Life Sciences Commercialisation in Ireland: Overview

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A Q&A guide to life sciences commercialisation in Ireland.

This Q&A provides a high-level overview of key practical issues, including the life sciences sector, pricing and state funding, distribution and sale, importing, advertising, patents, trade marks, competition law, and product liability.

Life Sciences Sector Overview

1. Give a brief overview of the life sciences sector in your jurisdiction.

The life sciences sector is a major industry in Ireland, employing over 40,000 people and accounting for 32% of the GDP in 2021. Major multinational and domestic pharmaceutical, diagnostic, and medical device companies, ranging from start-ups and university spin-outs to large multinationals and industry leaders have established operations in Ireland. Nine out of the top ten pharmaceutical companies, 14 out of the top 15 medical technologies companies and nine out of the top ten US technology companies operate in Ireland. Clients commonly seek legal advice in relation to establishing operations in Ireland and on all aspects and stages of the life cycle of a product, from clinical research and development through to manufacturing and marketing of finished products and post-marketing activities and compliance.

2. Give a brief overview of key life sciences funding issues in your jurisdiction.

Securing investment for, and providing support to, life sciences entities in Ireland is provided by several governmental agencies along with the provision of various financial and tax incentives.

Various governmental agencies operate funding and support programmes for companies seeking to establish operations in this jurisdiction:

- *Enterprise Ireland* (EI) is the Irish government agency responsible for the development and promotion of Irish enterprise. EI operates the Competitive Start Fund intended to accelerate the growth of start-up companies that have

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the demonstrated potential in global markets. Additionally, the Innovative HPSU Fund offers equity investment to high potential start-up clients to support the implementation of company business plans. The New Frontiers Entrepreneur Development Programme also provides support to high potential start-ups based on the date of incorporation, sales made within the last three years, and sector of operation.

- *InterTradeIreland* provides support to SMEs through various programmes, for example, the Aumen, Innovation Boost and Elevate programmes. Qualifying criteria for these programmes depends on factors including the size of the entity and the particular sector of operation.

In addition to these funding programmes there are various tax and financial incentives that provide support to life sciences companies:

- A corporation tax rate of 12.5%.
- The provision of a 25% tax credit for monies spent by companies on certain research and development activities.
- The "knowledge development box" corporation tax relief operates to provide companies with a deduction equal to 50% of its qualifying profits derived from certain intellectual property (IP) assets, meaning qualifying profits may be taxed at an effective rate of 6.25%.
- The Employment and Investment Incentive allows individual investors in life sciences companies to obtain tax reliefs on investments made, in each tax year, into certified qualifying companies.

Pricing, Government Funding, and Reimbursement

National Health Care System

> 3. What is the structure of the national health care system, and how is it funded? Briefly explain how pharmaceuticals are introduced into that system.

Structure and Funding

The Health Acts *1947* to *2023* (the Health Acts) set out the statutory basis for the structure of the national health care system. The public health care system is funded by the state through taxation and social security contributions. Private health care is funded by private insurance, social security schemes, and private funds.

The Department of Health determines health care policy and expenditure. This is implemented by the national health provider, the Health Service Executive (HSE), which was established by the *Health (Amendment) Act 2004*. The HSE integrates the delivery of health and personal social services through three service delivery units, namely:

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- Population Health, which promotes and protects public health, and is responsible for immunisation programmes, infection control, and environmental health.
- Primary, Community, and Continuing Care, which delivers health and personal social services in the community (except for acute hospitals).
- The National Hospitals Office, which provides acute hospital, ambulance, and other pre-hospital emergency response services throughout the country.

There are three categories of hospitals in Ireland:

- HSE hospitals, owned and funded by the HSE.
- Voluntary public hospitals, owned by private bodies but receiving state funding.
- Private hospitals, owned by private bodies and receiving no state funding.

The Health Information and Quality Authority (HIQA) is a statutory body responsible for monitoring the safety and quality of HSE funded hospitals. HIQA is responsible for regulating designated centres which are health care residential settings.

Interaction of the Life Sciences Industry with the Health Care System

The Corporate Pharmaceutical Unit (CPU) within the HSE is responsible for evaluating schemes operated by the HSE to provide drugs and medical devices to patients, in conjunction with the National Centre for Pharmacoeconomics (NCPE).

Price Regulation and Reimbursement

4. How are the prices of medicinal products regulated? When is the cost of a medicinal product funded by the government or reimbursed? How is a pharmacist compensated for dispensing services?

Price Regulation

The *Health (Pricing and Supply of Medical Goods) Act 2013* (Pricing and Supply Act) as amended, and the *Irish Pharmaceutical Health Care Association Agreement 2021* (2021 IPHA Agreement) are the key documents regulating the prices of medicinal products in Ireland.

The Pricing and Supply Act introduced generic substitution and reference pricing for groups of interchangeable medicinal products, to reduce health care expenditure in Ireland. The introduction of generic substitution allows pharmacists to dispense a less costly medicine than that prescribed, provided that the less costly medicine falls within the same group of interchangeable medicinal products. The Health Products Regulatory Authority (HPRA) draws up the list of groups of interchangeable medicinal products.

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Under the Pricing and Supply Act the HSE has set a common reimbursement price for groups of interchangeable medicinal products, known as the reference price, for the medicines in question. If a supplier wishes to charge above the reference price, the patient must pay the difference, as the HSE will only reimburse at the reference price.

In setting the reference price, the HSE must take into account:

- The ability of suppliers of the relevant items to meet patient demand.
- The value for money provided by the relevant items.
- The equivalent relevant prices (if practicably available) of the applicable items in all other member states where one or more of the applicable items is marketed.
- The relevant prices of therapeutically similar items.
- The resources available to the HSE.
- The terms of any agreement (entered into before, on, or after the commencement of the Pricing and Supply Act) between the HSE and any representative body of the suppliers of drugs, medicines, or medical or surgical appliances, where the agreement relates, whether directly or indirectly, to the price of one or more of those items. This requires the HSE to take into account the terms of the agreements entered into by the HSE with IPHA and Medicines for Ireland (formerly the Irish Generic Medicines Association (IGMA) and the Association of Pharmaceutical Manufacturers in Ireland (APMI)), the industry body representing manufacturers of generic medicinal products (see below).

Following the expiry of the 2016 IPHA Agreement, the 2021 IPHA Agreement governs the pricing and supply of medicinal products that are:

- Included on the HSE reimbursement list, and supplied to, or reimbursed by, the HSE, state-funded hospitals, or other publicly funded entities and state agencies providing similar services (hospital medicinal products).
- Subject to an application for inclusion on the reimbursement list, or for supply or reimbursement as a hospital medicinal product.

The 2021 IPHA Agreement includes an annual downward only price realignment, which commenced on 1 March 2022 and on the 1 March in each subsequent year. The price realignment is set as:

- For patented medicinal products, the average ex-factory price of 14 nominated member states.
- For off-patent medicinal products, for which there is no identical pharmaceutical form available for prescription within the reimbursement schemes, the currency-adjusted average price to the wholesaler in the nominated EU member states in which the medicinal product is available.

Under the 2021 IPHA agreement:

- On 1 of January 2022, the price of a medicinal product that has lost patent protection and for which a generic product has become available fell to 40% of the original ex-factory price. After 1 January 2022, those products that lose patent protection and for which a generic product has become available will fall to 40% of the ex-factory price as of 1 October 2021.

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- On 1 January 2022, patent-expired biological products were subject to a 62.86% reduction in price from the 31 July 2016 ex-factory price once a biosimilar enters the market. After 1 January 2022, patent-expired biological products will be subject to 62.86% reduction in price of the ex-factory price as of 1 October 2021.

If a new medicinal product is not available in any of the nominated EU member states the manufacturer/importer must propose a price. This will be considered by the HSE, in accordance with the principles set out in Schedule 1 of the 2021 IPHA Agreement and the Pricing and Supply Act.

Reimbursement

Medicinal products dispensed in the community are funded by the state, through reimbursement of the pharmacist, where the patient is eligible under one of the reimbursement schemes and the medicinal product is eligible for reimbursement.

Reimbursement schemes. The HSE Primary Care Reimbursement Service (PCRS) operates a General Medical Services (GMS) Scheme and a number of other community reimbursement schemes (Community Drug Schemes). Under these, it reimburses primary care contractors, including pharmacists, for the cost of providing health services and medicines to the public.

The GMS Scheme provides free general medical services, including access to doctors, surgeons, dentists, and medicines, to those who cannot afford such services. The Community Drug Schemes include the Drugs Payment Scheme, the Long Term Illness Scheme, the High Tech Drugs Scheme, and the European Economic Area Scheme, among others.

Reimbursement procedure. A medicinal product is eligible for reimbursement if it:

- Has a current marketing authorisation (MA).
- Is approved for reimbursement by the HSE.
- Is prescribed by a doctor.
- Is dispensed by a doctor or pharmacist.

New medicines for which an MA has been granted may become reimbursable within 75 days of application to the HSE for reimbursement approval, subject to certain exceptions. New and existing technologies that are of high cost or that may have a significant impact on the Irish health care budget may be referred by the HSE for pharmacoeconomic assessment.

Pharmacist Reimbursement

Payments to pharmacists are regulated by HSE Community Pharmacy Contractor Agreements and the *Health Professionals (Reduction of Payments to Community Pharmacy Contractors) (Amendment) Regulations 2017*, as amended.

Distribution and Sale

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5. Who is authorised to prescribe and supply medicines to patients or consumers? Who is authorised to distribute prescription medicines and over-the-counter medicines?

