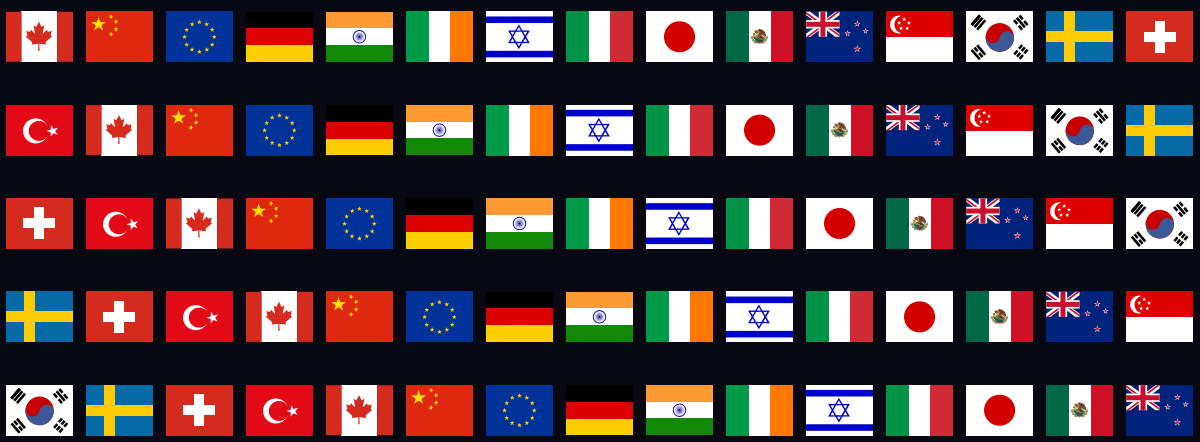
LIFE SCIENCES

Ireland



LEXOLOGY
Getting The Deal Through

Consulting editor
Ehlers Ehlers & Partner

Life Sciences

Consulting editors

Alexander Ehlers

Ehlers Ehlers & Partner

Quick reference guide enabling side-by-side comparison of local insights, including into organisation and financing; authorisation of providers; advertising; data protection, privacy and digitisation; collaboration with healthcare professionals and patient organisations; competition law; pricing and reimbursement; and recent trends.

Generated 13 December 2021

Table of contents

UPDATE AND TRENDS

Contributors

Ireland

Emma Doherty
emma.doherty@matheson.com
Matheson

Kate McKenna
kate.mckenna@matheson.com
Matheson

Simon Shinkwin
simon.shinkwin@matheson.com
Matheson

Roisin Walsh
Matheson

ORGANISATION AND FINANCING OF HEALTHCARE

Organisation

How is healthcare in your jurisdiction organised?

Healthcare policy in Ireland is determined by the Department of Health. Public healthcare services are provided by the Health Service Executive (HSE). There is a two-tier health service, comprising the public healthcare system and the private healthcare system. The HSE owns and runs public hospitals. Other hospitals, known as voluntary public hospitals, are owned by religious orders or similar institutions. There are also privately owned hospitals.

Law stated - 20 October 2021

Financing

How is the healthcare system financed in the outpatient and inpatient sectors?

The public healthcare system is generally funded by taxation and social welfare contributions, as well as co-payments from patients, and payments from private health insurers for treatment provided to private patients in public hospitals. Voluntary hospitals also receive state funding. The private healthcare system is funded by private funds and private insurance. Private hospitals have agreements in place with private health insurers to fund the treatment of patients.

Law stated - 20 October 2021

Basic structures

What are the basic structures of the provision of care to patients in statutory and private care?

In general, healthcare is 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 (GPs), nurses and health clinics. Secondary healthcare is delivered in hospitals to patients normally living at home; for example, outpatient clinics, and accident and emergency clinics.

There are limited differences between public and private care; the main differences being the cost (and method of paying) and the waiting list times for access to consultants and care.

