HPRA
An tÚdarás Rialála Táirgí Sláinte
Health Products Regulatory Authority

Health Products Regulatory Authority
Conflicts of Interest Policy for Staff Members

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CONTENTS

1 SCOPE

This policy document applies to HPRA staff members. Conflicts of interest for members of the HPRA Authority, (sub)committees and external experts are covered in a separate policy document. .

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. Staff 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 are derived from relevant statutory and other obligations as listed in Appendix 1.

The primary and most important of these is the Irish Medicines Board Acts, 1995 (as amended) 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, 1995 and 2001 require declarations in relation to interests held by specified persons.

It is expected and indeed desirable that some staff members will have worked in industries that the HPRA regulates. In cases where a staff member 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.

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. 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 HPRA requirements

In addition to complying with legislative requirements, and, where applicable, requirements of the Code of Practice, staff members 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, staff should consult their manager.

To avoid any conflicts of interest or the perception of conflicts, the HPRA requires 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 industry or organisation regulated by the HPRA.

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, distribution, marketing, sale or supply of medicinal products for human or veterinary use, medical devices, substances of human origin intended for human application (including blood, tissues and cells, organs), cosmetics, testing on animals for scientific purposes, and certain aspects of substances controlled under the Misuse of Drugs Act. Trade associations representing companies involved in such activities, consultancy companies providing advice or services relating to the above activities, contract research organisations, sponsors, funders and sites involved in clinical trials or clinical investigations are also included.

4.2 Close family members

These are considered to be first-line members of the family of the staff member (i.e. a spouse, partner, (step)children and (step)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 how to value the interest 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 staff members 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.

Where an interest relates to a specific substance or product, the name of the substance or product must 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, staff members 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. They may also seek the guidance of their manager or a designated staff member with responsibility for the evaluation of declarations of interests.

References to 'health products' in this policy are intended to refer to health products that fall within the HPRA's regulatory remit and do not include health products that are regulated by other competent authorities (e.g. food products, biocidal products, pesticides).

5.2 Direct interests

5.2.1 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
- Intellectual property rights including patents, trademarks, know-how and/or copyrights
- Business/trade with the company, e.g. a supplier to the company
- Compensation, fees, honoraria, grants or other funding (including rents, sponsorships and fellowships) 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, meals 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.

Staff members who passively acquire non-allowed financial interests, for example by way of an inheritance, should immediately submit an updated declarations of interest form with details of the new interest. That interest will need to be disposed of within a stipulated timeframe from acquisition of title to such interests, which will normally not be longer than six months. Appropriate restrictions will be put in place to prevent any conflicts of interest in the interim period.

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

Where the interest derives from an intellectual property right, the name of the substance, product or process concerned must be declared.

5.2.2 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
- Non-executive director
- Partner
- Consultant
- Member of a (scientific) advisory board, steering committee, executive committee

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.

5.2.3 Involvement in research organisations

Details of involvement (through employment or collaboration) in research organisations involved in activities subject to the HPRA's regulatory oversight should be provided. Examples include:
- Involvement in a unit of a research organisation that manufactures health products
- Involvement in a unit of a research organisation that makes regulatory applications or conducts regulated activities for health products
- Involvement in the conduct of research and development activities at a research organisation for health products subject to agreement with a company. This includes, for example, situations where the research organisation is involved in the development of a health product through sponsorship or any form of commercial arrangement with a company. It excludes activities related to the role of a (principal) investigator, consultancy/strategic

advisory roles and arrangement with a company related to the provision of health products for investigator-initiated trials.
- Involvement in a research organisation that conducts research involving animals for scientific purposes

5.3 Indirect interests

5.3.1 Clinical study interests

Involvement as a principal investigator or investigator responsible for the conduct of the following clinical studies should be declared:
- Clinical trials for medicinal products
- Clinical investigations for medical devices
- Performance studies for *in vitro* diagnostics

Participation in data monitoring committees or any involvement with sponsors, funders, or sites performing such studies should also be declared.

When declaring such interests, individuals should confirm the sponsor/instigator of the study in question.

Involvement in an ethics committee which reviews/approves clinical trials from an ethics perspective should also be declared.

5.4 Affiliation to a research organisation

Any involvement in (including employment) or association with any research organisation conducting research that could be subject to regulatory oversight or review by the HPRA, whether full-time or part-time, paid or unpaid.

In the event that the individual is involved in preparing regulatory submissions or requests for regulatory or scientific advice from the HPRA on behalf of a research organisation, this should be stated.

5.5 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 representative organisation that would have an interest in the outcome of the advice or decision.
- 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 for HPRA staff are evaluated by a designated officer with responsibility for conflicts of interest, in conjunction with the staff member's section manager, director or the Chief Executive as appropriate.