Prescription medicinal products can only be dispensed by a person lawfully conducting a retail pharmacy business, and must be dispensed by or under the personal supervision of a registered pharmacist according to a prescription issued by a registered medical practitioner, a registered dentist or, in certain circumstances, a registered nurse.

Certain non-prescription drugs (as set out in the *Medicinal Products (Prescription and Control of Supply) Regulations 2003*, as amended) can only be sold from a pharmacy under the supervision of a registered pharmacist.

General sale products can be placed on general sale, meaning that they can be sold in a pharmacy and any other outlet which is not a pharmacy, for example, a supermarket.

The supply of prescription-only medicines in Ireland by mail order is prohibited. Supply by mail order is defined as both:

- Any supply made, after solicitation of custom by the supplier, or by another person in the supply chain inside or outside Ireland.
- Without the supplier and customer being simultaneously present and using a means of communication at a distance, whether written or electronic, to convey the custom solicitation and the order for supply.

For information about the *Falsified Medicines Directive (2011/62/EU)*, see *Country Q&A, Life Sciences Regulation in Ireland: Overview, Question 13: Serialisation*.

6. How is the wholesale distribution of medicines regulated?

The *Medicinal Products (Control of Wholesale Distribution) Regulations 2007* to the *Medicinal Products (Control of Wholesale Distribution) (Amendment) Regulations 2013* (Wholesale Regulations) regulate the wholesale distribution of medicines. Wholesale distribution includes all activities consisting of procuring, holding, supplying, or exporting medicinal products, other than activities involving the sale or supply of these products to the public.

Persons who, in the course of a business, are engaged in the wholesale distribution of medicinal products for human use, require a wholesale distribution authorisation (WDA). The purpose of a WDA is to ensure that the standards of medicinal product quality, safety, and traceability which exist within the manufacturing sector are also maintained within the distribution chain to the point where the hospital or retailer (pharmacy or general sale) takes possession of the product. In certain circumstances a WDA is not required, for example where a registered pharmacy sells or supplies a medicinal product in accordance with a registered doctor's prescription.

To apply for a WDA, the appropriate HPRA application form must be completed. The applicant must show compliance with the principles of good distribution practice (GDP). Compliance with these principles is determined by the HPRA through regular site inspections. Generally, there is a timeframe of between two to eight weeks (a maximum of 90 days) and a possible inspection.

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Wholesale distributors supplying controlled drugs must hold an additional controlled drug licence or registration, which allows the holder to store and supply these products.

7. Which regulatory authority supervises the distribution of medicines? What are the consequences of non-compliance with the medicine distribution laws?

The HPRA is designated as the competent authority in Ireland for the authorisation of wholesale distributors of medicinal products for human use under section 4(1) of the *Irish Medicines Board Acts of 1995*, as amended (IMB Act). Breach of the Wholesale Regulations is an offence under the IMB Act, resulting in:

- On summary conviction, a fine of up to EUR2,000 or imprisonment for up to one year, or both.
- On conviction on indictment for a first offence, a fine of up to EUR120,000 or imprisonment for up to ten years, or both, and for a subsequent offence, a fine of up to EUR300,000 or imprisonment for up to ten years, or both.

If an offence is committed by a corporate body, and is proved to have been committed with the consent, connivance, or is attributable to the neglect of any person who is an officer or shareholder (if the shareholder manages the corporate body), this person may be personally liable for the offence.

Cross-Border Trade and Parallel Imports

8. What are the main requirements to import medicinal products into your jurisdiction? Are parallel imports of medicinal products into your jurisdiction allowed?

Import Requirements

To import medicinal products into Ireland from outside the EEA, the manufacturer must obtain a manufacturer's/importation authorisation (MIA). To obtain an MIA, an application must be made to the HPRA, and the applicant must provide information on manufacturing, importation, and testing operations. Further, the Medicinal Products (Control of Manufacture) (Amendment) Regulations 2013 require authorisation holders to ensure that imported medicinal products have undergone:

- A full qualitative analysis.
- A quantitative analysis of at least all of the active ingredients.
- Tests or checks necessary to ensure that the quality of medicinal products fulfils the requirements of the marketing authorisation.

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Parallel Imports

Parallel imports of medicinal products from other EU member states and EEA countries into Ireland are allowed under the following two schemes: dual pack import registration (DPR) and parallel product authorisation (PPA). Products centrally authorised by the European Commission are not covered by these schemes and require separate notification to the EMA before parallel importation.

Parallel importers who engage in labelling and repackaging must hold an MIA.

Parallel importers wholesaling a parallel product in Ireland that:

- Hold an MIA do not require a wholesaler's authorisation, provided that the manufacturer's authorisation covers the parallel imported products.
- Do not hold an MIA require a wholesaler's authorisation, that names dual pack or parallel imported products as a category of medicinal product that can be wholesaled.

Parallel importers must establish a clear audit trail from the supplier in the source country so that, in the event of a recall of a batch of the parallel-imported product in the source country, appropriate action can be taken by the importer and the HPRA.

DPR Registration. If the parallel imported product (parallel product) is identical in all respects to the product on the Irish market (original product), the importer can use the simplified DPR procedure. A DPR is granted by the HPRA if all the following criteria are fulfilled:

- The original product has a valid and current MA.
- The parallel product is imported from another EEA country and has a valid and current MA in that country.
- The parallel product is identical to the original product, including the packaging, label, package leaflet, shelf life, and summary of product characteristics (SmPC).
- The importer has given the original product marketing authorisation holder (MAH) one month's notice of its intention to parallel import before submitting its application for a DPR.

If the original product MAH responds to the notification, indicating the non-existence of joint packs between the relevant markets, the product is not eligible under the DPR scheme and the DPR application must not be submitted or withdrawn.

A DPR is valid indefinitely, provided the parallel importer submits an annual declaration of compliance with the above criteria.

The HPRA expects the DPR holder to keep up-to-date with any changes to the original product, so that each consignment of the parallel product complies with the above requirements.

Before placing the product on the market, the DPR holder must ensure that a label is placed on the packaging, with the phrase "parallel imported by" followed by the name of the DPR holder and its registration number commencing with the letters "DPR." This label must not obscure any of the original text on the pack.

PPA. A PPA is required if the parallel product differs in any respect from the original product. A PPA is granted by the HPRA if all the following criteria are met:

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- The original product has a valid and current MA, or the MA has only been withdrawn for commercial reasons.
- The parallel product is imported from another EEA country and has a valid and current MA in that country.
- The parallel product has the same active substance(s) and pharmaceutical form, and is identical to, or has no significant therapeutic differences from, the original product.

A PPA can be granted indefinitely or can be limited to five years for pharmacovigilance reasons. If renewed after this five-year period, it remains valid indefinitely.

A PPA can be granted or remain in force if the original product MA is withdrawn for commercial reasons or replaced by a new version, provided that there are no risks to public health. In these circumstances, the HPRA can request additional information from the parallel importer to monitor adverse reactions in Irish patients.

The PPA is invalidated if the parallel product ceases to have a valid MA in the country from which it is imported.

The parallel importer must provide the MAH in the Irish market with notice of its intent concerning parallel importation. Guidance from the HPRA indicates that 15 working days is considered reasonable notice.

Intellectual property rights (IPRs). There have been no reported cases on competition law issues arising from parallel imports of pharmaceuticals in Ireland to date. IP issues can arise if, for example, the patent holder has not already marketed the product in the EU, or if the imported product is repackaged in a way that may adversely affect the reputation of the trade mark and its owner.

In the EEA, if the IPR holder places or consents to the placement of the product on the market in an EEA state, it cannot generally rely on its rights to prevent that product being imported into or marketed in another EEA state.

IPRs can be used to oppose parallel imports from outside the EEA.

Advertising

9. What is the main legislation and what are the regulatory authorities that control pharmaceutical advertising? Does the industry have a system of self-regulation based on industry codes of conduct? What are the main elements of that system?

The advertising of medicinal products is regulated by the *Medicinal Products (Control of Advertising) Regulations 2007* (Advertising Regulations). The Advertising Regulations are enforced by the HPRA or IPHA (for IPHA members only).

Non-compliant advertisements can be required to be withdrawn and the person responsible for the advertisement may be required to publish a corrective statement. Breach of the Advertising Regulations is a criminal offence under the IMB Act, and liability is the same as for a breach of the *Medicinal Products (Control of Manufacture) Regulations 2007*, as amended (Manufacturing Regulations).

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The *Consumer Protection Act 2007* (CPA), the *European Communities (Misleading and Comparative Marketing Communications) Regulations 2007*, and the *Consumer Rights Act 2022* also apply to general advertising and commercial practices.

Self-regulation plays an important role, and members of IPHA must comply with:

- The Code of Practice for the Pharmaceutical Industry (Edition 8.5) (IPHA Industry Code). This applies to both prescription and non-prescription medicines.
- The Code of Standards of Advertising Practice for the Consumer Healthcare Industry (Edition 5.2) (IPHA Consumer Code). This applies to non-prescription medicines.

The IPHA Industry Code fully reflects the standards of the 1 March 2021 edition of the EFPIA Code on the Promotion of Prescription-only Medicines to, and Interactions with, Healthcare Professionals, as published by the European Federation of Pharmaceutical Industries and Associations (EFPIA).

The Advertising Standards Authority for Ireland (ASAI) has published a Manual of Advertising Self-Regulation with the Code of Standards for Advertising and Marketing Communications in Ireland (7th Edition March 2016) (ASAI Code). The ASAI Code applies to the advertising of medicinal products, except for specialised marketing communications addressed to the medical, veterinary, and allied professions.

