1 Sections 23 and 24 of the Irish Medicines Board Acts, 1995 and 2006 make requirements in respect of confidentiality of information and disclosure of interests.

2 Article 126b of Directive 2001/83/EC, as amended by Directive 2004/27/EC, requires staff and experts concerned with the authorisation and surveillance of medicinal products to have no financial or other interest in the pharmaceutical industry which might affect their impartiality.

'In order to guarantee independence and transparency, the Member States shall ensure that members of staff of the competent authority responsible for granting authorisations, rapporteurs and experts concerned with the authorisation and surveillance of medicinal products have no financial or other interests in the pharmaceutical industry which could affect their impartiality. These persons shall make an annual declaration of their financial interests.'

3 Article 9(1) of the Clinical Trials Regulation (Regulation (EU) No 536/2014) requires Member States to ensure that persons validating and assessing clinical trial applications do not have conflicts of interests and lists some specific expectations in this regard as well as requiring annual declarations of interests to be made.

'Member States shall ensure that the persons validating and assessing the application do not have conflicts of interest, are independent of the sponsor, of the clinical trial site and the investigators involved and of persons financing the clinical trial, as well as free of any other undue influence.

In order to guarantee independence and transparency, the Member States shall ensure that persons admitting and assessing the application as regards the aspects addressed in Parts I and II of the assessment report have no financial or personal interests which could affect their impartiality. These persons shall make an annual declaration of their financial interests.'

4 The Ethics in Public Office Acts, 1995 and 2001, Sections 17 and 18, require statements of interest from designated persons.

5 The European Medicines Agency requires all experts involved in its scientific work to sign a 'Public Declaration of Interests and Confidentiality Undertaking' form.