Holders of a state medical card (ie, public patients) are entitled to receive all health services free of charge, including GP services, prescribed medicines, all dental, ophthalmic and aural services, maternity services, inpatient services in public hospitals and specialist treatment in outpatient clinics of public hospitals.

The majority of the population do not hold medical cards (ie, private patients) but they are still entitled to free maternity services, inpatient services in public hospitals (subject to a daily charge), specialist services in outpatient clinics (subject to a daily charge), assistance towards the cost of prescribed medicines over a monthly limit (under the Drugs Payment Scheme) and assistance towards the cost of prescribed medicines for certain chronic conditions (under the Long-Term Illness Scheme) or high-cost treatments (under the High-Tech Drug Scheme). They must, however, pay for all GP consultations and all dental, ophthalmic and aural treatments. A GP visit card that allows for free GP care is available to all children under the age of six.

Law stated - 20 October 2021

HEALTHCARE SERVICES

Authorisation

What steps are necessary to authorise the provision of health services, and what law governs this?

Doctors

The Medical Practitioners Act 2007 (as amended) regulates the medical profession in Ireland. It provides for the registration and control of medical practitioners, outlines the membership and functions of the Medical Council and obliges the Medical Council to establish various committees to consider complaints made against practitioners. Under the Medical Practitioners Act 2007, an unregistered medical practitioner is not permitted to practise medicine in the state. Registration is on an annual basis.

Nurses and midwives

The Nurses and Midwives Act 2011 regulates nurses and midwives in Ireland and requires all nurses and midwives working in Ireland to register with the Nursing and Midwifery Board of Ireland.

Dentists

The dental profession in Ireland is regulated by the Dental Council (established by the Dentists Act 1985) and only dentists registered with the Dental Council can practise dentistry in Ireland.

Health and social care professionals

The Health and Social Care Professionals Council (CORU) is an independent regulator established by the Health and Social Care Professionals Act 2005 (as amended) to promote high standards of professional conduct and professional education, training and competence among registrants of health and social care professions. CORU currently maintains registers for dieticians, occupational therapists, radiographers and radiation therapists, social workers, speech and language therapists, optometrists and dispensing opticians, medical scientists and physiotherapists. In the future, CORU will also regulate clinical biochemists, orthoptists, podiatrists, psychologists and social care workers. Each member of these professions will be required to register with CORU when its respective register is established and, from then, only members registered with CORU can legally use the title of those professions.

Pharmacists

Pharmacists and pharmaceutical assistants must be registered with the Pharmaceutical Society of Ireland (PSI) to practise in Ireland. Under the Pharmacy Act 2007 , the PSI is responsible for defining and ensuring the standards of education and training for pharmacists qualifying in Ireland. Pharmacies must apply on an annual basis for continued registration and pay an annual fee.

Institutional healthcare providers

Institutional healthcare providers in Ireland are public and private hospitals, clinics and nursing homes.

The Health Act 2007 established the Health Information and Quality Authority (HIQA), which is responsible for setting standards for the safety and quality of public or publicly funded hospitals, social care services and residential services. HIQA is responsible for the registration and oversight of these services, which include public and private residential facilities for children and adults with disabilities, and nursing homes. HIQA is an independent authority established to drive high-quality and safe care for people using health and social care services in Ireland. HIQA does not currently regulate private hospitals, though its scope is due to be extended. Designated centres under HIQA's remit can be deregistered for failure to comply with safety and quality standards. HIQA can also bring summary proceedings for offences under the Health Act 2007. Public healthcare providers are not authorised or registered with HIQA under current legislation, but they do fall under its remit.

The Department of Health has prepared legislative proposals for a mandatory licensing system for public and private hospitals and other providers of high-risk healthcare activities. It aims to improve patient safety by ensuring that providers do not operate below core standards, which are applied in a consistent and systematic way. Under separate draft legislation, HIQA's remit will be extended to the private health service and HIQA will be given the function of setting standards for private hospitals and private acute services and monitoring compliance with standards in the same way as it does for the public health service.