Under the Advertising Regulations, advertising includes any form of door-to-door information, canvassing activity, or inducement designed to promote the prescription, supply, sale, or consumption of medicinal products, including in particular:

- Advertising medicinal products to the general public.
- Advertising medicinal products to persons qualified to prescribe or supply them.
- Visits by medical sales representatives to persons qualified to prescribe medicinal products.
- The supply of samples of medicinal products.
- Providing inducements to prescribe or supply medicinal products, by the gift, offer, or promise of a benefit or bonus, in money or in kind.
- Sponsorship of promotional meetings attended by persons qualified to prescribe or supply medicinal products.
- Sponsorship of scientific congresses attended by persons qualified to prescribe or supply medicinal products, in particular paying their travelling and accommodation expenses.

10. Is there a definition of advertising or advertisement in relation to pharmaceuticals? What kinds of activities, channels and communications meet those definitions (and are therefore subject to restrictions), and what falls outside (and is therefore permitted)?

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Advertising is defined in the Advertising Regulations as any form of door-to-door information, canvassing activity, or inducement designed to promote the prescription, supply, sale, or consumption of medicinal products. This specifically includes:

- Advertising to the general public and those who are qualified to prescribe or supply medicinal products.
- Supplying samples.
- Inducements to prescribe or supply by the gift, offer, or promise of any benefit or bonus, in money or in kind.
- Sponsorship of promotional meetings and scientific conferences attended by persons qualified to prescribe or supply.
- In particular, the payment of travelling and accommodation expenses associated with such conferences.

An advertisement of a medicinal product made to persons qualified to prescribe or supply must contain certain prescribed information. A number of restrictions are also imposed on promotional materials, and medical sales representatives must comply with certain requirements in their meetings with persons qualified to prescribe or supply.

11. Do companies have to set up internal procedures for managing and approving their advertising of pharmaceuticals?

The Advertising Regulations require that a scientific service be established within the company to compile and collate all information relating to products. Medical sales representatives must be adequately trained and have sufficient scientific knowledge to enable them to provide information which is as precise and as complete as possible about the product they are promoting. Companies must keep available samples of all advertising coming from their undertaking together with information indicating the persons to whom it was addressed, the method of dissemination, and the date of first dissemination, and this information must be supplied to the HPRA on request.

The Pharmaceutical Code requires that the scientific service must include a doctor or, where appropriate, a pharmacist or other suitably qualified person who must approve all promotional material before release. This person must certify that the advertisement complies with the Pharmaceutical Code and all applicable laws, is consistent with the relevant SmPC, and is a fair and truthful presentation of the facts concerning the medicinal product being promoted. The Pharmaceutical Code requires that each company appoint at least one senior employee who is responsible for supervising compliance with the Code.

12. Does pharmaceutical advertising have to be approved by a regulator?

Advertising need not be pre-approved by a regulatory or industry authority. However, the HPRA reserves the right to pre-review advertisements.

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13. Are there rules on comparative advertising that apply to pharmaceutical advertising?

From a general perspective, comparative advertising is permitted under the *Trade Marks Act 1996*, as amended (Trade Marks Act), provided it is in accordance with honest practices in industrial or commercial matters and does not take unfair advantage of, or is not detrimental to, the distinctive character or reputation of the trade mark.

Advertising must also comply with the Advertising Regulations, the CPA, and the European Communities (Misleading and Comparative Marketing Communications) Regulations 2007, which prohibit misleading comparative advertising. Brand names cannot be used in comparator advertisements without the prior consent of the relevant brand owner (Pharmaceutical Code). In addition, the products, services, and promotions of other companies cannot be disparaged in advertising either directly or implicitly. Due to the prohibition on the promotion of unauthorised medicinal products, unauthorised competitor products should not be referenced in promotional material.

14.Is it possible to share information about pharmaceuticals or indications that are unlicensed and is there a risk that this could be caught by advertising rules?

There are limited exceptions to the general prohibition on promotion of unauthorised medicinal products. Indications regarding unlicensed medicines may be shared at independent international conferences held in Ireland, subject to the following requirements:

- The medicine must be authorised in at least one other EEA member state.
- Any informational material relating to the unlicensed product must include a statement stating that the product is not authorised in Ireland.
- Any informational material relating to the unlicensed product must outline that the product has been licensed in another EEA member state with different licensing conditions to those in Ireland.

15. Are there particular rules or issues with the use of the internet and social media for advertising pharmaceuticals?

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The general rules relating to the advertising of medicinal products apply to the use of the internet and social media. Only non-prescription medicinal products can be advertised to the public, and this includes marketing that is conducted online or by post, telephone, email, or other electronic communications. The advertisement must not give the impression that a medical consultation or surgical operation is unnecessary, particularly by offering a diagnosis or by suggesting treatment remotely. Prescription medicinal products can be advertised through the internet, but only to individuals qualified to prescribe or supply them, and only with the individual's prior consent. Restricted information should only be placed in a secure part of a website for registered users or subscribers only.

The Pharmaceutical Code includes Annex IV on Guidance on Digital Communication in the Pharmaceutical Sector. It states that providing responses to inquiries received from health care professionals through digital channels is acceptable if performed in accordance with the Pharmaceutical Code. The use of electronic data communications for promotion is prohibited except with the prior permission, or on request from, the recipient. The responsibility rests with the company to ensure that receipt of the response is restricted to the health care professional making the inquiry or their nominee. It may be acceptable to contact patients through social media channels in certain circumstances (for example, reminding them to regularly take their prescribed medication) if documented approval from both the health care professional and the patient is received and, in the example given, the message carries no purpose other than supporting patient compliance with the medication schedule instructed by the patient's health care professional.

Annex IV advises that it is a question of policy for a pharmaceutical company as to whether it is appropriate to correct erroneous entries on non-company mediated sites. It cautions that care needs to be exercised since, if a company corrects certain information but omits to correct other information that may be perceived as related, this behaviour may be interpreted as a breach of the Pharmaceutical Code.

16. What are the consequences of non-compliance with the rules on advertising pharmaceuticals? How are the rules enforced and by which authorities or organisations?

The HPRA can require non-compliant advertisements to be withdrawn and the person responsible for the advertisement may be required to publish a corrective statement. A breach of the Advertising Regulations is a criminal offence and liability is the same as for a breach of the Manufacturing Regulations, that is:

- On summary conviction, a fine of up to EUR2,500 or imprisonment for up to one year, or both.
- On conviction on indictment for a first offence, a fine of up to EUR120,000 or imprisonment for up to ten years, or both, and for a subsequent offence, a fine of up to EUR300,000 or imprisonment for up to ten years, or both.

The CPA and the European Communities (Misleading and Comparative Marketing Communications) Regulations 2007 also apply to general advertising and commercial practices.

Advertising to the Public

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17. Which pharmaceuticals can and cannot be advertised to the public? What information must and must not be included in advertising of pharmaceuticals to the public?

Subject to certain exceptions for promotional materials at international congresses and symposia held in Ireland, a product cannot be advertised before the grant of an MA or certificate of traditional-use registration. All advertisements must:

- Comply with the terms of the MA and the SmPC.
- Encourage rational use of the product and not exaggerate its properties.
- Not be misleading.

The advertisement of a medicinal product to the general public is prohibited if it is either:

- A prescription-only product.
- A controlled drug under the *Misuse of Drugs Act 1977*, as amended.

Where an advertisement of a non-prescription medicinal product to the public is permitted, the advertisement must clearly identify the product as a medicinal product, be easily intelligible to the consumer, and contain an express and legible invitation to carefully read the instructions for use. The IPHA Consumer Code requires that where cautionary warnings are contained in television advertisements, they must appear on the screen for a minimum of four seconds, regardless of the length of the commercial or television slide.

Advertisements of medicinal products must also state, at a minimum:

- The name of the medicinal product, and, where it contains only one active ingredient, the common name of the medicinal product.
- The information necessary for the correct use of the medicinal product.

An advertisement to the public must not contain material which, among other things:

- Gives the impression that a medical consultation or surgical operation is unnecessary, in particular by offering a diagnosis or by suggesting treatment by mail.
- Suggests that the effects of taking the medicinal product are guaranteed, are unaccompanied by adverse reactions, or are better than, or equivalent to, those of another treatment or medicinal product.
- Suggests that the health of the subject can be enhanced by taking the medicinal product.
- Suggests that the health of the subject could be affected by not taking the medicinal product. (This prohibition does not apply to vaccination campaigns if they have been approved by the minster.)

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- Is directed exclusively or principally at children.
- Refers to a recommendation by scientists, health professionals, or persons who are neither of these but who, because of their celebrity status, could encourage consumption of medicinal products.
- Suggests that the medicinal product is a foodstuff, cosmetic, or other consumer product.

Exceptions and carve-outs are available for advertising registered homeopathic medicines, reminder advertising, and approved vaccination campaigns.

The IPHA Consumer Code also imposes certain requirements on advertisements to the public.

The general rules relating to the advertising of medicinal products apply to the use of the internet and social media. Only non-prescription medicines can be advertised to the public, and this includes marketing conducted online or by post, telephone, email, or other electronic communications. The IPHA Industry Code includes Annex IV on digital communication in the pharmaceutical sector.

18. Is it permitted to provide free samples to the public? Are there restrictions on special offers and other types of inducements?

Free samples of medicine (both prescription-only and over-the counter medicines) must not be supplied to members of the public or to any person who is not qualified to prescribe that product. This is prohibited under Irish legislation and the IPHA Industry Code.

Engagement with Patient Organisations

19. What activities are permitted (or required) in relation to engagement with patient organisations? What restrictions apply?

Annex III of the Pharmaceutical Code contains guidelines for pharmaceutical companies on working with patient organisations. Pharmaceutical companies must ensure that the independence of patient organisations is respected and guaranteed. Medicinal products must not be directly or indirectly promoted through these groups.

