

Health Products Regulatory Authority

Code of Conduct



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1 SCOPE

This Code of Conduct sets out the values, standards and principles of ethics and behaviour which apply to those working in the HPRA or involved in its activities.

The requirements outlined in this document apply to the members of the HPRA (appointed by the Minister for Health under Section 7 of the Irish Medicines Board Acts 1995 and 2006 (hereafter referred to as 'members of the Authority'), to its committees, subcommittees and working parties, and experts, and to all staff of the HPRA, whether full-time or part-time, and to staff on special leave such as career breaks, except where specific requirements only apply to staff at work. In the context of this document, 'Authority, committees, external experts and staff' is taken to include all of the above groups.

Specific rules on conflicts of interest are detailed in a separate document, the HPRA Conflicts of Interest Policy.

2 INTRODUCTION

The HPRA's mission is to ~~protect and enhance public and animal health through the regulation of medicines, medical devices and other healthcare products~~ regulate medicines and devices for the benefit of people and animals. Its role has a significant impact on the availability of products which are safe and effective to use and which contribute to the health of patients, users and animals. In fulfilling its duties to Irish society, the Authority requires that its activities are conducted with professional integrity, high standards of service and appropriate behaviours at work.

The objectives of this Code of Conduct are to:

- establish an agreed set of values, standards and principles of ethics and behaviour
- promote and maintain confidence and trust
- prevent the development or acceptance of unethical practices

A copy of this Code of Conduct and the Conflicts of Interest Policy is given to all members of the Authority, committees, external experts and staff when they become associated with the activities of the HPRA and they are required to confirm that they have read and understood the documents and will comply with them. These documents are available on the HPRA's website and a copy of each document can be provided directly to any member of the public who requests it.

The Code of Conduct and the Conflicts of Interest Policy are reviewed on a regular basis.

3 STANDARDS OF INTEGRITY

3.1 Improper influence

Members of the Authority, committees, external experts and staff must not:

- be guided by any outside influences of whatever kind, including political, commercial or stakeholder influences, or by personal interests
- be involved in taking a decision on a matter concerning their own beneficial interests or those of their family members and partners

3.2 Conflicts of interest

The rules on conflicts of interest are derived from the following legislative sources:

- Irish Medicines Board Acts, 1995 and 2006,
- Ethics in Public Office Acts, 1995 and 2001.
- Directive 2001/83/EC

Section 24(1) of the Irish Medicines Board Acts states 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.*

All persons contributing to the activities of the HPRA must declare and describe any potential conflict of interest before undertaking any activity and signing this declaration is a condition of appointment. They may not participate in matters where they have a conflict of interest. Staff are specifically prohibited from having a financial or other interest in the industries which the HPRA regulates. In addition, staff must not be involved in outside employment or business interests in conflict with or in potential conflict with the HPRA's business or benefit financially from external sources by virtue of their HPRA employment. Staff members who intend to resign from the HPRA and take up employment in a sector or organisation

regulated by the HPRA must declare this as an interest prior to accepting any employment offer and appropriate restrictions will be applied.

Gifts and hospitality must not be solicited, either directly or indirectly, for personal use, gain or benefit. The offer of any unsolicited gift or hospitality which could affect, or could be considered to affect, the ability of members of the Authority, committees, external experts and staff to perform their activities with independence and impartiality must be refused. However, gifts or hospitality of a modest nature may be retained provided the offer is declared to the individual's manager or committee chairperson.

Members of the Authority, committees, external experts and staff must comply with specific guidance on declarations of interest, gifts, hospitality, invitations to speak, fees, external activities and employment and expectations of employment as may be laid down from time-to-time.

Further information and direction on these and other aspects related to conflicts of interest is provided in the HPRA's Conflicts of Interest Policy.

4 STANDARDS OF SERVICE

4.1 Disclosure of information

Under the Freedom of Information Act 2014, individuals may access and correct personal information, may request access to all records held by the HPRA (consistent with the public interest and third-party rights in relation to the data) and may request access to the reasons for a decision taken by the HPRA. Staff will comply with the requirements of the Freedom of Information Act and will facilitate where possible other requests for information including oral requests. Guidance on how information is provided by the HPRA is given in the 'Guide to Information held by the HPRA'.

Staff who deal with personal data concerning members of the public will comply with applicable Irish and EU data protection legislation. Staff are prohibited from processing personal data for non-legitimate purposes or the transmission of such data to non-authorised persons.

Much of the information provided to the HPRA is of a confidential nature, relating to patients, healthcare professionals and the industries the HPRA regulates. Members of the Authority, committees, external experts and staff are obliged not to disclose any information obtained while performing, or as a result of performing, any activities on behalf of the HPRA. This does not apply to information in the public domain or in the possession of the person prior to undertaking the activities. The disclosure of information to government Ministers, to regulatory authorities in EU Member States, to other agencies with which the HPRA has appropriate reciprocal confidentiality agreements, or to parties with whom there is a

legitimate requirement to share information may be permitted in compliance with legal obligations. Members of the Authority, committees, external experts and staff sign a confidentiality undertaking as a condition of appointment, and renew the undertaking annually.