Law stated - 20 October 2021

Structure

Which types of legal entities can offer healthcare services?

There are no specific rules in Ireland around the types of legal entities that can offer healthcare services.

Law stated - 20 October 2021

Services of foreign companies

What further steps are necessary for foreign companies to offer health services?

Foreign companies must comply with the same requirements as companies incorporated in Ireland.

Law stated - 20 October 2021

ADVERTISING

Legislation

Which legislation governs advertising of medicinal products to healthcare professionals?

Advertising of medicinal products is governed by the Medicinal Products (Control of Advertising) Regulations 2007 (the Advertising Regulations). In addition to legislation, there is a code of practice published by the Irish Pharmaceutical Healthcare Association (IPHA) that sets rules around interactions between the pharmaceutical industry and healthcare providers (HCPs). The IPHA Code of Practice for the Pharmaceutical Industry, Edition 8.4 (the IPHA Code) transposes the European Federation of Pharmaceutical Industries and Associations Code of Practice. The IPHA Code is only binding on members of IPHA but its provisions represent best practice in Ireland.

In addition, the general rules around advertising also apply.

Law stated - 20 October 2021

Main principles

What are the main rules and principles applying to advertising of medicinal products aimed at healthcare professionals?

The IPHA Code (updated in 2021) requires that the promotion of a medicinal product be consistent with the terms of the marketing authorisation (MA) and that all promotion encourages the rational use of the medicinal product by presenting it objectively and not exaggerating its properties. A medicinal product must not be promoted prior to receipt of the MA permitting its sale or supply.

The Advertising Regulations provide that the advertising of authorised medicinal products to HCPs must include, at least, the following information:

- essential information compatible with the summary of product characteristics;
- the name of the product and the list of the active ingredients;
- the classification of the product;
- one or more indications for use of the product;
- information regarding adverse reactions and contraindications;
- the dosage and method of use of the product; and
- details of the MA and MA holder.

Law stated - 20 October 2021

Advertising of medical devices

Is the advertising of medical devices to healthcare professionals regulated as rigorously as advertising in the pharmaceuticals sector? What are the main differences?

The advertising of medical devices is not regulated as rigorously as the advertising of medicinal products. However, only medical devices that are CE marked may be marketed and promoted (subject to limited exceptions regarding trade shows or exhibitions). Advertisements of medical devices must comply with the general laws on advertisements.

In addition, the codes of ethics of the representative bodies of medical device manufacturers do not contain the same level of obligations and restrictions as those contained in the IPHA Code.

The Medical Devices Regulation (Regulation (EU) No. 2017/745) (MDR) contains provisions in relation to the advertising of medical devices, including a prohibition on advertising that would mislead the user or the patient with regard to the device's intended purpose, safety or performance. The MDR became fully applicable on 26 May 2021 (having been delayed for one year owing to the covid-19 pandemic).

The IPHA Code now also applies to certain medical devices – namely medical devices that are available to consumers to purchase without prescription for selfcare use are listed as 'consumer medical devices'.

Law stated - 20 October 2021

DATA PROTECTION, PRIVACY AND DIGITISATION IN HEALTHCARE

Digitisation

What are the legal developments regarding digitisation in the healthcare sector and industrial networks or sales channels?

In December 2013, the Department of Health introduced its eHealth strategy in line with the EU eHealth Action Plan 2012 to 2020. eHealth Ireland was set up to focus on the promotion and implementation of an eHealth agenda. Initial priority areas included e-prescribing, online referrals and scheduling, telehealth (particularly in respect of the management of chronic diseases) and the development of summary patient records. The Health Identifiers Act 2014 was prioritised and introduced in 2015. It provides the legal basis for Individual Health Identifiers for health service users and unique identifiers for health service providers. The Health Information and Quality Authority published draft recommendations for the national, community-based e-prescribing programme in Ireland in June 2018. The report states that legislative and policy changes will be required for an electronic prescription to be recognised as a legal prescription in Ireland. These changes include legislation for digital signatures and other measures.