It is permissible for a pharmaceutical company to donate to a patient organisation either for general purposes, for a particular project or piece of research, by sponsoring speakers for events or for undertaking projects of joint interest. Each company must make publicly available a list of patient organisations to which it provides financial support, or significant indirect/non-financial support, or both. This should include a description of the nature of the support, including the monetary value of financial support

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and of invoiced costs. For significant non-financial support that cannot be assigned a meaningful monetary value, the description must describe clearly the non-monetary benefit that the patient association receives. This information may be provided on a national or European level and should be updated at least annually.

When a pharmaceutical company provides financial support, significant indirect support, or significant non-financial support to patient organisations, they must have in place a written agreement. This must set out:

- The amount of funding and the purpose (for example, core funding or a specific meeting or publication).
- A description of significant indirect support (for example, the donation of a public relations agency's time and the nature of its involvement).
- Significant non-financial support.

A pharmaceutical company may contract services from patient organisations, but only where they are provided for the purpose of supporting health care or research. A written contract is required. The compensation must be reasonable and not exceed the fair market value of services provided. A company must make publicly available a list of patient organisations that it has engaged to provide significant contracted services and the total amount paid per patient organisation over the reporting period. No one company should fund a patient organisation to the exclusion of other available and willing sponsors, except by the choice of the patient organisation, which is free to exercise its independence in determining who it wants to work with.

Any hospitality provided by a pharmaceutical company to patient organisations, and their members, should be reasonable, and secondary to the main purpose of the event for which it is provided, and must not involve sponsoring or organising entertainment. Hospitality can only be extended to persons who qualify as participants in their own right, but in exceptional cases, can be provided to a bona fide carer of a participant in the case of clear health needs.

Finally, pharmaceutical companies should not offer free samples to patient organisations.

Advertising to Health Care Professionals and Organisations

20. What are the definitions of a health care professional and a health care organisation? What information must be included in advertising to them?

Under the Advertising Regulations health care professionals include registered medical practitioners, dentists, pharmacists, and nurses. In addition, section 4 of the *Health and Social Care Professionals Act 2005*, as amended, designates clinical biochemists, dietitians, occupational therapists, physiotherapists, psychologists, radiographers, social workers, speech and language therapists, optometrists, orthoptists, and dispensing opticians and others as health care professionals.

A health care organisation is defined in the IPHA Code as any health care, medical or scientific association or organisation, for example, a hospital, clinic, foundation, university, or other teaching institution or learned society (except for a patient organisation) whose business address, place of incorporation, or primary place of operation is in Europe or an organisation through which one or more HCPs or other relevant decision makers provide services.

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The Advertising Regulations require certain minimum information to be provided to health care professionals, including:

- The product's name.
- A list of active ingredients using the common name placed immediately adjacent to the most prominent display of the product name.
- The classification for the sale or supply of the product.
- One or more of the product's indications.
- The method of administration (where it is not obvious).

A clear and legible statement of the information in the SmPC regarding adverse reactions, precautions, and contraindications, dosage, and method of use relevant to the indications must be positioned within the advertisement to enable the reader to readily appreciate the relationship between this information and the claims and indications of the product. The name and address of the holder of the MA, certification of registration or certificate of traditional use registration, or the business name and address of the part of the business responsible for placing the medicinal product on the market, should also be provided along with the authorisation number. If applicable, the words "traditional herbal medicinal product for use in…," followed by one or more therapeutic approved indications, and followed by the words "exclusively based upon long-standing use," should be included.

Separate requirements exist for abbreviated reminder advertisements. The Pharmaceutical Code adds that this information should be clear, legible, and an integral part of the promotional material.

Gifts and Incentives

21. What are the restrictions on marketing practices such as gifts, sponsoring, consultancy agreements or incentive schemes for health care establishments or individual medical practitioners?

The promotion of medicinal products to health care establishments and professionals is governed by the Advertising Regulations and the IPHA Industry Code (see *Question 9*).

The supply, offer, or promise of any gift, pecuniary advantage, or benefit in kind to a person qualified to prescribe or supply medicinal products is prohibited, unless it is inexpensive and relevant to the practice of medicine or pharmacy. For example, pharmaceutical companies can provide pens or paper pads exclusively during company organised meetings, provided that they are non-product branded and inexpensive.

Items of medical utility aimed directly at the education of health care professionals and patient care are not considered gifts and can therefore be supplied, provided they are inexpensive and do not offset the cost of routine business practice of the recipient.

In addition, the transmission of company branded informational or educational materials is permitted, provided the materials are all of the following:

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- Inexpensive.
- Directly relevant to the practice of medicine or pharmacy.
- Directly beneficial to the care of patients.

Hospitality can still be provided at sales promotions or other events for purely professional and scientific purposes, provided it is all of the following:

- Reasonable in level.
- Limited to the main purpose or scientific objective of the event.
- Not provided to persons other than those qualified to prescribe or supply medicinal products.
- Not including the sponsorship or organisation, directly or indirectly, of entertainment, sporting, or leisure events.
- Not an event taking place outside Ireland, unless there is a valid reason to do so.

Where pharmaceutical companies provide or offer meals to health care professionals, the value of each meal (including food and beverages) cannot exceed the current monetary threshold set by the IPHA of EUR80 per recipient. This threshold includes VAT but excludes gratuities, and only applies to events held in Ireland. Hospitality occurring in another member state bound by the EFPIA Code must comply with the hospitality threshold in that member state.

Companies are not prevented from providing the following, provided certain conditions are met:

- Healthcare Support Services (HSS) (defined in the IPHA Industry Code as a process enhancement initiative or medical service support provided by a pharmaceutical company that ultimately improves patient care and welfare).
- Educational, research, or employment grants.
- Donation or sponsorship of equipment.

A donation or sponsorship of equipment must be relevant to the practice of medicine or pharmacy, and must be given to an institution and intended solely for use in the institution.

Any grants must be paid directly to an institution rather than to an individual health care professional, and must not be linked in any way to product promotion.

Financial support in the form of grants, donations, and sponsorship must be reasonable, modest, and in proportion to the scale and scope of the recipient institution.

Health care professionals can enter into consultancy agreements with pharmaceutical companies to provide speaking or advisory services. These agreements must satisfy a number of criteria, and importantly must not constitute an inducement to prescribe, purchase, sell, or supply a particular medicinal product. A legitimate need must be clearly identified before the request for services. Consultants must be chosen based on criteria directly related to this identified need, and must be compensated at fair market value given the services provided.

Under the IPHA Industry Code, direct and indirect transfers of value (subject to limited exceptions) from pharmaceutical companies to health care professionals and health care organisations must be documented and publicly disclosed by pharmaceutical companies.

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Transparency and Disclosure

22. Do pharmaceutical companies have to disclose details of transfers of value to health care professionals or health care organisations?

Health Care Professionals

It is prohibited to supply, offer, or promise gifts, pecuniary advantages, or benefits in kind to health care professionals, in the course of promoting medicinal products. Health care professionals are also prohibited from accepting these items.

On 1 July 2014, the limited exemptions that were previously in place were abolished and a blanket prohibition on gifts came into force. The prohibition does not apply to the transmission of information or educational materials or to items of medical utility which will be permitted in certain circumstances (see *Question 21*).

Companies may provide items including pens and paper pads exclusively during company organised meetings, if they are non-product branded and inexpensive. Items of medical utility aimed directly at the education of health care professionals and patient care may be provided if they are inexpensive and do not offset the cost of routine business practice of the recipient. These are not considered gifts. These items may be company branded only if the brand name is essential for the correct use of the medicine.

In addition, section 15 of the Ethics in Public Office Act 1995 imposes a disclosure obligation on the recipient for any gift given to a health care professional employed by the state or their spouse, civil partner, or child, which exceeds a monetary value of EUR650.

Health Care Organisations

A pharmaceutical company may provide support in the form of HSSs, educational, research, or employment grants and the donation or sponsorship of medical equipment for the betterment of patients. The support must be in response to a written request from the health care organisation or health care professional for a specific type of support that must be genuinely needed. While health care professionals can request the support provided, support must be paid directly to the relevant health care organisation only and the support provided must be relevant to the practice of medicine or pharmacy and be intended for use solely in the organisation. The provision of any support must not be conditional on the prescription, supply, or use of the company's products or be linked in any way to promotion. The support must be modest, reasonable, and in proportion to the scale and scope of the recipient institution. The Pharmaceutical Code also obliges companies to make publicly available information in relation to these donations, grants, and sponsorship and from 1 January 2016, companies have been required to make public, on an annual basis, details of all transfers of value. There are no monetary limits for these forms of support. Companies should actively check that their support has been spent as intended and the written agreement must require that the support has been spent as agreed.

HSSs are defined as process enhancement initiatives or medical service supports (for example, patient compliance initiatives and sharps bin services) provided by a pharmaceutical company that ultimately improves patient care and welfare. An HSS must have the objectives of monitoring disease activity, achieving better health care outcomes, and enhancing patient care. They must be non-promotional, must not be designed as an inducement to prescribe, and must not be designed or operated in a promotional

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manner. The operation of the HSS must be monitored with reference to its objectives. An HSS may be provided directly or indirectly to patients. Contractual arrangements with service providers should clearly outline the service, the requirements for safety reporting, and adherence to data privacy requirements. Information collected in the provision of an HSS cannot be used for promotional purposes and cannot be used for clinical research purposes without the appropriate prior written consent of the health care provider and the patient.

