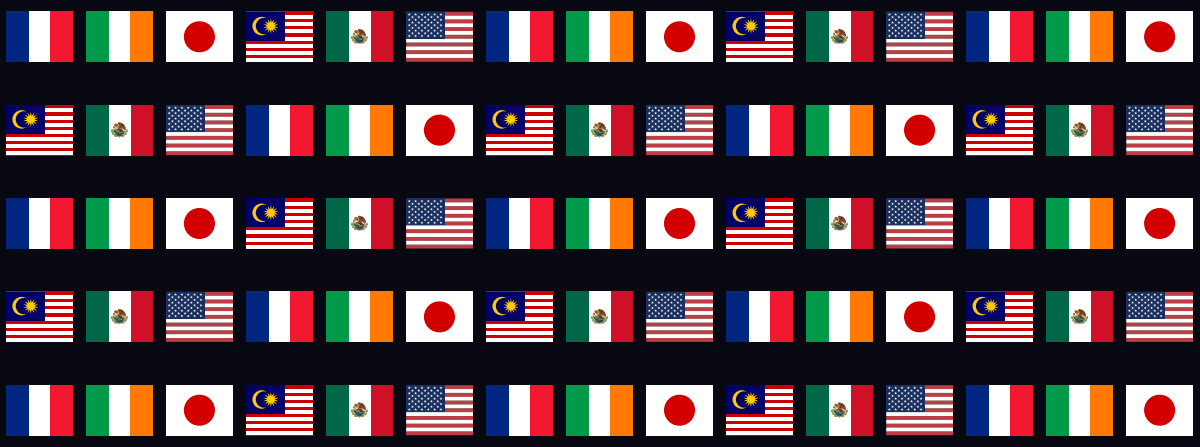
HEALTHCARE ENFORCEMENT & LITIGATION

Ireland



LEXOLOGY
Getting The Deal Through

Consulting editor
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Healthcare Enforcement & Litigation

Consulting editors

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Mintz

Quick reference guide enabling side-by-side comparison of local insights into the applicable regulatory, enforcement and litigation framework (for pharmaceutical products and medical devices, relationships between healthcare professionals and suppliers, and healthcare delivery); private enforcement, cross-border enforcement and extraterritoriality; and recent trends.

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OVERVIEW

Healthcare funding

In general terms, how is healthcare, including access to medicines and medical devices, funded in your jurisdiction? Outline the roles of the public and private sectors.

There is a two-tier health service in Ireland, comprising the public healthcare system and the private healthcare system. The public healthcare system is funded by the state. The private healthcare system is funded by private funds and private insurance.

Healthcare policy and expenditure in Ireland is determined by the Department of Health. Public healthcare services are provided by the Health Service Executive (HSE). The HSE owns and runs public hospitals. Other hospitals, known as voluntary public hospitals, receive state funding but are owned by religious orders or similar institutions.

In Ireland, every citizen is entitled to free or subsidised medicines and certain medical and surgical aids and appliances. The prices paid by the HSE for medicines are maintained on an official reimbursement list, and are set by reference to the Health (Pricing and Supply of Medical Goods) Act 2013 and industry agreements.

On 30 May 2017, the All-Party Oireachtas Committee on the Future of Healthcare published the Sláintecare Report, making recommendations on the future of healthcare in Ireland. The report makes recommendations such as free GP care for all, free public hospital care, cuts to the prescription charge and the cost of monthly drugs. All of the benefits listed in the report were to be phased in over the preceding years.

Throughout the covid-19 pandemic and the HSE cyber-attack, work progressed on the implementation of the reform priorities. There were, however, some inevitable impacts on timelines, as responding to the pandemic and maintaining service provision had to be prioritised.

In 2023, the Government published the Sláintecare 2023 Action Plan. This plan sets out the ongoing reform priorities aligned with the Programme for Government, the Sláintecare Implementation Strategy and Action Plan 2021–2023, Department of Health priorities and the HSE's National Service Plan 2023.

Law stated - 08 September 2023

Delivery

In general terms, how is healthcare delivered in your jurisdiction? Outline the roles of the public and private sectors.

Healthcare is mainly delivered by way of primary or secondary care. Primary healthcare services are provided outside of hospitals to people living in the community, for example by general practitioners, nurses, health clinics and so on. Secondary healthcare is delivered in hospitals to patients normally living at home, for example outpatient clinics, accident and emergency clinics. In recent years, more health insurers have provided secondary care such as 'home nursing' or 'treat at home' schemes.

Most medical treatment is available free of charge or subject to a subsidised charge under the public health system. In addition to private hospitals, a limited number of private beds in public hospitals facilitate the treatment of patients who opt for private health insurance. Recent Health Insurance Authority statistics suggest that approximately 47 per cent of the Irish population had private health insurance in 2021, a key benefit of which is avoiding lengthy public waiting lists for elective procedures.

Law stated - 08 September 2023

Key legislation

Identify the key legislation governing the delivery of healthcare and establishing the regulatory framework.

A wide variety of legislation governs the delivery of healthcare, including:

- the Health Acts 1947–2019: the statutory framework governing the national healthcare system;
- the Health Act 2007: establishing the Health Information and Quality Authority (HIQA); and
- the Medical Practitioners Act 2007 (as amended): establishing the Medical Council.