During the covid-19 pandemic, new legislative provisions were adopted to facilitate the electronic transfer of prescriptions from the prescriber to a pharmacy via an approved electronic system: the Health Service Executive's Healthmail system. This change, introduced in April 2020 by the COVID Emergency Legislative Provisions, removed the requirement for a paper copy of a prescription to be forwarded to a pharmacy provided it is sent and received through the closed-system electronic service. The explanatory memorandum to the COVID Emergency Legislative Provisions described the rules as temporary measures but there is no express temporal period built into the provisions themselves. As such, it is unclear how long these new electronic prescription measures will be in place.

Law stated - 20 October 2021

Provision of digital health services

Which law regulates the provision of digital health services, and to what extent can such services be provided?

There is currently no specific legislation governing the provision of digital health services (aside from temporary measures around e-prescriptions) but legislation is due to be introduced to align with the future eHealth strategy.

Law stated - 20 October 2021

Authorities

Which authorities are responsible for compliance with data protection and privacy, and what is the applicable legislation? Have the authorities issued specific guidance or rules for data protection and privacy in the healthcare sector?

The Data Protection Commission is responsible for compliance with data protection and privacy in Ireland. The Data Protection Act 2018 , which transposed Regulation (EU) 2016/679 (General Data Protection Regulation (GDPR)) into Irish law. This is supplemented by some unrepealed provisions in the Data Protection Acts 1988 and 2003.

The Health Research Regulations 2018 sets out measures that must be taken where a controller is processing personal data for the purposes of health research. These Regulations require the controller to obtain the explicit consent of the data subject.

Law stated - 20 October 2021

Requirements

What basic requirements are placed on healthcare providers when it comes to data protection and privacy? Is there a regular need for qualified personnel?

The basic requirements placed on healthcare providers (HCPs) are the same as on any organisation acting as a controller or processor of personal data. An HCP must adhere to the seven principles of the GDPR, namely:

- lawfulness, fairness and transparency;
- purpose limitation;
- data minimisation
- accuracy;
- storage limitation;
- integrity and confidentiality; and
- accountability.

Under article 6 of the GDPR, the processing of personal data by an HCP shall only be lawful where one of the following applies:

- the consent of the data subject has been obtained;
- processing is necessary for the performance of a contract;
- processing is necessary for compliance with a legal obligation;
- processing is necessary to protect the vital interests of the data subject or third party;
- processing is necessary for the performance of a task carried out in the public interest; and
- processing is necessary for the purposes of the legitimate interests of the controller.

HCPs will often be dealing with 'special categories of personal data', as defined by article 9(1) of the GDPR. The processing of this sensitive data is prohibited unless one of the exceptions listed in article 9(2) applies.

There is a regular need for qualified personnel in the form of a data protection officer. Article 37(1) of the GDPR states that a controller or a processor shall designate a data protection officer in any case where the core activities of the controller or the processor consist of processing on a large scale of special categories of data pursuant to article 9. As the core activities of healthcare providers involve processing data concerning health and special categories of personal data, they should appoint a qualified and competent data protection officer.

Law stated - 20 October 2021

Common infringements

What are the most common data protection and privacy infringements committed by healthcare providers?

While this information is not publicly available, generally, the most common data protection and privacy infringements committed by HCPs in practice derive from a failure to obtain adequate consent from patients and or failing to establish a lawful basis for processing under article 6 of the GDPR.

Law stated - 20 October 2021

COLLABORATION

Legislation

Which legislation governs the collaboration of the pharmaceutical industry with healthcare professionals? Do different rules apply regarding physicians in the outpatient and inpatient sectors?

The Medicinal Products (Control of Advertising) Regulations 2007 provide a legal framework for the collaboration of the pharmaceutical industry with healthcare providers (HCPs). In addition, the Irish Pharmaceutical Healthcare Association Code of Practice for the Pharmaceutical Industry, Edition 8.4 (the IPHA Code) governs the collaboration of the pharmaceutical industry with HCPs. The rules do not differentiate between physicians in the outpatient and inpatient sectors.

