Healthcare Enforcement & Litigation

Contributing editors
Michael K Loucks, Jennifer L Bragg and Alexandra M Gorman

2018

GETTING THE DEAL THROUGH

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Ireland

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Overview

1 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.

2 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, etc. Secondary healthcare is delivered in hospitals to patients normally living at home, for example outpatient clinics, accident and emergency clinics, etc. 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 indicate that 45.8 per cent of the Irish population hold private health insurance as of December 2016, a key benefit of which is avoiding lengthy public waiting lists for elective procedures.

3 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 1947–2017: the statutory framework governing the national healthcare system;
- the Health Act 2007: this established the Health and Information Quality Authority (HIQA); and
- the Medical Practitioners Act 2007: this established 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.

4 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:

- The 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. The 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). The HIQA is funded by the Irish government. The HIQA does not currently regulate private hospitals, though its scope is due to be extended imminently.
- 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 Irish Nursing Board, 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.

5 What is the scope of their enforcement and regulatory responsibilities?

The 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 deregistered for failure to comply with safety and quality standards. The 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 (see question 24).

Other regulators, including those named in question 4, have investigative and enforcement powers.

6 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 Ireland responsible for performing conformity assessments to ensure compliance with medical device legislation and for awarding CE marks.

7 What is the scope of their enforcement and regulatory responsibilities?

The HPRA is the regulatory authority 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. The HPRA 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. 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 (see questions 4 and 5).

Summary offences under the NSAI Act 1996 (as amended) may be prosecuted by the Minister for Jobs, Enterprise and Innovation. Indictable offences are prosecuted by the DPP.

8 Which other agencies 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 Commissioner, 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.

9 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.

Regulation of pharmaceutical products and medical devices

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

The HPRA (and its authorised officers) have wide-ranging powers to investigate regulatory breaches. 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.

An authorised officer of the NSAI may, on request, obtain access to the place of manufacture or storage of medical devices and make such examinations, tests, or inspections as it considers appropriate. An authorised officer may also apply to the District Court for a warrant to seize medical devices that are not in compliance with the regulations, or to compel information from a person in relation to that device.

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

The HPRA has an inspection programme for carrying out proactive and reactive inspections and auditing. In 2015, the HPRA carried out 319 national inspections and audits and 25 foreign inspections and audits. Of the total number of inspections and audits carried out, 67 per cent were completed within 90 days. On average, in 2015, an inspection and audit took 106 days to close out.

12 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.

Ireland's data protection and freedom of information laws contain exceptions that allow a body to decline access to data or records kept for the purpose of investigating offences.

13 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.

14 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.*

Generally speaking, the HPRA and other entities have the authority to initiate proceedings to prosecute summary offences through the Irish criminal justice system. More serious indictable offences are prosecuted by the DPP.

15 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 €2,000, or imprisonment for up to one year, or both; or
- on conviction on indictment to a fine up to €300,000 and/or imprisonment up to 10 years, or both.

16 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, the directors, managers or other officers of the company may also be prosecuted when the offence is proved to be committed by the company with consent, connivance or attributable neglect on the part of the particular individual. 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.

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

The defences available will typically depend on the nature of the allegations.

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.

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

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.

19 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 VIII, a cross-border coordinated effort targeting the sale of falsified medicines, was conducted in June 2015. It resulted in the detention of medicines including sedatives, erectile dysfunction, illegal cosmetics, anabolic steroids and weight loss units. Recent efforts by the Irish authorities have also focused on the online sale of weight loss substances due to high-profile media reports of adverse reactions. Only one prosecution was initiated by the HPRA in 2015.

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

There are a number of 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 a Code of Practice for the Pharmaceutical Industry Edition 8.2 (IPHA Code) which 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 have the authority to impose a number of 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.

The Association of Pharmaceutical Manufacturers of Ireland (APMI) is an industry body representing manufacturers of generics. It has published the APMI Code of Practice on Advertising of Medicinal Products.

The Irish Medical Device Association and the Irish Medical and Surgical Trade Association have published codes of ethical business practice. These codes reflect the Eucomed Code of Ethical Business Practice. There are no formal complaints procedures or sanctions contained in these codes.

Relationships between healthcare professionals and suppliers

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

The IPHA Code aims to bring greater transparency to the interaction between pharmaceutical companies, healthcare professionals (HCPs) and healthcare organisations (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 attendance at medical meetings, conferences or symposiums.

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

22 How are the rules enforced?

See question 20.