Other legislation governs healthcare professions such as the Dentists Act 1985, the Nurses and Midwives Act 2011, the Pharmacy Act 2007 and the Health and Social Care Professionals Act 2005.

Law stated - 08 September 2023

Responsible agencies

Which agencies are principally responsible for the enforcement of laws and rules applicable to the delivery of healthcare?

A number of bodies are responsible for the enforcement of laws and rules applicable to the delivery of healthcare. For example:

- HIQA is responsible for setting standards for the safety and quality of public or publicly funded hospitals and healthcare services, and social care and residential services. HIQA is responsible for the registration, oversight and scrutiny of designated health and social care services, which include public and private residential facilities for children and adults with disabilities and nursing homes (called designated centres). HIQA is funded by the Irish government and does not currently regulate private hospitals.
- the Medical Council is responsible for regulating doctors in Ireland. It is funded by the registration fees of medical practitioners.

Numerous other statutory bodies regulate other healthcare professionals, such as the Dental Council of Ireland, the Nursing and Midwifery Board of Ireland, the Pharmaceutical Society of Ireland and the Health and Social Care Professionals Council.

Many statutory bodies have the power to prosecute summary offences under applicable legislation. In Ireland, a summary offence is one that can only be dealt with by a judge in the lower courts sitting without a jury. Summary proceedings carry lower fines and penalties. Indictable offences are more serious and are heard in the higher courts and, in certain circumstances, must be tried before a judge and jury. The Director of Public Prosecutions (DPP) directs and supervises public prosecutions on indictment.

Law stated - 08 September 2023

Scope of enforcement

What is the scope of their enforcement and regulatory responsibilities?

HIQA sets standards for safety and quality in healthcare. It has a monitoring function and carries out investigations as to the safety, quality and standards of healthcare and social care services under its remit. Designated centres under its remit can be de-registered for failure to comply with safety and quality standards. HIQA can also bring summary proceedings for offences under the Health Act 2007, which carry penalties of:

- on summary conviction, a fine not exceeding €5,000 or imprisonment for up to one year, or both; or
- on conviction or indictment, a fine up to €70,000 or imprisonment for up to two years, or both.

The Medical Council investigates complaints against doctors and can impose sanctions. Other regulators have investigative and enforcement powers.

Law stated - 08 September 2023

Regulation of pharmaceutical products and medical devices

Which agencies are principally responsible for the regulation of pharmaceutical products and medical devices?

The Health Products Regulatory Authority (HPRA) is responsible for regulating medicinal products, medical devices, controlled drugs and cosmetic products. The HPRA was established under the Irish Medicines Board Act 1995 (as amended) (the IMB Act) – before 1 July 2014, the HPRA was called the Irish Medicines Board.

The HPRA is predominantly self-funded through the collection of fees, with any shortfall provided by the Department of Health. The National Standards Authority of Ireland (NSAI) is the notified body in the country responsible for performing conformity assessments to ensure compliance with medical device legislation and for awarding CE marks.

Law stated - 08 September 2023

Scope of enforcement

What is the scope of their enforcement and regulatory responsibilities?

The HPRA is responsible for authorisations for manufacturing, marketing, importing, exporting or distributing medicinal products, and for the assessment of clinical trials. The HPRA is also responsible for monitoring the safety and quality of medicinal products placed on the Irish market, and it is the competent authority for monitoring the safety of medical devices.

The HPRA investigates activities associated with the illegal supply, manufacture or advertising of health products or devices. Where significant risk to public health has been detected, or where compliance cannot be achieved or other aggravating factors exist, the HPRA will prosecute the offender. The HPRA can prosecute certain summary offences. Indictable offences are prosecuted by the DPP.

Summary offences under the NSAI Act 1996 (as amended) may be prosecuted by the Minister for Business, Employment and Retail. Indictable offences are prosecuted by the DPP.

Law stated - 08 September 2023

Other agencies

Which other agencies (eg, competition or securities regulators, prosecutors) have jurisdiction over healthcare, pharmaceutical and medical device cases?

Other agencies that have jurisdiction over healthcare, pharmaceutical and medical device cases include:

- the Data Protection Commission, responsible for the enforcement of data protection laws;
- the Director of Corporate Enforcement, responsible for the enforcement of company laws;
- the Competition and Consumer Protection Commission, responsible for the enforcement of competition and consumer laws;
- the Health and Safety Authority, responsible for the enforcement of occupational health and safety laws; and
- the Revenue Commissioners, responsible for the assessment and collection of taxes and duties.

Law stated - 08 September 2023

Simultaneous investigations

Can multiple government agencies simultaneously conduct an investigation of the same subject? Does a completed investigation bar another agency from investigating the same facts and circumstances?

Multiple government agencies can simultaneously conduct investigations. However, agencies are usually obliged to ensure that their investigations do not interfere with another investigation.

Law stated - 08 September 2023

REGULATION OF PHARMACEUTICAL PRODUCTS AND MEDICAL DEVICES

Monitoring powers

What powers do the authorities have to monitor compliance with the rules on drugs and devices?