Law stated - 20 October 2021

Collaboration with healthcare professionals

What are the main rules and principles applying to the collaboration of the pharmaceutical industry with healthcare professionals?

Gifts, pecuniary advantages and benefits in kind may not be given to HCPs.

However, companies are not precluded from providing reasonable educational support, grants or donating equipment for the betterment of patients where this is:

- in response to a written request from an HCP or institution and a written agreement must be signed in advance of the commencement of the support;
- relevant to the practice of medicine or pharmacy;
- not linked to product promotion;
- paid to the institution rather than an individual;
- reasonable, modest and in proportion to the scale of the institution; and
- in relation to employment grants, provided directly or indirectly for positions that are predominantly research-based and for a defined period of time.

Companies must also actively check that their support has been spent as intended, and obtain confirmation from the recipient of such. In addition, companies can provide a healthcare support service, which is defined as ‘a process enhancement initiative or medical service support . . . provided by a pharmaceutical company that ultimately provides patient care and welfare’.

The healthcare support services must have the following objectives:

- monitoring disease activity;
- achieving better healthcare outcomes; and
- enhancing patient care.

The healthcare support services must:

- not be designed as an inducement to prescribe;
- not be designed or operated in a promotional manner;

- have decisions based on objective criteria linked to a defined purpose;
- be reviewed in advance, by an appropriate non-promotional function within the company and provided under their supervision; and
- include a written agreement covering the nature of the support, scope, timelines and objectives, to be signed before commencement.

Free samples may be given to HCPs subject to certain conditions including that:

- samples are provided on an exceptional basis and do not exceed four per year under the IPHA Code;
- any free samples are given in response to a written request;
- these samples are no larger than the smallest presentation of the product on the market and are marked 'free medical sample – not for sale' or with words of like effect; and
- the sample is accompanied by a copy of the summary of product characteristics.

Collaboration with HCPs can also involve engaging HCPs to provide services. This, too, is governed by the IPHA Code. HCPs may provide services such as speaking, advisory or research services provided:

- there is a legitimate need for these services and selection of consultants is related directly to this need;
- there is a written contract governing these services;
- no more consultants are retained than necessary;
- records of services are maintained;
- hiring of HCPs is not an inducement to prescribe, purchase, supply or sell a particular product; and
- compensation for these services is reasonable and reflects fair market value.

Companies may organise and sponsor conferences and events with HCPs provided these are held at appropriate venues that are conducive to the main purpose of the events. In addition, companies may sponsor meetings of HCPs provided expenditure does not extend beyond the general expenses of the meeting. Major meetings or series of meetings should not be sponsored by one company to the exclusion of other available and willing sponsors.

The IPHA Code also contains a set of industry rules relating to the disclosure of 'transfers of value' from pharmaceutical companies to HCPs and healthcare organisations (HCOs). The disclosure rules oblige every member pharmaceutical 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. Disclosure 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 IPHA Code obliges members to publish transfers of value , subject to internal corporate compliance and feasibility.

Law stated - 20 October 2021

Collaboration with patient organisations

What are the main rules and principles applying to the collaboration of the pharmaceutical industry with patient organisations?

The IPHA Code provides guidelines on the collaboration of the pharmaceutical industry with patient associations or organisations. At a general level, the independence of a patient organisation must be guaranteed and, where there is

joint cooperation, full transparency is required. Promotion of a company's products cannot be undertaken directly or indirectly by a patient organisation. Free samples may not be provided to patient organisations.

Funding of a patient organisation is acceptable, for example, where a donation is made without reference to the specific purpose; funding for a publication meeting, project or piece of research where a company has little or no involvement; for projects of joint interest; or providing or sponsoring speakers and making contributions for travel expenses. A number of principles apply, including:

- companies cannot seek to influence the text of materials they sponsor in a manner favourable to their own commercial interests;
- companies must publish a list of patient associations to which they provide financial support or significant indirect or non-financial support. This should include a description of the nature of support given; and
- companies must publish a list of patient associations they have engaged to provide significant contracted services. This should include a description of the nature of the services provided. They must also disclose the total amount paid per patient organisation.