Disclosure

The requirements for companies to make publicly available information about transfers of value is set out in the self-regulatory Pharmaceutical Code and are applicable only to members of the IPHA or EFPIA. Pharmaceutical companies must disclose transfers of value made by them, whether directly or indirectly. This obligation does not extend to transfers of value that are:

- Solely related to over-the-counter medicinal products.
- Not listed in Section 4 of Annex V of the Pharmaceutical Code, including items of medical utility, meals and drinks, and samples.
- Part of the ordinary course of purchases and sales of medical products by and between a pharmaceutical company and a health care professional or health care organisation.

Disclosures must be made from 1 January 2016 on an annual basis and each reporting period covers a full calendar year.

The Pharmaceutical Code allows for disclosure through either the company's website, or a central platform. Disclosures must be made by pharmaceutical companies within six months after the end of the relevant reporting period (a calendar year), and the information disclosed must remain in the public domain for a minimum of three years after the information is first disclosed, unless there is a valid legal reason not to do so. Disclosures must be made under the national code of the country where the recipient has its physical address. Pharmaceutical companies must document all transfers of value required to be disclosed and maintain the relevant records of the disclosures for a minimum of five years after the end of the relevant reporting period.

Pharmaceutical companies must disclose, on an individual basis for each clearly identifiable recipient, the amounts attributable to the transfers of value to the recipient in each reporting period which can be reasonably allocated to one of the following categories:

- In relation to transfers of value to a health care organisation, disclosure requirements are in respect of amounts related to donations and grants, contribution to costs related to events, or fees for service and consultancy.
- In relation to transfers of value to a health care professional, disclosure requirements are in respect of amounts related to contribution to costs related to events or fees for service and consultancy.

Where a transfer of value, which would otherwise reasonably be allocated to one of the above categories, cannot be disclosed on an individual basis for valid legal reasons, a pharmaceutical company must disclose the amounts attributable to the transfers in each reporting period on an aggregate basis.

23. What are the consequences of non-compliance with the rules on marketing to health care professionals?

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The *Criminal Justice (Corruption Offences) Act 2018* (Corruption Offences Act) provides that it is an offence for any person to corruptly do any of the following:

- Give or receive a bribe.
- Give, offer, request, or accept a bribe to exert influence over the act of an official in relation to the official's office or employment.
- Create or use a false document, with the intent to induce another person to do an act in relation to their office or employment, to the prejudice of that or another person.

If a company is found guilty of an offence under the Corruption Offences Act, 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, that person can also be guilty of the offence.

The *Ethics in Public Office Acts 1995* and *Standards in Public Office Act 2001*, as amended and the Civil Service Code of Standards and Behaviour are also relevant. Holders of certain public positions (including senior personnel in the HSE, HPRA, the Department of Health, and in voluntary hospitals) must disclose certain interests to the Standards in Public Office Commission. These include gifts and the provision of travel facilities, living accommodation, meals, or entertainment valued at more than EUR650 in total in any given year. While responsibility for compliance rests with the recipient of the gift, the provider of the gift can be asked to assist the Standards in Public Office Commission in its investigations, and failure to do so can be a criminal offence.

Patents

Conditions for Patentability

24. Provide a brief definition of a patent, the key legal requirements to obtain it and the law that applies.

Conditions and Legislation

Medicinal products and related substances, and the processes for their production, can be patent protected, provided they meet certain criteria.

The relevant legislation is the *Patents Act 1992*, as amended (Patents Act). Patents granted under the Patents Act can be for 20 years (full-term patent) or ten years (short-term patent). To obtain protection on a long-term patent, an invention must:

- Be new.
- Involve an inventive step.

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- Be capable of industrial application.
- Not fall within any of the excluded categories (for example, a mathematical method or scientific theory).

The criteria for a short-term patent are similar. The key difference is that, for a short-term patent, there is a lower standard of inventiveness required and the applicant does not need to provide evidence of novelty in respect of the invention.

To fulfil the criteria of novelty and inventiveness for a full term patent, the invention must not form part of the state of the art (which includes anything made available to the public before the date of filing of the patent application) and must not be obvious to a person skilled in the art.

Patent protection can be applied to a wide range of inventions, for example, appliances and mechanical devices, biological and chemical inventions, and computer related inventions.

Types of Patent Available

Full term patents. These provide protection for up to 20 years (supplementary protection certificates (SPCs) can be obtained in certain circumstances to extend the duration of a patent for medicinal and plant products by up to five years). The applicant must provide evidence of the invention's novelty, for example, by requesting a Search Report from the Irish Patents Office.

Short-term patents. Short-term patents are granted by the Patents Office for a ten-year period. The applicant does not need to provide evidence of the invention's novelty.

If applications are made for both a short-term patent and a full-term patent for the same invention, the short-term patent becomes void once the full-term patent is granted.

Main Categories Excluded from Patent Protection

A patent will not be granted for:

- A plant or animal variety or an essentially biological process for the production of plants or animals, other than a micro-biological process or its product.
- A method for treatment of the human or animal body by surgery or therapy and a diagnostic method practised on the human or animal body. (However, products in particular substances or compositions, for use in any such method, can be patented.)

(Section 10(1), Patents Act.)

Specific Provisions for the Life Sciences Industry

Biotechnological inventions that are capable of protection must also fulfil the requirements for patentability set out in the Patents Act (see above, *Conditions and Legislation*). Biotechnological inventions are patentable if they concern any of the following:

- Biological material isolated from its natural environment or produced by means of a technical process, even if it previously occurred in nature.
- Plants or animals, if the technical feasibility of the invention is not confined to a particular plant or animal variety.

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- A microbiological or other technical process, or a product obtained by means of that process, other than a plant or animal variety.

(European Communities (Legal Protection of Biotechnological Inventions) Regulations 2000.)

Registering a Patent

25. Which authority registers patents? Briefly outline the key stages and timing in obtaining a patent.

Patent Registration Authority

Patents can be registered through filing an application with either:

- The *Intellectual Property Office of Ireland* (IPOI) for a patent that is effective in Ireland.
- The *European Patents Office* (EPO) for a patent which is effective in Ireland if the applicant designates Ireland on the EPO application.

Details of current fees and guidance on the application process are available at *IPOI: Turning ideas into assets*, and on the *EPO website*.

Ireland is a signatory to the International Agreement on a Unified Patent Court. The Unified Patent Court will hear disputes in respect of infringement and validity of European patents, including those with unitary effect. Unlike other European countries, Ireland must hold a referendum to ratify the unitary patent system, to allow the transfer of judicial powers from the current Irish court system to the Unified Patent Court.

A patent application must include a detailed description of the patent including what the invention is, what it does, and how it works. The description must be sufficiently clear and complete, allowing a person reasonably skilled in the art to be able to fully replicate the invention without needing further details.

Process and Timing

Domestic patents. For an Irish patent, a filing date will be issued to the applicant by the IPOI once the minimum requirements for requesting the grant of a patent have been supplied (that is, an indication that a patent is sought, information identifying the applicant, and a description of the invention and the patent claims) subject to any further requested information being provided within prescribed time limits.

The invention is assessed as at this date for patentability by the IPOI Examiner. If satisfied that the invention is patentable, the IPOI Examiner will allow the grant of the patent. On payment of the appropriate fee, a certificate of grant is issued and a notice of grant published in the *Patents Official Journal*.

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The application process for a full-term patent typically takes a minimum of two to five years. A short-term patent is typically granted within 12 months of the filing date. If applications are made for both a short-term patent and a full-term patent in respect of the same invention, the short-term patent will become void when the full-term patent is granted.

The filing fee for a short-term patent is 50% of that for a full-term patent and generally this is of particular interest to small enterprises and single inventors.

The date a patent application for an invention is first filed establishes a priority date. Applicants who file an application at a later date for the same invention are not entitled to a patent due to the earlier priority date. The main effect of the priority right is that the filing date of the first application counts as the date from which the state of the art is assessed against the application. If two or more persons make an invention independently, the right to a patent belongs to the person whose filing date or claimed priority date is the earliest.

EPO patents. An application for a European Patent is examined by a division of the EPO to determine whether the invention meets the requirements of the European Patent Convention (EPC). Applicants can apply for a patent which is effective in all member states. Alternatively, a patent can be sought for only a number of EPC countries, which have been designated on the application.

A published European Patent application provides provisional protection no less than that offered by a contracting state for a national application. The standard term of a European patent is 20 years from the date of filing (provided the annual renewal fees are duly paid).

When a European Patent designating Ireland is granted, the EPO transmits the particulars of the patent to the IPOI. Any European patents granted on or after 4 March 2012 do not require a translation to take effect in Ireland.

EPO patents following domestic application. If, following a domestic application, an application for the same invention is filed in the EPO or a country party to the Paris Convention for the Protection of Industrial Property 1883 (Paris Convention) within 12 months of the initial filing date, the initial filing date becomes the priority date of the new application.

If there has been more than one earlier filing for the same invention this can give rise to more than one priority date. Time limits run from the earliest of the priority dates.

Length of Patent Protection

26. When does patent protection start and how long does it last? Can monopoly rights be extended by other means?

Duration

In relation to domestic patents, provided the annual renewal fees are paid and the patent is not revoked or deemed invalid:

- A full-term patent lasts for 20 years from the date of filing.

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- A short-term patent lasts for ten years from the date of filing.

Extending Protection

The term of full-term and short-term patents (see *Question 24, Conditions and Legislation*) can be extended, for a maximum of five years, by granting an SPC. These are granted for medicinal products or plant production products when the patent's commercial exploitation period is reduced by the process of obtaining an MA.

When an SPC is granted, it does not take effect until the end of the term of the basic patent, and extends protection only to the specific product which was the subject of the MA, rather than the patent as a whole.