The Health Products Regulatory Authority (HPRA) – and its authorised officers – have wide-ranging powers under the Irish Medicines Board Act 1995 (as amended) (the IMB Act) to investigate regulatory breaches for both medicines and medical devices. For example, authorised officers can enter premises to carry out inspections, investigations, tests or examinations and can inspect, copy, remove and detain records, documents or samples for review and testing.

Law stated - 08 September 2023

Investigation time frames

How long do investigations typically take from initiation to completion? How are investigations started?

The HPRA annual report for 2015 outlined that on average an inspection and audit took 106 days to close out. More recent statistics are, unfortunately, not available.

Before conducting an audit, the HPRA will contact the company to arrange the date, time and duration of the audit. In

the case of a proactive audit, the company will generally be given at least four weeks' notice prior to the audit. A confirmation letter will be sent to the company specifying the date and time agreed and a list of the areas the audit will cover.

Law stated - 08 September 2023

Access to investigation materials

What rights or access does the subject of an investigation have to the government investigation files and materials?

In the context of a prosecution, the accused is entitled to certain evidence. For prosecutions on indictment, the prosecution has a statutory duty to provide the accused with the Book of Evidence intended to be given at trial. In summary prosecutions, there is no general duty on the prosecution to provide the accused with the statements of witnesses or documents. However, a District Court judge may order that statements and documents are handed over to the defence if it is deemed necessary in the interests of justice. The criteria used to determine a judge's decision include:

- the seriousness of the charge;
- the importance of the statements or documents;
- whether the accused had been adequately informed of the nature and substance of the accusation; and
- the likelihood of risk of injustice in failing to furnish the statements or documents to the accused.

This order is commonly known as a 'Gary Doyle' order.

An individual may submit a data subject access request under Article 15 of the General Data Protection Regulation. However, the Data Protection Act 2018 restricts this right in certain circumstances, including for the prevention, detection, investigation and prosecution of criminal offences and in connection with legal claims or proceedings. This restriction may not apply, however, in the case of regulatory investigations. The Freedom of Information Act 2014 also contains exceptions that allow a body to decline access to data or records kept for the purpose of investigating offences.

Law stated - 08 September 2023

Investigations abroad

If pharmaceutical products or medical devices are made in a foreign country, may the authorities conduct investigations of the manufacturing processes in that other country?

Yes. This is generally done with the cooperation of the local, national or EU regulatory authority. The HPRA has carried out inspections of manufacturing sites and clinical trial sites in many countries in recent years.

Law stated - 08 September 2023

Enforcement proceedings

Through what proceedings do agencies enforce the rules?

Depending on the severity of the offence, a regulator may try to work with an offender to correct non-compliances in a

non-adversarial manner. For example, the HPRA typically notifies the offender that they are in breach and affords them an opportunity to cease the offending practice before more serious action is taken. The HPRA's policy on enforcement is to 'prosecute where significant risk to public health has been detected, or where compliance cannot be achieved, or other aggravating factors exist'.

The HPRA and other entities have the authority to initiate proceedings to prosecute summary offences through the Irish criminal justice system. For summary offences under the IMB Act, proceedings may be brought by the Minister for Health, the Chief Executive of the HPRA, the CEO of the Health Service Executive or the Council of the Pharmaceutical Society of Ireland. More serious indictable offences are prosecuted by the Director of Public Prosecutions.

Law stated - 08 September 2023

Sanctions

What sanctions and other measures can the authorities impose or seek in enforcement actions against drug and device manufacturers and their distributors?

Any person found guilty of an offence under the IMB Act is liable:

- on summary conviction to a fine not exceeding €2,500 or imprisonment for up to one year, or both; or
- on conviction on indictment to a fine up to €120,000 or imprisonment up to 10 years, or both in the case of a first offence, or to a fine up to €300,000 or imprisonment up to 10 years, or both in the case of subsequent offences.

Law stated - 08 September 2023

Actions against employees

Can the authorities pursue actions against employees as well as the company itself?

Yes. When an offence under the IMB Act has been committed by a company with consent, connivance or attributable neglect on the part of directors, managers or other officers, they may also be prosecuted. A company does not have to be charged with, or convicted of, an offence for a director, manager or other officer to be charged or convicted.

Law stated - 08 September 2023

Defences and appeals

What defences and appeals are available to drug and device company defendants in an enforcement action?

The defences available typically depend on the nature of the allegations. Summary proceedings under the IMB Act must be initiated within two years of the date of the offence. There is no time limit for the prosecution of indictable offences.

An appeal of a prosecution for breaches of pharmaceutical products and medical devices laws is taken through the criminal justice system. For criminal cases, the Circuit Criminal Court hears appeals of decisions from the District Court, and the Court of Appeal hears appeals against convictions or sentences imposed by the Circuit Criminal Court, the Central Criminal Court (High Court) and the Special Criminal Court.

Law stated - 08 September 2023

Minimising exposure

What strategies should companies adopt to minimise their exposure to enforcement actions and reduce their liability once an enforcement action is under way?

Companies should have in place appropriate policies and procedures to ensure regulatory compliance and minimise risk. These policies should contain appropriate reporting lines, record-keeping requirements and regular reviews. Once an enforcement action is under way, the company should immediately seek to remedy any breach and cooperate fully with the investigation by complying with all directions and recommendations of the investigating body. The company should also seek legal advice.