Contracts between companies and patient organisations for the provision of services to companies are only allowed for the purpose of supporting healthcare research. Patient organisations can be engaged as experts and advisers for services such as advisory board meetings and speaker services. Certain criteria must be fulfilled, for example:

- there must be a written contract specifying the nature of the services and basis of payment;
- a legitimate need must be identified and documented in advance;
- engaging a patient organisation is not an inducement to recommend a particular product; and
- the compensation for the services is reasonable and does not exceed fair market value.

The IPHA Code also provides that no one company should fund a patient organisation to the exclusion of others. However, the organisation's independence must be recognised in terms of whom they wish to work with exclusively. A company must have permission to use a patient organisation's logo or proprietary material.

There are also restrictions on hospitality; for example, any hospitality provided should be reasonable and secondary to the main purpose of an event and directly linked to the event itself.

Law stated - 20 October 2021

Common infringements

What are the most common infringements committed by pharmaceutical manufacturers regarding collaboration with healthcare professionals?

This information is not publicly available.

Law stated - 20 October 2021

Collaboration on medical devices

Is the collaboration of manufacturers of medical devices with healthcare professionals and patient organisations regulated as rigorously as collaboration in the pharmaceuticals sector? What are the main differences?

The code of ethics for representative bodies of medical device manufacturers do not contain the same level of obligations and restrictions as those contained in the IPHA Code (noting this code applies to a small segment of medical devices) around collaboration with HCPs and patient organisations.

Law stated - 20 October 2021

COMPETITION LAW

Authority enforcement

Are infringements of competition law by healthcare providers pursued by national authorities?

The Irish national competition authority, the Competition and Consumer Protection Commission, has statutory powers to investigate suspected breaches of competition law by healthcare providers on its own initiative or in response to complaints from third parties.

Law stated - 20 October 2021

Private enforcement

Is follow-on private antitrust litigation against healthcare providers possible?

Yes, follow-on private antitrust litigation against healthcare providers is possible, but no such action has proceeded to judgment before the Irish courts to date.

Law stated - 20 October 2021

Anti-corruption and transparency

What are the main anti-corruption and transparency rules applicable to healthcare providers?

Under the Criminal Justice (Corruption Offences) Act 2018 (the Corruption Offences Act), it is an offence for any person to corruptly:

- give or receive a bribe (the offences of 'active' and 'passive' corruption);
- give, offer, request or accept a bribe to exert influence over the act of an official (ie, a politician or any person working for the state or a public body) in relation to the official's office or employment (the offences of active and passive trading in influence); or
- create or use a false document with the intention of inducing another person to do an act in relation to their employment or position to the prejudice of that or another person.

The Corruption Offences Act provides that if a company is found to be guilty of a corruption offence and the offence was committed with the 'consent, or connivance, or was attributable to any wilful neglect' of a director, manager, secretary or other officer of the company then that individual can also be found guilty of the offence.

The Corruption Offences Act also provides for the 'corporate offence' that enables a body corporate to be held liable for the corrupt actions committed for its benefit by any director, manager, secretary, employee, subsidiary or agent of the body corporate with the intention of obtaining an advantage for the body corporate. The single defence available to corporates for this offence is demonstrating that the company took 'all reasonable steps and exercised all due diligence' to avoid the offence being committed. While there is no Irish guidance on the legislation yet, such 'reasonable

steps' will include ensuring adequate policies and procedures are in place and that steps are taken to promote and ensure a corporate culture of reporting suspicions or concerns in relation to corruption.

'Corruptly' is defined in the Corruption Offences Act as including:

. . . acting with an improper purpose personally or by influencing another person, whether by means of making a false or misleading statement, by means of withholding, concealing, altering or destroying a document or other information, or by any other means.