A holder of an SPC can apply for a further extension of six months if the protected product has been tested for paediatric use and the relevant studies have complied with an agreed paediatric investigation plan. The granting of an SPC is governed by the *European Communities (Supplementary Protection Certificate) Regulations 2008*.

Section 42 of the Patents Act governs acts not within the scope of a patent (that is, specific acts that a third party can carry out without infringing the patent rights of a patent holder). Section 42(g) was inserted by the *European Communities (Limitation of Effect of Patent) Regulations 2006* by transposing the Bolar exemption language of Article 10(6) of *Directive 2004/27/EC amending the Code for Human Medicines Directive* and Article 13(6) of *Directive 2004/28/EC amending Directive 2001/82EC on veterinary medicinal products*. This was further amended by the *Intellectual Property Miscellaneous Provisions Act 2014* (IP (Miscellaneous Provisions) Act).

The Bolar exemption means that any necessary studies, experiments, tests, and trials (including clinical trials and field trials) required to obtain an MA in any jurisdiction will not amount to patent infringement.

Patent Infringement

> 27. What rights does a patent grant to its owner? On what grounds can a patent infringement action be brought? What are the main defences to a patent infringement action? How is a claim for patent infringement made and what remedies are available?

Rights Granted by a Patent

A patent confers on its holder, for a limited period of time and in countries of protection, a right to exclude others from exploiting (making, using, selling, or importing) the patented invention without the consent of the patentee.

Grounds for Patent Infringement

In Ireland, patents can be directly or indirectly infringed.

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Direct infringement. If a third party uses the patented invention without the owner's consent, the owner can take action to enforce their rights, including by preventing any other party from:

- Making, offering, putting on the market, or using a product which is the subject of a patent or importing or stocking the product for those purposes.
- Using a process which is the subject of a patent.
- Doing the above in relation to a product obtained directly by a process which is the subject of the patent, in each case without the patent holder's consent.

(Section 40, Patents Act.)

Indirect infringement. A patent can also be indirectly infringed by a person who supplies or offers to supply any of the means, relating to an essential element of the invention, for putting the invention into effect (section 41, Patents Act).

The following are some relevant exemptions from infringement in the Patents Act:

- Acts done for experimental purposes relating to the subject matter of the relevant patented invention do not constitute infringement of a patent (section 42(b) Patents Act).
- The (IP (Miscellaneous Provisions) Act introduced new Bolar style provisions (section 42(h)) into the Patents Act, which expand on and co-exist with the previous Bolar style provisions (section 42(g)) (see *Question 26*).
- A person who, before the priority date in Ireland, did in good faith an act which would have infringed the patent if it had been in force, or made in good faith effective and serious preparations to do that act, can continue the act (section 55, Patents Act).
- There is a specific defence for the extemporaneous preparation for individual cases in a pharmacy of a medicine in accordance with a medical prescription issued by a registered medical practitioner, or acts concerning the prepared medicine (section 42(c), Patents Act).

Defences to a Patent Infringement Action

Patent invalidity can be raised as a defence to infringement proceedings in the following circumstances:

- As a defence to infringement proceedings.
- As a defence to a groundless threats action.
- As a stand-alone court application for revocation of the patent.

Section 42 of the Patent Act provides limitations that also operate as statutory defences to patent infringement, including:

- Acts done privately for non-commercial purposes.
- Acts done for experimental purposes relating to the subject matter of the patented invention.

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- The extemporaneous preparation for individual cases in a pharmacy of a medicine in accordance with a medical prescription issued by a registered medical practitioner, or acts concerning that medicine.
- Acts done in studies, tests, and trials that are conducted with a view to satisfying the application requirements for an MA in respect of a human or veterinary medicinal product.

Research exemption. Acts done for experimental purposes relating to the subject matter of the relevant patented invention will not constitute infringement of a patent (section 42(b), Patent Act). A specific application of the research exemption is the Bolar exemption. Section 42 of the Patent Act provides for a similar research exemption, stating that the rights conferred by a patent will not extend to acts done in studies, tests, and trials that are conducted with a view to satisfying the application requirements for an MA in respect of a human or veterinary medicinal product.

IP exhaustion. As a member state of the EU, the European doctrine of exhaustion of rights applies to patent rights in Ireland. The doctrine of exhaustion means that where a patented product is put on the market in one member state of the EU by or with the consent of the patentee, the patentee cannot then use their patent rights to prevent or hinder the importation of that product into a second member state or prevent its sale there.

Other exemptions. The Patents Act sets out a number of additional defences that may be available to a defendant, including the following:

- The rights conferred by a patent do not extend to any acts which, under the obligations imposed by the EU treaties, cannot be prevented by the patent proprietor (section 43, Patents Act).
- Where a patent has lapsed bona fide and a third party commences or makes serious preparations to do an act that would constitute an infringement if the patent had not lapsed, that person has the right to continue the acts even if the patent is subsequently restored (section 37, Patents Act).
- A person who, before the filing date of the patent application or the priority date, does in good faith an act that would constitute infringement of the patent if it were then in force or makes in good faith effective and serious preparations to do that act has the right to continue to do that act (section 55, Patents Act).

Additionally, where a defendant can prove that they were not aware and had no reasonable grounds to suppose that the patent being infringed existed at the date of infringement, the defendant can claim in their defence that neither damages nor an account of profit should be awarded.

International IP Treaties

28. Is your jurisdiction party to international treaties that facilitate the recognition of foreign IPRs in your jurisdiction?

General

Ireland is party to the *WTO Agreement on Trade Related Aspects of International Property Rights* (TRIPS).

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Patents

Ireland is a signatory to or has ratified a number of international treaties relating to patents, including:

- The *Agreement on a Unified Patent Court* (UPC Agreement).
- The *Patent Law Treaty (2000)* (PLT).
- The Patent Cooperation Treaty (1970) (PCT).
- The *European Patent Convention (2000)*.

Trade Marks

Ireland is a signatory to or has ratified a number of international treaties in relation to trade marks including:

- The *Protocol Relating to the Madrid Agreement Concerning the International Registration of Marks 1989* (Madrid Protocol).
- The *Paris Convention for the Protection of Industrial Property 1883* (Paris Convention).
- The *Nice Agreement Concerning the International Classification of Goods and Services for the Purposes of the Registration of Marks 1957*.
- TRIPS.
- *Singapore Treaty on the Law of Trademarks*.

Trade Marks

Legal Requirements to Obtain a Trade Mark

29. Provide a brief definition of a trade mark, the key legal requirements to obtain it, and the law that applies.

Irish trade marks are governed by:

- The Trade Marks Act.
- The *Trade Mark Rules 1996*.

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- *Regulation (EU) 2017/1001 on the European Union trade mark* (EUTM Regulation) which replaced Regulation *207/2009/EC* as of 1 October 2017.
- *European Union (Trade Marks) Regulations 2018* (Trade Mark Regulations). These transposed the *2015 Trade Mark Directive ((EU) 2015/2436)* into Irish law.

For a trade mark to qualify for registration, it must be:

- A sign.
- Capable of being represented graphically.
- Capable of distinguishing goods or services of one undertaking from those of other undertakings.

(Section 6(1), Trade Marks Act.)

A registered trade mark grants its proprietor a potentially interminable monopoly right to prevent others from using an identical mark in relation to identical goods or services for which it is registered, or a confusingly similar mark with respect to identical or similar goods or services.

Registering a Trade Mark

30.Which authority registers trade marks? Briefly outline the key stages and timing to obtain a registered trade mark.

Trade Mark Registration Authority

Trade marks can be registered by filing one of the following:

- An application for a national registration to the Controller in the IPOI.
- An application for a European Union Trade Mark (EUTM) with the European Union Intellectual Property Office (EUIPO) in Alicante, Spain.
- An application under the Madrid Protocol, an international system of registration, administered by the International Bureau of WIPO. This allows a trade mark proprietor to apply to protect its trade mark in several countries through one application with a single office.

Details of applicable fees and guidance on the application process for a national trade mark are available at *IPOI: Turning ideas into assets*, and for an EUTM at *EUIPO: Trade marks*.

The HPRA does not review proposed trade marks to determine whether they should be registered by the IPOI.

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Process and Timing

An application for the registration of an Irish trade mark is made to the IPOI. The application will be granted a filing date on submission of:

- A completed prescribed application form (or otherwise submitting the requested information).
- The name and address of the applicant.
- A representation of the mark.
- A statement or list of the goods and/or services for which registration of the mark is sought in the relevant Nice Classification.

The application then goes through an examination process to ensure that an identical or confusingly similar mark has not already been registered as an Irish trade mark or an EUTM. If registration is refused, the applicant will be given an opportunity to make further submissions in support of it.

Once the application is accepted for registration, details of the mark are published in the *Patents Official Journal*. Opposition to the registration can be lodged with the IPOI by a third party (usually a proprietor of a confusingly similar trade mark) within three months of publication.

An applicant can claim a right to priority for an identical trade mark application registration it has filed in a jurisdiction that is a party to the Paris Convention, within six months of the application date of the Irish trade mark. Where priority is claimed, a certified copy of the original application, as filed, must be submitted to the IPOI within three months of the application for the Irish trade mark.

The length of time taken to obtain a registration depends on several factors, including whether the IPOI raises any objection to the application, or the application is opposed by a third party.