Law stated - 08 September 2023

Recent enforcement activities

What have the authorities focused on in their recent drugs and devices enforcement activity and what sanctions have been imposed?

A key focus for the authorities has been on falsified medicines that pose a health risk to the public. Operation Pangea X, a cross-border coordinated effort targeting the sale of falsified medicines and illicit medical devices, was conducted in September 2017. It resulted in the detention of medicines including dietary supplements, pain reduction pills, epi lepsy medication, erectile dysfunction pills, anti-psychotic medication and nutritional products. In total, more than 200,000 units of illegal prescription medicines were detained, compared with 60,000 in 2016.

Recent enforcement data released by the HPRA showed that it detained 940,000 dosage units of falsified and illegal medicines in 2022.

The most significant categories of illegal products detained included:

- sedatives (26 per cent);
- anabolic steroids (22 per cent);
- erectile dysfunction medicines (9 per cent);
- analgesics (7 per cent); and
- stimulants (5 per cent).

Law stated - 08 September 2023

Self-governing bodies

Are there self-governing bodies for the companies that sell pharmaceutical products and medical devices? How do those organisations police members' conduct?

There are self-governing bodies in Ireland representing companies that manufacture and sell medicinal products and medical devices.

The Irish Pharmaceutical Healthcare Association (IPHA) is the industry association that represents the international research-based pharmaceutical industry in Ireland. Its member companies include manufacturers of prescription and non-prescription medicines. The IPHA is a member of the European Federation of Pharmaceutical Industries and Associations (EFPIA) and has published the Code of Practice for the Pharmaceutical Industry Edition 8.3 (IPHA Code)

that reflects the standards of the July 2014 edition of the EFPIA Code on the Promotion of Prescription-only Medicines to, and Interactions with, Healthcare Professionals. The IPHA Code also provides practical guidance on implementing the Medicinal Products (Control of Advertising) Regulations 2007.

Although the IPHA Code is a self-regulatory code and is only binding on members of the IPHA, it reflects best practice in Ireland. The IPHA has a Code of Practice Panel, a Code Council who hear complaints in the first instance and an appeals board. The Code Council has the authority to impose sanctions including:

- reprimanding a company;
- ordering the recovery of material or correction of inaccurate information;
- publishing a decision;
- referring a matter to the Minister for Health (in the case of difficult or persistent breaches); and
- recommending the suspension or expulsion of the offending party to the IPHA board of directors.

Medicines for Ireland (formerly the Irish Generic Medicines Association) is an industry body representing manufacturers of generic and biosimilar medicines.

The Irish Medtech Association has published a Code of Ethical Business Practice that reflects the Code of Ethical Business Practice of MedTech Europe.

Law stated - 08 September 2023

RELATIONSHIPS BETWEEN HEALTHCARE PROFESSIONALS AND SUPPLIERS

Relationship rules

What are the rules prohibiting or controlling the financial relationships between healthcare professionals and suppliers of products and services?

The Medicinal Products (Control of Advertising) Regulations 2007 prohibit the supply, offer or promise of any gift, pecuniary advantage or benefit in kind to persons qualified to prescribe or supply medicinal products in the course of promoting medicinal products to those persons, unless it is inexpensive and relevant to the practice of medicines or pharmacy. This does not prohibit the provision of hospitality at sales promotion events or other events for purely professional or scientific purposes, provided such hospitality is reasonable, strictly limited to the main purpose of the event and not extended to persons other than health professionals. There are also restrictions around the provision of free samples to healthcare professionals (HCPs). These provisions do not, however, apply to the negotiation of prices, margins and discounts in the ordinary course of business, provided such prices, margins and discounts are incorporated in the sales invoice as a consequence of such negotiations.

The Code of Practice for the Pharmaceutical Industry Edition 8.3 (IPHA Code) contains similar provisions and more detail around the provision of hospitality, grants and donations and consultancy arrangements with HCPs and healthcare organisations (HCOs).

Law stated - 08 September 2023

Enforcement

How are the rules enforced?

The Medicinal Products (Control of Advertising) Regulations 2007 are enforced by the Health Products Regulatory Authority.

Law stated - 08 September 2023

Reporting requirements

What are the reporting requirements on such financial relationships? Is the reported information publicly available?

The IPHA Code aims to bring greater transparency to the interaction between pharmaceutical companies, HCPs and HCOs. It contains a set of industry rules relating to the disclosure of transfers of value from pharmaceutical companies to HCPs and HCOs.

The disclosure rules oblige every member company to document and publicly disclose all transfers of value (subject to certain exceptions) it makes to HCPs or HCOs. These include items such as:

- donations;
- grants;
- consultancy or speaking fees; and
- hospitality, sponsorship or funding for attending medical meetings, conferences or symposiums.

The IPHA Code provides that contractual provisions consenting to disclosure must be incorporated into contracts with HCPs and HCOs.

The disclosure of transfers of value must be made on an annual basis within six months of the end of the reporting period. A reporting period is a full calendar year. The first reporting period was 2015. Disclosures may be made on a company's website, provided that they are unrestricted and publicly available. The information must remain in the public domain for three years.