Consequences for breach of anti-corruption laws include imprisonment, fines or both.

There is no requirement under Irish legislation to publicly report information about Transfers of Value, which they provide to healthcare professionals, healthcare organisations or patient organisations. However, the Irish Pharmaceutical Healthcare Association (IPHA) Code of Practice for the Pharmaceutical Industry (edition 8.5 – effective 1 March 2021) (the Code), a self-regulatory or voluntary code, sets out the requirements on companies to make information regarding Transfers of Value publicly available. These requirements only apply to members of the IPHA and reflect the EFPIA standards (IPHA is a member of the EFPIA. The Code provides that each member must document and publicly disclose (subject to internal corporate compliance and feasibility), the Transfers of Value which it makes, either directly or indirectly, on the IPHA Central Report, in order to allow a comprehensive report to be made available from IPHA on Transfers of Value in Ireland. These disclosures may also be made on each company's relevant website; however, this is provided the disclosures are unrestricted and publicly available.

Law stated - 20 October 2021

PRICING AND REIMBURSEMENT

Price regulation

To what extent is the market price of a medicinal product or medical device governed by law or regulation?

The statutory powers covering the pricing of medicinal products are contained in the Health (Pricing and Supply of Medical Goods) Act 2013 (the 2013 Act). Historically, the price of medicinal products was governed by framework agreements in place between pharmaceutical associations, the Department of Health and the Health Service Executive (HSE) on the supply terms, conditions and prices of medicines. Since the introduction of the 2013 Act, the framework agreements are no longer the sole criterion for determining price but remain a key factor to be considered.

The prices paid by the HSE for medicines supplied under Ireland's community drugs schemes are maintained by the HSE on an official reimbursement list. The prices are set by the HSE by reference to criteria set out in the 2013 Act.

The 2013 Act also introduced a system of generic substitution and reference pricing in Ireland, which operates as follows:

- the HPRA publishes and maintains a 'list of interchangeable medicines', which contains products grouped together according to their active substance, strength, pharmaceutical form and route of administration;
- the HSE sets one price, called the reference price, that it will pay for medicines in a group of interchangeable medicines. This is typically the price of the cheapest medicine in the group;
- pharmacists are obliged, in certain circumstances, to dispense the product that is the lowest cost to the HSE; and
- if a patient wants the more expensive medicine in the group, the patient must pay the difference between the

reference price and the retail price.

Law stated - 20 October 2021

Negotiations between manufacturers and providers

Must pharmaceutical and medical device manufacturers negotiate the prices of their products with public healthcare providers?

The HSE maintains a reimbursement list and must follow the processes set out in the 2013 Act to add products to the reimbursement list and to set the reimbursement prices for those products. For products dispensed under the state-sponsored community drug schemes, the reimbursement price of items is set by the HSE by reference to the criteria set out in the 2013 Act. The framework pricing agreements are one of the factors in setting the reimbursement price for products. The latest Framework Agreement was signed in July 2016 for a period of four years.

Where a supplier applies to the HSE to have a medicinal product or medical device added to the reimbursement list, the HSE may add the product to the reimbursement list at a price agreed with the supplier subject to the criteria in the 2013 Act.

When considering the price of a product that is already on the reimbursement list, the HSE must take account of the criteria in the 2013 Act. Although this pricing procedure does not entail negotiation with the manufacturer per se, the manufacturer is entitled under the Act to make representations to the HSE in relation to the price changes.

Law stated - 20 October 2021

Reimbursement

In which circumstances will the national health insurance system reimburse the cost of medicines?

Any person who is ordinarily resident in Ireland is legally entitled to either free or subsidised approved prescribed medicines and certain medical and surgical aids and appliances. For products dispensed under the state-sponsored community drug schemes, the reimbursement price of items is set by the HSE by reference to the criteria set out in the 2013 Act. Pharmacy contractors provide community pharmacy services to the eligible population across the various community drug schemes operated in Ireland. In return, pharmacy contractors are paid a dispensing fee and are reimbursed for the price of the product.