For the purpose of this policy, a current interest shall mean an interest that exists at the time of the completion of a declaration of interest or at the time of involvement in a specific activity. An engagement/contact of a recurring nature is considered a current interest.

6.2 Evaluation criteria

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

1 Staff who hold any 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.

2 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 period of three years after their work with the company or organisation ended. For individuals who previously held very senior/executive roles or were non-executive directors and partners, 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 acted as consultants, investigators or as members of a steering committee or a (scientific) advisory board, steering committee, executive 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. However, in the event that the HPRA only has access to a limited number of staff with essential expertise, no other suitable staff member is available and the need for such expertise is considered to outweigh any concerns in relation to a potential competing interest, it may be agreed to engage the staff member to in relation to a product for the same condition other than the one that they were personally involved in. In such cases the rationale for using the staff member and their input should be clearly documented, subject to appropriate quality assurance steps and be limited to aspects where their specialised expertise is needed.

Persons who in the past 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 and an indefinite restriction should be applied relating to that product.
Where the specific responsibility for product development included clinical or non-clinical development, persons should also be considered to have a conflict of interest in relation to products intended for the same condition for a period of three years after their involvement in product development ended. In justified and documented cases, exceptions may be made with respect to products that although intended for the same condition, have separate and clearly distinct clinical applications which mean that they are not in competition with each other in clinical practice.
Where the specific responsibility for product development was limited to quality aspects, the three-year restriction related to other products will be limited to products containing the same active substance(s).

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 as appropriate.

3 The assessment of conflicts of interest declared with respect to close family members should focus on current involvement in industry, organisations and products regulated by the HPRA. Such interests should lead to a restriction preventing involvement in HPRA decision-making and associated discussions relating to the relevant industry, organisation or product for the duration of the relevant interest.

4 Persons who are employed by or are affiliated with research organisations conducting research that could be subject to regulatory oversight or review by the HPRA should be subject to appropriate restrictions on their involvement in HPRA decision making related to that organisation for a period of three years after the employment/affiliation ended. In the event that the HPRA only has access to a limited number of staff or experts with essential expertise, no other suitable expert is available and the need for such expertise is considered to outweigh any concerns in relation to a potential competing interest, a similar approach to that described in point 2 above may also be considered in this scenario.

It will be a matter for the manager, 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

For staff members, following the review of any declared interests by the designated officer in conjunction with the staff member's section manager, director or the Chief Executive as appropriate, scheduling restrictions will be defined. These restrictions will be communicated to the staff member and the relevant department scheduler(s) who, along with the relevant manager, will apply those restrictions.

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. 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 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.

Gifts to a spouse or child of 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.

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 staff members 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.

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 their 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.

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.

10.2 Preparation and delivery

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

Table 1: Difference between official and unofficial presentations

	Official presentation undertaken on behalf of the HPRA	Unofficial presentation, undertaken in a private capacity
Subject matter:	Knowledge and experience of regulatory and scientific issues derived from official business	Knowledge and expertise derived from professional training and background, e.g. pharmacy, medicine
Time of preparation and delivery:	HPRA time and resources	Own time and resources
Benefits (remuneration, raised profile, prestige):	Accrue to HPRA	Accrue to individual

The preparation of official external presentations and publications undertaken on behalf of the HPRA may be done within working hours and using HPRA resources. The subject matter will be based on knowledge and experience of regulatory and scientific issues derived from official business. 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. Any benefits (remuneration, prestige) are accrued to the HPRA.

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. The subject matter will be based on knowledge and experience of derived

from professional training and background. Any benefits (remuneration, prestige) are accrued to the individual.

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, so long as it complies with the requirements for gifts specified in section 8 above. For lectures or talks at a meeting or conference, it is acceptable that the participation fee is waived and/or travel expenses are paid for by the inviting organisation.

Staff members 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 industry 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 Development 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.

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 their 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

Staff members 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

2 Ethics in Public Office Act, 1995 and 2001

3 Article 126b of Directive 2001/83/EC on medicinal products for human use

4 Article 123(8) of Regulation (EU) 2019/6 on veterinary medicinal products

5 Article 9(1) of Regulation (EU) 536/2014 on clinical trials of medicinal products for human use

6 Articles 35(2), 71(1) and 107 of Regulation (EU) 2017/745 on medical devices

7 Article 67(1) and Regulation (EU) 2017/746 on *in vitro* diagnostic medical devices

8 Article 6 of Regulation (EU) 2024/1938 on standards of quality and safety for substances of human origin intended for human application

9 In line with the Memorandum of understanding (MoU) between national competent authorities (NCAs) and the European Medicines Agency (EMA), NCAs have the obligation to monitor the scientific level and independence of evaluation carried out by NCAs for services to be provided to the EMA.