The IPHA Code provides for two forms of disclosure: individual and aggregate. Individual disclosure is where the monetary amounts attributed to all transfers of value to each clearly identifiable HCP or HCO are disclosed. The IPHA Code provides that, as a preference, individual disclosure should be used, except where certain information cannot be disclosed on an individual basis for valid legal reasons. In those circumstances, the transfers of value can be disclosed on an aggregate basis. Aggregate disclosure is where a company discloses the aggregate amounts attributable to transfers of value under specific categories.

Law stated - 08 September 2023

REGULATION OF HEALTHCARE DELIVERY

Authority powers

What powers do the authorities have to monitor compliance with the rules on delivery of healthcare?

The Health Information and Quality Authority (HIQA) has powers of entry and inspection of premises under its remit. Authorised officers have broad powers, including the power to take copies and remove documents and records, inspect computers and interview patients and staff.

The Medical Council is responsible for investigating complaints about doctors. If a complaint against a doctor is upheld, the Medical Council has the power to impose sanctions such as:

- an advice or admonishment, or a censure, in writing;

- a censure in writing and a fine not exceeding €5,000;
- the attachment of conditions to the practitioner's registration, including restrictions on the practice of medicine that may be engaged in by the practitioner;
- the transfer of the practitioner's registration to another division of the register;
- the suspension of the practitioner's registration for a specified period;
- the cancellation of the practitioner's registration; and
- a prohibition from applying for a specified period for the restoration of the practitioner's registration.

Law stated - 08 September 2023

Investigation time frames

How long do investigations of healthcare providers typically take from initiation to completion? How are investigations started?

The length of an investigation can vary, depending on the complexity of the issue.

HIQA is responsible for undertaking investigations as to the safety, quality and standards of services if it believes there is a serious risk to the health or welfare of a person receiving those services. The Minister for Health may require HIQA to undertake an investigation.

Medical Council investigations of complaints can last for months or years, depending on the issues being considered. The Medical Council provides an online and postal complaints procedure, and any person can complain to the Medical Council about a doctor through this forum.

Law stated - 08 September 2023

Access to investigation materials

What rights or access does the subject of an investigation have to the government investigation files and materials?

In the case of complaints to the Medical Council, a doctor is provided with the core evidence during the investigation process, including witness statements and expert reports, and is allowed an opportunity to comment on new evidence.

Law stated - 08 September 2023

Enforcement agencies

Through what proceedings do agencies enforce the rules?

HIQA inspectors engage directly with service providers under its remit to address non-compliance with standards and regulations, including through issuing safety notices. HIQA can prosecute certain summary offences.

The Fitness to Practise Committee of the Medical Council conducts inquiries of complaints about doctors. Hearings are generally held in public. For serious sanction, the Medical Council must apply to the High Court to affirm its decision.

Law stated - 08 September 2023

Sanctions

What sanctions and other measures can the authorities impose or seek in enforcement actions against healthcare providers?

HIQA sets standards for safety and quality in healthcare. It has a monitoring function and carries out investigations as to the safety, quality and standards of healthcare and social care services under its remit. Designated centres under its remit can be de-registered for failure to comply with safety and quality standards.

Under the Health Act 2007, enforcement action may be taken through:

- civil action (refusing registration, imposing new conditions, varying or removing conditions or cancelling registration); or
- criminal prosecution: HIQA can bring proceedings for offences under the Health Act 2007, which carry penalties of:
  - on summary conviction, a fine not exceeding €5,000 or imprisonment for up to one year, or both; or
  - on conviction or indictment, a fine up to €70,000 or imprisonment for up to two years, or both.

HIQA has powers of entry and inspection of premises under its remit. Authorised officers have broad powers, including the power to take copies and remove documents and records, inspect computers and interview patients and staff.

The Medical Council is responsible for investigating complaints about doctors. If a complaint against a doctor is upheld, the Medical Council has the power pursuant to section 71 of the Medical Practitioners Act 2007 to impose one or more than one of the following sanctions:

- an advice or admonishment, or a censure, in writing;
- a censure in writing and a fine not exceeding €5,000;
- the attachment of conditions to the practitioner's registration, including restrictions on the practice of medicine that may be engaged in by the practitioner;
- the transfer of the practitioner's registration to another division of the register;
- the suspension of the practitioner's registration for a specified period;
- the cancellation of the practitioner's registration; and
- a prohibition from applying for a specified period for the restoration of the practitioner's registration.

The Nursing and Midwifery Board of Ireland is responsible for investigating complaints about nurses and midwives. If a complaint against a nurse or a midwife is upheld, the Nursing and Midwifery Board has the power pursuant to section 69 of the Nurses and Midwives Act 2011 to impose one or more than one of the following sanctions:

- an advice or admonishment, or a censure, in writing;
- a censure in writing and a fine not exceeding €2,000;
- the attachment of conditions to the nurse's or midwife's registration, including restrictions on the practice of nursing or midwifery that may be engaged in by the nurse or midwife;
- the transfer of the nurse's or midwife's registration to another division;
- the suspension of the nurse's or midwife's registration for a specified period;
- the cancellation of the nurse's or midwife's registration from the register of nurses and midwives or a division of that register; and
- a prohibition from applying for a specified period for the restoration of the nurse's or midwife's registration in the

register of nurses and midwives or a division.

The Dental Council is responsible for investigating complaints about dentists. If a complaint against a dentist is upheld, the Dental Council may decide that the name of the person should be erased or suspended from the relevant register.