Competition Law Issues

Competition Authorities and Legislation

31. Briefly outline the competition law framework in your jurisdiction and how it impacts on the pharmaceutical sector.

Competition Law and Main Provisions

Anti-competitive agreements. Arrangements between undertakings that prevent, restrict, or distort competition in trade in any goods or services in Ireland are prohibited and are rendered void (section 4(1), *Competition Act 2002*, as amended (Competition Act)). Horizontal agreements between competitors involving price fixing, market sharing, or output limitation will constitute

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a hard core cartel offence in breach of section 4(1). The Competition and Consumer Protection Commission (CCPC) tends to investigate and seek prosecution of hard core cartel offences on the criminal standard and can also impose civil fines of up to EUR10 million (or 10% of the company's worldwide turnover during the previous financial year) for an infringement of competition law.

Vertical agreements between operators at different levels of the supply chain, for example, between pharmaceutical suppliers and independent wholesalers or between wholesalers and retailers, can also breach section 4(1) where they have the object or effect of restricting competition, for example, where they provide for resale price maintenance. The CCPC tends to investigate and seek enforcement in respect of vertical agreements that it considers breach section 4(1) on the civil standard and can issue a public statement of objections setting out its preliminary views on why the agreement in question does not comply with Irish competition law.

In 2007, the Competition Authority, the predecessor to the CCPC, investigated allegations of an anti-competitive concerted practice among pharmacy contractors in Ireland. In 2008 the Competition Authority concluded the investigation and entered into an agreement with, and obtained undertakings from, the pharmacy contractors to confirm that the pharmacies would not in future engage in any concerted action contrary to section 4.

Apart from public enforcement, parties who claim to be aggrieved by a competition law infringement can take proceedings in the Irish courts and claim injunctive relief, declaratory relief, and damages. There are no reported private competition law actions in the pharmaceutical sector to date in relation to anti-competitive arrangements as prohibited by section 4(1).

Abuse of a dominant position. Abuse by one or more undertakings of a dominant position in trade for any goods or services in Ireland or any part of Ireland is prohibited (section 5(1), Competition Act). Therefore, dominant undertakings should exercise caution when engaging in certain practices that can constitute an abuse of dominance, for example, excessive pricing, predatory pricing, price discrimination, certain forms of rebates, exclusivity, tying or bundling products, or refusal to supply, unless there is an objective justification. Abuse of dominance cases are likely to be investigated and enforced on the civil standard.

Neither the CCPC nor the Competition Authority has reported abuse of dominance cases in the pharmaceutical sector. There has been one private action where a drug wholesaler was accused of abusing a dominant position in a region of Ireland by discontinuing supply to a pharmacist. The case was settled.

Merger control. Mergers or acquisitions that meet certain financial thresholds must be notified to and approved by the CCPC. The CCPC can block mergers or acquisitions that result in a substantial lessening of competition in markets for goods or services in Ireland.

Competition Authority

The CCPC does not have any specific regulatory powers of which companies active in the pharmaceutical sector should be aware, other than the investigatory and merger control powers (see above, *Competition Law and Main Provisions*) (which apply equally in respect of the pharmaceutical sector).

Investigations and enforcement of competition law is not particularly common in the pharmaceutical sector compared with other sectors and, other than the two examples above (see *Competition Law and Main Provisions*), there are no instances of anti-competitive agreements or abuse of dominance in this sector.

In terms of merger control, the most notable transaction relating to the pharmaceutical sector is the recent Uniphar/Navicorp deal, which is the first transaction that the Irish competition authority has blocked since 2008. The transaction related to the proposed acquisition by Uniphar plc (which provides sales, marketing, and distribution services to pharmaceutical and medical devices manufacturers) of Navicorp Limited (a pharmacy solutions business). Following an in-depth review of the proposed

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transaction lasting almost a year, the CCPC ultimately determined in December 2022 that the result of the proposed transaction would be to substantially lessen competition in relation to the provision of pharmacy buying group services in Ireland and the provision of pharmacy common management and branding services in Ireland. On this basis, the CCPC determined that the proposed transaction could not be put into effect and Uniphar decided to abandon the deal.

There have been a few other notable transactions related to the pharmaceutical sector notified to the CCPC in last two years, for example:

- **Uniphar/LXV Remedies (Sam McCauley).** This relates to the acquisition by Uniphar plc of LXV Remedies Holdings Limited and its subsidiary, Sam McCauley Chemists Limited, which owns and operates a group of 37 retail pharmacies located across the country trading as McCauley Health & Beauty Pharmacy. Following its initial review of the transaction, the CCPC cleared the transaction subject to a number of legally binding commitments from Uniphar, including the divestment of three pharmacies located across Ireland. It is noteworthy that the CCPC was reviewing this transaction at the same time as the Uniphar/Navicorp transaction, and issued a clearance decision a month after prohibiting the Navicorp deal.
- **Tennants Consolidated/Brockley Holdings.** This relates to the acquisition by Tennants Consolidated Limited (a London-based conglomerate group involved in chemical manufacturing and distribution) of Brockley Holdings Limited (a chemical distribution company based in Ireland). The CCPC cleared the transaction under its simplified merger notification procedure within 15 working days, though its clearance decision has yet to be published at the time of writing.
- **Murano Bidco/Vectura Group.** This relates to the acquisition by Murano Bidco Limtied (an indirect subsidiary of funds managed by the Carlyle Group, Inc) of Vectura Group plc (a UK-based pharmaceutical company). Although one of the portfolio companies controlled by the acquirer (Albany Molecular Research Inc) was active in a relevant sector for the purposes of the CCPC's review, it ultimately determined that the transaction would not give rise to a substantial lessening of competition in any market in the state and issued a clearance decision.
- **Caldic/Brand-Nu and BNL.** This notification relates to the acquisition by Caldic BV (a full-line distributor of commodity and speciality chemicals, ultimately owned by the Goldman Sachs Group, Inc) of Brand-Nu Laboratories, Inc and BNL Sciences Limited (which are involved in the blending, formulation, supply, and distribution of chemicals). Although the parties overlapped in respect of the distribution of chemicals in the state, the CCPC ultimately determined that the transaction would not give rise to a substantial lessening of competition in any market in the state and issued a clearance decision.

32. Has pharmaceutical competition case law in your jurisdiction focused on any key areas?

There have been no reported cases in Ireland relating to the generic entry of pharmaceuticals and no reported abuse of dominance cases in the pharmaceutical sector.

There are also no reported cases on competition law issues arising from parallel imports of pharmaceuticals in Ireland to date. IP issues can arise if, for example, the patent holder has not already marketed the product in the EU, or if the imported product is repackaged in a way that may adversely affect the reputation of the trade mark and of its owner.

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Within the EEA, if the IPR holder places or consents to the placement of the product on the market in one EEA state, it cannot generally rely on its rights to prevent that product being imported to or marketed in another EEA state.

IPRs can be used to oppose parallel imports from outside the EEA.

Commercial Contracts and Competition Law

33.Briefly outline the competition issues that can arise in relation to commercial contracts and other business arrangements relating to medicinal products.

Irish competition law is based on EU competition law and is interpreted and applied by analogy. There is no equivalent under Irish competition law to *Commission Regulation (EU) 316/2014 on the application of Article 101(3) of the Treaty on the Functioning of the European Union (TFEU) to categories of technology transfer agreements* (Technology Transfer Block Exemption Regulation) but Irish competition law would be likely to be interpreted in a manner consistent with it. Specific issues have not arisen in any reported Irish competition law cases to date involving technology transfer licensing agreements or patent licensing.

A variety of potential competition issues can arise in commercial arrangements concerning manufacturers of pharmaceuticals, wholesalers, and retail distributors. Anti-competitive practices arise where pharmaceutical companies abuse their dominant position in the market or enter into agreements that are restrictive of competition. The most widespread competition concern in the pharmaceutical sector relates to companies abusing their dominant market position. Common abuses are excessive or unfair pricing for medicines and "pay-for-delay," that is, where the entry of generic medicines or biosimilars into the market is delayed or hindered by the incumbent originator. Restrictive agreements between competitors (for example bid rigging, price fixing, and market sharing) and restrictions on parallel trade can also artificially reduce or eliminate competition. Vertical restraints in commercial agreements which prohibit distributors from promoting and selling products of competing manufacturers or seek to co-ordinate the retail prices of medicines can also be restrictive of competition.

The CCPC's Declaration in respect of Vertical Agreements and Concerted Practices exempts certain categories of agreements and concerted practices from the prohibition set out in section 4 of the Competition Act. This Declaration is, in all material respects, equivalent to the Vertical Block Exemption Regulation and Vertical Guidelines issued by the European Commission.

Licensing Approvals and Formalities

34. Does a patent or trade mark licence and payment of royalties under it to a foreign licensor have to be approved by a government or regulatory body? Are there any formalities or other requirements to make the licence enforceable?

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Provided any patent licences comply with Irish and EU competition law, there are no restrictions on licensing or transferring patents to foreign parties. Changes in ownership or an interest in a patent or a patent application must be recorded on the register (section 85(1), Patents Act).

Compulsory licensing applies in certain situations, for example, to meet demand for a product in Ireland or for the manufacture of medicinal products for developing countries, subject to certain conditions (section 70, Patents Act).

The commercialisation or exploitation of inventions developed with the support of public grants or resources is governed by the terms of the agreements under which the grants or resources were made available. They are subject to any restrictions or conditions set out in such agreements on their transfer. Typically, the consent of the funding body is required.

There is no requirement for a patent or a trade mark licence to be approved by any government or regulatory body. However, an exclusive licence must be recorded in the IPOI. Failure to register an exclusive patent licence means that it will only be admitted in court as evidence of the title of a person to an interest in a patent if the court so directs. Failure to register an exclusive trade mark licence within six months of the grant of the licence will adversely affect the ability of the exclusive licensee to take enforcement proceedings and to recover its costs arising from any that action.

For a Community trade mark (CTM), an exclusive licence can be entered on the register at the request of one of the parties.