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

Since January 2015, the disclosure of transfers of value must be made on 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.

Regulation of healthcare delivery

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

The 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:

- advice, admonishment or censure in writing;
- fines of up to €5,000;
- to attach conditions to a doctor's registration; or
- to suspend or cancel a doctor's registration.

25 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.

The 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 the HIQA to undertake an investigation.

Medical Council investigations of complaints can last a number of 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.

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

See question 12.

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.

27 Through what proceedings do agencies enforce the rules?

The HIQA inspectors engage directly with service providers under its remit to address non-compliance with standards and regulations, including through issuing safety notices. The 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 most types of sanction, the Medical Council must apply to the High Court to affirm its decision.

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

See questions 5 and 24.

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

In relation to the HIQA, an appeal of a prosecution for breach of the Health Act 2007 can be brought through the criminal justice system (see question 17). Designated centres for children or adults with disabilities, or the elderly, that are refused registration or are deregistered can appeal the 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 (see question 39). 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.

30 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 applicable 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.

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

The HIQA has recently focused on investigations into the safety, quality and standards provided by the HSE in various hospitals. For example, the HIQA carried out 66 inspections in 2016, with a focus on the prevention and control of healthcare-associated infections and on nutrition and hydration.

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

32 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. See question 24 in relation to policing members' conduct.

33 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-compliances. However, where non-compliances persist, this can result in the contractor having to undergo mandatory training, the withholding of funding, the suspension of certain services or termination of the agreement.

Private enforcement

34 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 the case 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.

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

In Ireland, the framework for clinical negligence claims is governed by the law of tort. In order 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, which was causative of 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 his or her profession, it does not make him or her 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 his or her 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 in order to put the plaintiff as far as possible back in the position he or she 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 on the basis of 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.

36 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 in Ireland 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 HPRA.

37 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.

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

There is no specific Irish legislative provision dealing with class actions. Litigation is conducted by individually named parties. However, in situations where there are numerous separate claims arising from the same circumstances, it is not uncommon for a representative test case to be taken, where an agreement is reached between the parties that the balance of the cases would be stayed pending the outcome of the representative action. The judgment in the representative action can become the benchmark by which the remaining cases are managed, by virtue of the doctrine of precedent. Subsequent litigation is often resolved by agreement on the basis of the outcome of the representative action.

The Law Reform Commission published a report in 2005 on multiparty litigation. It recommended that a procedure called a multiparty action (MPA) be introduced to deal collectively with cases that are sufficiently similar. The Commission recommended that the procedure operate on the basis of an opt-in system whereby individual litigants would only be included in the group where they decided to join. A single legal representative would be nominated by the MPA members to deal with the common issues arising within the MPA. To date, the recommendation has not been implemented.

39 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.

40 Are there any legal protections for whistleblowers?

While Irish legislation contains a number of provisions for whistleblower protection in relation to discrete offences, the principal protections are contained in the Protected Disclosures Act 2014 (Protected Disclosures Act), 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 Protected Disclosures Act also makes provision for a cause of action in tort for the worker for detriment suffered as a result of making a protected disclosure.

However, a disclosure will only be 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 which 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, he or she can require the employer to pay compensation of up to 260 weeks' remuneration to the worker.

While the motivation for making the disclosure is irrelevant, these protections are not available to those who deliberately make false

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disclosures, as these are not considered to meet the test for having a 'reasonable belief' that a wrongdoing has occurred.

41 Does the country have a reward mechanism for whistleblowers?

The purpose of the Protected Disclosures Act is to protect workers who make protected disclosures from penalisation. Consequently, there is no reward mechanism for whistleblowers in the Protected Disclosures 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). In order to benefit from this immunity, a number of requirements must be met, most notably that the whistleblower is the first member of the given cartel to have satisfied the requirements.

42 Are mechanisms allowing whistleblowers to report infringements required?

Under the Protected Disclosures Act, public sector bodies must put whistleblowing policies in place. While there is no such requirement for private sector businesses, we strongly recommend policies be put in place. Where a policy already exists, we recommend that the policy be reviewed to ensure it is in line with the provisions of the Protected Disclosures Act.

Cross-border enforcement and extraterritoriality

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

Yes. For example, as noted above, the HPRA, the Irish Revenue Commissioner's Customs Service and the Irish police took part in Operation Pangea, which is an international week that targets the sale of falsified medicines online.

44 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.

45 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 or not 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.

Getting the Deal Through

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