Regardless of whether there is a finding of professional misconduct or unfitness to practise, the Dental Council can also:

- attach such conditions as it thinks fit to the retention of the name of the relevant person on the relevant register; and
- advise, admonish or censure such persons in relation to their professional conduct.

Law stated - 08 September 2023

Defences and appeals

What defences and appeals are available to healthcare providers in an enforcement action?

In relation to HIQA, an appeal of a prosecution for breach of the Health Act 2007 can be brought through the criminal justice system. Designated centres for children or adults with disabilities or the elderly that are refused registration or are deregistered can appeal HIQA's decision to the District Court.

When the Medical Council imposes sanctions such as advice, admonishment or censure in writing, there is no statutory right of appeal, and the only option available is judicial review. If the Medical Council imposes sanctions such as conditions, suspension or cancellation of a doctor's registration, there is a statutory right of appeal to the High Court.

Law stated - 08 September 2023

Minimising exposure

What strategies should healthcare providers adopt to minimise their exposure to enforcement actions and reduce their liability once an enforcement action is under way?

Healthcare providers should familiarise themselves with all rules and guidelines applicable to their activities. Once an enforcement action is under way, the healthcare provider should attempt to remedy the breach and cooperate with the body bringing the action. The healthcare provider should also seek legal advice.

Law stated - 08 September 2023

Recent enforcement activities

What have the authorities focused on in their recent enforcement activity and what sanctions have been imposed on healthcare providers?

In 2022, HIQA continued to place a focus on safeguarding and human rights, including in the national standards and guidance, and in how services are regulated.

It also carried out:

- 1,329 inspections of designated centres for people with disabilities;
- 726 inspections of nursing homes;
- 63 ionising radiation inspections in public and private hospitals and dental facilities;
- 54 inspections of children's services; and
- 20 inspections of acute and community hospitals.

The Medical Council must investigate all of the complaints it receives.

Law stated - 08 September 2023

Self-governing bodies

Are there self-governing bodies for healthcare providers? How do those organisations police members' conduct?

The Medical Council is the self-governing body for medical practitioners.

The Medical Council has a statutory role in protecting the public by promoting the highest professional standards amongst doctors practising in Ireland. The Medical Council also sets the standards for medical education and training in Ireland.

Allegations made concerning a medical practitioner in respect of public protection or a breach of standards is investigated by the Medical Council and its various investigatory committees.

Similar processes exist with the Dental Council of Ireland, the Nursing and Midwifery Board of Ireland, the Pharmaceutical Society of Ireland and the Health and Social Care Professionals Council.

Any proven allegations will result in a sanction.

Law stated - 08 September 2023

Remedies for poor performance

What remedies for poor performance does the government typically include in its contracts with healthcare providers?

Typically, government contracts contain performance issue procedures that give contractors multiple opportunities to correct non-compliance. However, where non-compliance persists, it can result in the contractor having to undergo mandatory training, withholding of funding, suspension of certain services or termination of the agreement.

Law stated - 08 September 2023

PRIVATE ENFORCEMENT

Causes of action

What private causes of action may citizens or other private bodies bring to enforce a healthcare regulation or law?

The enforcement of healthcare regulations or laws is generally undertaken by the appropriate regulatory body or a state prosecutor. However, there are some instances where citizens may bring private enforcement actions when they are directly affected by the breach or infringement of that regulation or law; for example, in cases of personal injuries

arising out of medical or clinical negligence (malpractice) by a healthcare professional or out of a defective pharmaceutical product or medical device.

Law stated - 08 September 2023

Framework for claims

What is the framework for claims of clinical negligence against healthcare providers?

In Ireland, the law of tort governs the framework for clinical negligence claims. To succeed in a clinical negligence action, the plaintiff must prove that a duty of care exists between the plaintiff and a healthcare provider, and that there has been a breach of that duty, causing the plaintiff's injuries.

The principles for establishing breach of duty against a healthcare provider are set out in the seminal case of Dunne v National Maternity Hospital . The test is the 'reasonable standard of care', in other words, whether a healthcare practitioner is guilty of such failure as no practitioner of equal status and skill would be guilty if acting with ordinary care. Provided that the practitioner acted in accordance with a practice accepted as proper by a body of responsible opinion within their profession, it does not make them negligent if a separate body would have adopted a different practice. The test acknowledges that there may be a variance of medical opinion within a particular field. However, the practice followed by the practitioner must have been free of any inherent and obvious defects.

The plaintiff must then prove that this breach of duty caused or made a material contribution to the plaintiff's injury. The standard of proof is 'on the balance of probabilities'. However, in certain circumstances the doctrine of res ipsa loquitur may be applied. This means that negligence is presumed on the part of the defendant since the object causing injury was under their control. It reverses the burden of proof and places the onus on the healthcare provider to disprove an allegation of negligence.

The Irish courts are not reluctant to penalise public or quasi-public healthcare providers.