Patients are required to make co-payments under certain government schemes. Whether or not a co-payment is required, and the level of the co-payment, depends on the scheme under which the medicinal product is dispensed.

Under the General Medical Services (GMS) scheme a patient receives their medicine after paying a nominal fee per item prescription charge. The GMS scheme is a means-tested scheme that applies to those who do not have sufficient means to pay for their medicine. There is an exception to these charges under the related Hi-Tech Scheme, which covers expensive medicines required for long-term care, the Health Amendment Act 1996 scheme, which covers hepatitis C treatment as a result of contaminated blood and the Misuse of Drugs Regulations 1998, which covers methadone. Under these schemes, no co-payment is required. Under the Drug Payment Scheme, the patient pays a maximum co-payment for all medicines supplied to them and their family. Under the Long-Term Illness Scheme, the patient receives medicines for specific long-term medical conditions, such as diabetes and epilepsy, free of charge and no co-payment is required.

Law stated - 20 October 2021

Price adjudication

If applicable, what is the competent body for decisions regarding the pricing and reimbursability of medicinal products?

The HSE is the competent body for determining the price and reimbursability of medicines. HSE policy is determined by the Department of Health. In addition, the HSE use Health Technology Assessments and other mechanisms to generate information about the clinical and cost-effectiveness of health technologies to determine the reimbursement status (or continued reimbursement status) of medicines. These are carried out by the Health Information and Quality Authority or groups within the HSE.

Law stated - 20 October 2021

Discount

Are manufacturers or distributors of medicinal products statutorily obliged to give a discount to health insurance schemes or third parties?

The framework agreements referred to above contain provisions for discounts to state-funded hospitals and agencies, subject to conditions. Discounts are available for orders above a certain amount in respect of products from a single manufacturer on the basis of monthly settlement of accounts. Discounts are not available where orders are placed with a distributor for products for which the distributor is not the nominated distributor of an individual supplier.

Law stated - 20 October 2021

UPDATE AND TRENDS

Key developments of the past year

Is there any legislation expected in the near future that will have a major impact on the current legal environment for medicines or medical devices?

Two new regulations, the Medical Devices Regulation (Regulation (EU) No. 2017/745) (MDR) and the In-Vitro Diagnostic Devices Regulation (Regulation (EU) No. 2017/746) (IVDR), entered into force and replaced the suite of directives that previously governed the law on medical devices. The MDR and the IVDR are subject to a staggered transitional period; some aspects became legally binding after six months. The MDR was to become fully applicable after three years; however, the introduction of the MDR was postponed for one year owing to the covid-19 pandemic to May 2021. The MDR became applicable on 26 May 2021 and was implemented in Ireland by way of SI No. 261/2021 – Medical Devices Regulations 2021. The introduction of the IVDR remains set for May 2022 (but a recent EU proposal has been made to extend the timing of introduction due to delays in testing or backlog among national notified bodies). The aim of the MDR and IVDR is to strengthen the previous regulatory system for medical devices. As the legislation is now in the form of a regulation, rather than a directive, it is directly applicable at a national level without requiring transposition through specific national legislation. This will allow for greater legal certainty and prevent variation in the approach taken or in the rules relating to medical devices that are applied across EU member states.

Law stated - 20 October 2021

Jurisdictions

Canada	Stikeman Elliott LLP
China	East & Concord Partners
European Union	Simmons & Simmons LLP
Germany	Ehlers Ehlers & Partner
India	LexOrbis
Ireland	Matheson
Israel	S Horowitz & Co
Italy	CMS Legal
Japan	Anderson Mōri & Tomotsune
Mexico	OLIVARES
New Zealand	Tompkins Wake
Singapore	Drew & Napier LLC
South Korea	Lee & Ko
Sweden	Cirio Advokatbyrå AB
Switzerland	Wenger Vieli Ltd
Turkey	Gün + Partners