Former members of the Authority should not retain documentation obtained during their terms as Authority members. Should they require access to papers from the time of their term, this can be facilitated by the Secretary to the Authority. The annual confidentiality undertaking signed by members of the Authority, its committees, external experts and staff includes provisions related to the handling and disposal of confidential documents.

Where, exceptionally, it is proposed to release confidential information in the public interest, the HPRA ensures that appropriate consultation with relevant third parties takes place prior to the release of any such information,

Those involved in the preparation and review of the HPRA's annual report and financial statements ensure that they accurately reflect the performance of the organisation and are not misleading or designed to be misleading.

4.2 Respect for the law

Members of the Authority, committees, external experts and staff will:

- act according to law and apply the rules and procedures laid down in Irish and European legislation;
- take due care that decisions which affect the rights or interests of individuals have a basis in law and that their content complies with the law; and
- exercise powers solely for the purposes for which they have been conferred by the relevant provisions of the legislation and in particular avoid using those powers for purposes which have no basis in the law or which are not motivated by any public interest.

4.3 Financial transactions

All activities relating to financial transactions, purchase of materials or the employment of staff are conducted in an open and objective manner to ensure that choices are seen to be based upon merit.

All persons engaged in purchasing goods or services on behalf of the HPRA have a duty to:

- act in the interests of the financial integrity of the HPRA and to seek value for money
- comply with tendering and purchasing procedures, as well as complying with prescribed levels of authority for sanctioning any relevant expenditure
- ensure that the requirements of the conflict of interest provisions are met in respect of any beneficial interest in a company which may supply goods or services to the HPRA
- comply with the system of internal controls to prevent fraud, corruption and other irregularities

4.4 Professionalism

When dealing with stakeholders, staff will be service-minded, courteous and accessible. The 'Standards of Service' section of the HPRA website outlines the standards of service which stakeholders may expect when contacting the HPRA.

Staff will follow the HPRA's procedures and practices, unless there are legitimate grounds for departing from them in an individual case.

When taking decisions, staff will:

- ensure that the measures taken are proportional to the aim pursued
- avoid restricting the rights of stakeholders or imposing charges on them when those restrictions or charges are not reasonable in relation to the purpose of the action pursued
- strike a fair balance between the interests of individual stakeholders and the general interests of public and animal health
- take into consideration the relevant factors and give each of them its proper weight in the decision, whilst excluding any irrelevant elements from consideration
- respect the legitimate and reasonable expectation of stakeholders that decisions will be consistent both between different staff and at different times

4.5 Fairness

Staff will act fairly and reasonably by:

- complying with employment equality and equal status legislation
- avoiding any unjustified discrimination between individuals based on nationality, sex, racial or ethnic origin, religion or belief, disability, age, or sexual orientation
- ensuring equality of treatment, i.e., persons who are in the same situation are treated in a similar manner
- ensuring that actions do not arbitrarily affect any stakeholder adversely or give preferential treatment to any stakeholder on any grounds whatsoever
- ensuring that any difference in treatment is justified by the objective relevant features of the particular case.

Internal audits are regularly performed to ensure ongoing compliance with these standards of service and members of the Authority, committees, external experts and staff are expected to participate as required and co-operate with the internal audit process.

5 BEHAVIOURS AT WORK

5.1 Loyalty

Members of the Authority, committees, external experts and staff will be loyal to the HPRA and fully committed in all its activities, and conform to the highest standards of conduct.

Members of the Authority and its committees will use their reasonable endeavours to attend all respective meetings.

5.2 Regard for resources

Staff are required to take reasonable care of public funds and HPRA property and not to use them for unauthorised purposes. They should ensure that expenses, particularly travel and subsistence payments, are claimed only as appropriate to business needs and in accordance with good practice in the public sector and are not incurred unnecessarily by themselves or by staff who report to them.

Members of the Authority, committees, external experts and staff must not use the HPRA's resources or time for personal gain or for the benefit of persons or organisations unconnected with the HPRA or its activities.

5.3 Fraud, wrongdoing and unethical behaviour

Members of the Authority, its committees, external experts and staff have a duty to conform to the highest standard of business ethics.

Each member of the Authority and all those who occupy designated positions of employment under the Ethics in Public Office Acts must comply with relevant provisions of the legislation.

All staff have a responsibility to help to prevent fraud, wrongdoing and unethical behaviour such as improper use of resources or the pursuit of a benefit or advantage in violation of this Code. Staff who are concerned about fraud, wrongdoing or unethical behaviour should raise their concerns in writing with senior management and will be considered to have done their duty even if reasonable grounds for believing the concern to be true are not found so long as the concern was raised in good faith. Any staff member against whom a justified concern has been raised will be subject to the disciplinary procedure.

6 WORK / EXTERNAL ENVIRONMENT

The HPRA places the highest priority on promoting and preserving the health and safety of employees.

With regard to the external environment, the HPRA ensures that community concerns are fully considered and that any detrimental impact of its operations on the environment are minimised.