In Ireland, damages are awarded to put the plaintiff as far as possible back in the position they would have been had the wrong not occurred. There are two main categories of damages available: general and special damages. General damages compensate for non-pecuniary losses suffered by the plaintiff as a result of the wrongdoing. Such losses include pain and suffering, loss of amenity and loss of expectation of life. Special damages may also be awarded for any financial loss suffered and expense incurred by a plaintiff as a result of the wrongdoing. A claim for special damages is usually formulated based on expenses and liabilities incurred up to the date of trial and future loss, being the estimated anticipated loss, usually based on actuarial evidence. In exceptional circumstances, exemplary or punitive or aggravated damages may also be awarded.

Recent legislative developments in Ireland will have an impact on the management of clinical negligence claims. A pre-action protocol in clinical negligence actions was introduced under the Legal Services Regulation Act 2015 and is expected to be published shortly. The protocol will focus on reducing the number of claims, early resolution of claims, early identification of issues and promoting timely communication between parties.

Clinical negligence claims will also be affected by amendments to the rules of the court. The new rules provide that personal injuries claims, including clinical negligence actions, may be time managed by the court with a trial judge making orders as to time limitations and the manner in which a case is presented. There is a marked emphasis in both the protocol and the new rules on the expedient resolution of clinical negligence claims.

Furthermore, the Mediation Act 2017 came into force on 1 January 2018. The Act obliges solicitors to provide advice and information on mediation prior to initiating proceedings, and allows the court to invite parties to a dispute to consider mediation and take an unreasonable refusal to engage in mediation into account when making an order on costs. This reflects a general shift towards facilitating methods of alternative dispute resolution and attempting to minimise the quantity of cases that reach trial.

Law stated - 08 September 2023

Seeking recourse

How and on what grounds may purchasers or users of pharmaceuticals or devices seek recourse for regulatory and legal infringements?

The purchaser or a user of pharmaceuticals or devices can seek recourse for regulatory and legal infringements through the Irish courts, for example, under product liability rules. In Ireland, liability for defective products falls under four main headings: statute, tort, contract and criminal. The principal product liability statute is the Liability for Defective Products Act 1991. This Act supplements the remedies in tort and contract and provides for a strict liability regime, making a producer of the defective product liable in damages in tort for damage caused wholly or partly by a defect in the product. A purchaser or user may also sue in tort for any reasonably foreseeable damage caused to them, or in contract where the pharmaceutical or device was not of merchantable quality.

It is also open to the purchaser or user of a pharmaceutical product or a device to make a complaint to the Health Products Regulatory Authority.

Law stated - 08 September 2023

Compensation

Are there any compensation schemes in place?

In Ireland, compensation schemes have been set up in circumstances where an organ of the state may have liability. Such schemes are ad hoc, rather than statutorily required.

The State Claims Agency manages these schemes. Examples of compensation schemes include the Hepatitis C Compensation Tribunal, which was set up in 1997 to compensate women who had become infected with hepatitis C, having been transfused with infected blood products during pregnancy. In July 2013, the government approved the establishment of the Lourdes Hospital Redress Scheme, to compensate former patients of an obstetrician who performed unnecessary surgeries. More recently, a state compensation scheme was set up for women seeking damages in respect of symphysiotomy operations carried out between 1945 and 1982.

In 2020, the Minister for Health established the CervicalCheck Tribunal. This Tribunal had the jurisdiction to hear and determine a certain limited number of claims arising in respect of the state's cervical screening programme. With the consent of the parties concerned, it provides an alternative legal mechanism, outside of the court process, for the hearing and determination of eligible claims. Its determinations are subject to confirmation by the High Court and parties enjoy a right of appeal.

Law stated - 08 September 2023

Class and collective actions

Are class actions or other collective claims available in cases related to drugs, devices and provision of care?

The EU Directive on Representative Actions for the Protection of the Collective Interests of Consumers (RAD) requires EU member states, by June 2023, to fully implement its terms. The RAD will enable consumers to seek collective redress when they claim to have been harmed by a business through breaches of certain European consumer laws.

The Representative Actions for the Protection of the Collective Interests of Consumers Act 2023 signed into law on 11

July 2023. This Act allows for representative actions to be brought on behalf of groups of consumers by designated qualified entities (QEs) in respect of infringements of a wide range of EU consumer protection laws in areas such as financial services, data protection and telecommunications. Ireland is one of the first EU member states to transpose the Directive in its entirety. The Act is awaiting commencement, and there are several operational aspects that will need to be provided for by ministerial regulation, most of which relate to the role of the QEs.

Law stated - 08 September 2023

Review

Are acts, omissions or decisions of public and private institutions active in the healthcare sphere subject to judicial or administrative review following a complaint from interested parties?

Yes. Judicial review proceedings are heard in the High Court. Judicial review in Ireland is a two-stage process, comprising:

- an application to the High Court for permission to bring judicial review proceedings; and
- the substantive hearing.

The time limit for commencing judicial review proceedings can vary depending on the applicable legislation; however, typically, an application for leave to apply for judicial review must be made within three months from the date when the grounds for the application first arose. The Irish courts apply a 'sufficient interest' test to determine whether a party bringing judicial review proceedings has the requisite standing to litigate. However, the courts apply this test liberally. In judicial review the High Court's primary focus is not whether the public entity made the right decision, but to see that the decision was made in the proper manner. The common grounds for judicial review include that there has been an error of law, a procedural error, lack of fair procedures, an error of fact or, in limited circumstances, that the decision is manifestly unreasonable. The High Court can quash the decision or remit the decision back to the public entity to be re-decided.

Law stated - 08 September 2023

Whistleblowers

Are there any legal protections for whistleblowers?

While Irish legislation contains provisions for whistle-blower protection in relation to discrete offences, the principal protections are contained in the Protected Disclosures Act 2014, which protects workers in circumstances where they report suspicions of illegal activity.

Where a worker makes a protected disclosure, the employer in question is prevented from:

- dismissing or penalising the worker;
- taking an action for damages or an action arising under criminal law; or
- disclosing any information that might identify the person who made the disclosure.

The Act also makes provision for a cause of action in tort for the worker for detriment suffered because of making a protected disclosure.

However, a disclosure is only considered to be a 'protected disclosure' when it is a disclosure of information, made by a

worker, which in their reasonable belief tends to show a 'relevant wrongdoing' and came to their attention in connection with their employment. A relevant wrongdoing is broadly defined as relating to:

- the commission of an offence;
- non-compliance with a legal obligation (except one arising under the worker's employment contract);
- a miscarriage of justice;
- endangerment of health and safety;
- damage to the environment;
- misuse of public funds;
- mismanagement by a public body; or
- concealing or destroying information relating to any of the above.

The definition of 'worker' is very broad and covers employees (including temporary and former employees), interns, trainees, contractors, agency staff and consultants.

If the protected disclosure is part of an unfair dismissals claim by the worker, and a Workplace Relations Commissioner finds in favour of the worker, the worker can require the employer to pay them compensation of up to 260 weeks' remuneration.

While the motivation for making the disclosure is irrelevant, these protections are not available to those who deliberately make false disclosures, as these are not considered to meet the test for having a 'reasonable belief' that a wrongdoing has occurred.

Law stated - 08 September 2023

Does the country have a reward mechanism for whistleblowers?

The purpose of the Protected Disclosures Act 2014 is to protect workers who make protected disclosures from penalisation. Consequently, there is no reward mechanism for whistle-blowers in the Act. However, in relation to competition law, the Irish Competition and Consumer Protection Commission operates an immunity programme for members of a cartel who confess their involvement in breaches of the Competition Act 2002 (as amended). To benefit from this immunity, a number of requirements must be met, most notably that the whistle-blower is the first member of the given cartel to have satisfied the requirements.

Law stated - 08 September 2023

Are mechanisms allowing whistleblowers to report infringements required?

Under the Protected Disclosures Act 2014, public sector bodies must put whistle-blowing policies in place. While there is no such requirement for private sector businesses, such policies are strongly recommended.

Law stated - 08 September 2023

CROSS-BORDER ENFORCEMENT AND EXTRATERRITORIALITY

Cooperation with foreign counterparts

Do prosecutors and law enforcement authorities in your country cooperate with their foreign counterparts in healthcare cases?

Yes. For example, the Health Products Regulatory Authority (HPRA), the Irish Revenue Commissioner's Customs Service and the Irish police took part in Operation Pangea X, which is an international campaign that targets the sale of falsified medicines online.

Law stated - 08 September 2023

Triggering investigations

In what circumstances will enforcement activities by foreign authorities trigger an investigation in your country?

This is determined on a case-by-case basis. The HPRA will take enforcement activities by foreign authorities into account when deciding whether an investigation is required.

A complaint can be made to the Medical Council about a medical practitioner on the grounds of a conviction outside of Ireland that would constitute an indictable offence in Ireland.

Law stated - 08 September 2023

Pursuing foreign entities for infringement

In what circumstances will foreign companies and foreign nationals be pursued for infringements of your country's healthcare laws?

Enforcement of Irish healthcare laws is applied to offences committed in Ireland, and whether foreign companies or nationals are pursued will depend on who is the offender. If the entity does not have an establishment in Ireland, prosecution can be more difficult.

Law stated - 08 September 2023

UPDATE AND TRENDS

Key developments of the past year

What are the authorities' enforcement priorities likely to be in the coming year? Are there any noteworthy cases pending? Are there any current developments or emerging policy or enforcement trends that should be noted?

The Health Products Regulatory Authority's (HPRA) legislative changes will occur over the next few years, with the implementation of EU regulations on clinical trials, veterinary medicines, medical devices and in-vitro diagnostics, and each regulation will impact significantly on the operation of the relevant regulatory system. For the HPRA, these constitute major projects that require contribution to national legislation, extensive engagement with all stakeholders and development of information resources for those affected by the legislation.

The Health Information and Quality Authority's (HIQA) corporate plan 2022–2024 outlines that in the next three years they will continue to address the outcomes and recommendations of the Nursing Home Expert Panel on covid-19. This will include an expanded and more diverse programme of inspections across nursing homes and residential disability services. HIQA will also build on its successful National Care Experience Programme, with the introduction of a survey of nursing home residents and their relatives, as well as a survey on end-of-life care across acute, community and other home-based services. In addition, HIQA will continue to undertake a programme of evidence synthesis to assist with the government's policy formation as we continue to respond to the impact of covid-19 on our health and social care

services.

Law stated - 08 September 2023

Jurisdictions

France	LexCase
Ireland	Matheson LLP
Japan	Mori Hamada & Matsumoto
Malaysia	Raja, Darryl & Loh
Mexico	OLIVARES
USA	Mintz