Compulsory licensing applies in certain situations, for example, to meet demand for a product in Ireland or for the manufacture of medicinal products for developing countries, subject to certain conditions (section 70, Patents Act).

For information on pharmaceutical pricing and state funding, manufacturing, marketing, clinical trials, advertising, and labelling, see *Country Q&A: Life Sciences Regulation in Ireland: Overview*.

Product Liability

Regulators

35. Outline the key regulators and their powers in relation to medicinal product safety.

The HPRA is the competent authority responsible for regulating medicinal products. The Market Compliance Section of the HPRA is responsible for overseeing the recall of medicinal products in Ireland. All proposed recalls of a medicinal product from the market must be notified to the HPRA, so that the terms of the recall can be agreed and the implications for other products, the supply chain, and for patients/users can be evaluated.

In addition, the HPRA can order a recall under the Manufacturing Regulations. Failure to comply can lead to suspension or revocation of the product's MA.

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The IMB Act 1995 provides general powers of inspection to the HPRA authorised officers and other authorised officers. These powers are to require any person at the premises or the owner or person in charge of the premises, and any person employed there, to give the officer assistance and information and produce to the officer books, records, or other documents in that person's power or procurement (and in the case of documents or records stored in non-legible form, to produce a legible reproduction of them).

Medicinal Product Liability Law

36. Outline the key areas of law applicable to medicinal product liability, including key legislation and recent case law.

Legal Provisions

Liability can arise under the following:

- **Contract.** Liability can arise under the *Sale of Goods Act 1893*, as amended by the *Sale of Goods and Supply of Services Act 1980*.
- **Tort.** The general common law principle of duty of care applies in Ireland. Therefore, product manufacturers owe a duty of care to all those who may be foreseeably injured or damaged by their products.
- **Statutory liability.** The *Liability for Defective Products Act 1991* (LDPA) implements the *Product Liability Directive (85/374/EEC)* into Irish law.
- **Criminal.** The *European Communities (General Product Safety) Regulations 2004* (GPSR) implement *Directive 2001/95/EC on general product safety* (General Product Safety Directive or GPSD). Once the *proposal on Consumer Product Safety* (which was adopted by the European Commission in February 2013) is finalised and comes into force, the General Product Safety Directive will be repealed.

Substantive Test

Contract. Where goods are sold by a seller under contract, there is an implied warranty that those goods are of merchantable quality where a seller sells them in the course of business (section 10, Sale of Goods and Supply of Services Act 1980).

Essentially, this means that the goods must be for the purpose or purposes for which goods of that kind are commonly bought and durable as it is reasonable to expect having regard to any description applied to them, the price (if relevant), and all other relevant circumstances.

Statutory test. A producer is liable for damages in tort for injury resulting wholly or partly from a defect in the producer's product (section 2, LDPA). This is a strict liability regime. The burden is on the injured person to prove the damage, defect, and causal relationship between the defect and damage (section 4, LDPA). A product is defective if it fails to provide the safety which a person is entitled to expect taking all circumstances into account (section 5, LDPA), including:

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- The presentation of the product.
- The use to which the person could expect that the product would be put.
- The time when the product was put into circulation.

Therefore, in the context of pharmaceutical products, specific circumstances may be taken into account when determining safety.

The European Commission has launched a public consultation on the Product Liability Directive.

Negligence. For an action against the manufacturer or producer of a product to be made in negligence, the following must be present:

- A duty of care owed by the producer or manufacturer of the product to the consumer.
- A breach of that duty of care.
- A causal relationship between the breach of duty and the damage caused to the user of the product.

The burden of proof rests on the claimant and the standard of proof is on the balance of probabilities. A two-stage test has traditionally been applied to determining whether a duty of care exists:

- Is there a relationship of proximity or neighbourhood between the parties and is there foreseeability of damage?
- Is there a public policy reason as to why that duty should not be imposed?

An objective standard applies when assessing whether there has been a breach of duty. Factual and legal causation must be established during the assessment of the causal relationship. An act is held to be the cause of an event if the event would not have occurred without it.

If the circumstances of an accident speak for themselves, they give rise to a presumption of negligence (*res ipsa loquitor*). Consequently, the burden is on the defendant to prove that the defendant was not negligent.

Liable Parties

37. Who is potentially liable for defective medicinal products?

A producer is liable for damages in tort for damage caused wholly or partly by a defect in the producer's products (section 2(1), LDPA). Producer is defined broadly in section 2(2) of the LDPA and can, in the context of medicinal products, include any of the following persons or entities in the supply chain:

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- The manufacturer or producer of a finished product, raw material, or component part of a product.
- A person who, by putting their name, trade mark, or other distinguishing feature on the product or using their name or any mark or feature in relation to the product, has held themself out to be the producer of the product.
- A person who imports the product from outside the EEA to, in the course of a business, supply it to another.
- A person who supplied the product (to the person who suffered the damage, the producer of any product in which the product is included, or any other person), in certain circumstances where the producer of the product cannot by taking reasonable steps be identified.

The GPSR give rise to potential criminal liability for producers who place an unsafe product on the market.

Businesses cannot exclude or limit liability for death or personal injury. An injured person's recourse to legal remedies/right to compensation arises on the basis of the common law principle of negligence.

Defences

38. What defences are available to product liability claims? Is it possible to limit liability for defective medicinal products?

Statutory Defences (under the LDPA)

A producer is free from liability under the LDPA if it proves any of the following:

- The producer did not put the product into circulation.
- It is probable that the defect causing the damage came into being after the product was put into circulation by the producer.
- The product was not manufactured for profit-making sale.
- The product was not manufactured or distributed in the course of a business.
- The defect was due to compliance of the product with mandatory regulations issued by public authorities.
- The state of the scientific and technical knowledge at the time when the product was put into circulation was not such as to enable the defect to be discovered (development risks defence).
- In the case of a manufacturer of a component of the final product, the defect was attributable to the design of the product or to the instructions given by the product manufacturer.

The LDPA provides for a long stop period, whereby the rights conferred on the injured party under the LDPA are extinguished on the expiry of ten years from the date on which the producer put into circulation the product which caused the damage (unless the injured party has brought proceedings against the producer in the interim) (section 6, LDPA).

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Substantive Defences

In negligence, a defendant essentially seeks to establish that:

- The defendant was not negligent.
- The defendant did not owe a duty of care.
- There was no causal link between the action/inaction and the injury.

Contributory Negligence/Concurrent Wrongdoers

Damages are reduced if there is contributory negligence (*Civil Liability Act 1961* (CLA)).

If two or more persons are liable under the CLA for the same damage, they are jointly and severally liable to the injured person as concurrent wrongdoers (LDPA).

The CLA also provides a defence of voluntary assumption of risk, although this is not often relied on.

Product Liability Claims

39. How can a product liability claim be brought?

Limitation Periods

There is a limitation period of three years from the date on which a claimant became aware (or should reasonably have become aware) of the damage, the defect, and the identity of the producer (section 7(1), LDPA). Rights conferred on an injured party are extinguished after ten years from the date on which the producer puts the actual product which caused the damage into circulation (section 7(2), LDPA).

The *Civil Liability and Courts Act 2004* reduced the limitation period for personal injury cases from three years to two years, with effect from 31 March 2005. However, the Irish courts have considered this point (on a preliminary basis only) and held that the limitation provisions of the LDPA remain unaffected by the enactment of the Civil Liability and Courts Act 2004. It follows that in a personal injury action, this longer limitation period could apply to any element of the claim relating to statutory liability for defective products.

Contract claims can be made within six years from the date the breach of contract occurred.

Class Actions

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There is no mechanism for class actions in Ireland. However, multiple product claims are frequently brought in Ireland following international class actions or other multi-party litigation.

Irish law provides for representative actions, when numerous persons have the same interest. However, the same interest requirement is very strictly construed. Remedies are limited to injunctive and declaratory relief, that is, no damages are available. In these circumstances one or more persons can sue on behalf of all interested persons. As a result, multi-party litigation in Ireland has historically been managed through test cases rather than representative actions. Findings in test cases are frequently applied by analogy to subsequent cases.

The Irish Law Reform Commission made recommendations in a report on multi-party litigation in 2005, but so far they have not been made law.

The Multi-Party Actions Bill 2017 is currently before the government. The Bill seeks to introduce certain procedural changes in civil actions, to provide for bringing multi-party actions and reduce the overall cost of litigation.

Remedies

40. What remedies are available to the claimant? Are punitive or exemplary damages allowed for product liability claims?

Compensatory Damages

Compensatory damages can be sub-divided into:

- General damages, which cannot easily be quantified in monetary terms and are presumed to flow from the wrong of a defendant.
- Special damages, which are the specifically quantifiable expenses that the claimant has incurred due to the defendant's tortious act.

Aggravated Damages

Aggravated damages are available, and are awarded where the claimant suffers further injury due to some or all of the following:

- The manner in which the wrong was committed.
- The conduct of the defendant after commission of the wrong.
- The defendant's conduct in the defence of their action, including the trial.

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GPSR

A non-compliant producer is guilty of a criminal offence and liable to a fine up to EUR3,000 or up to three months' imprisonment, or both (GPSR).

Punitive Damages

Exemplary damages exist in Ireland and are punitive, not compensatory, in nature. However, they are only awarded in exceptional circumstances. This has been done by the civil courts, particularly where there has been an infringement of the claimant's constitutional rights, but even then at a relatively low level. There has only been one example of significant exemplary damages in Ireland (that is, exceeding EUR1 million). There have been no cases to date where exemplary damages have been awarded for a product liability claim.

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- Advising a wide range of pharmaceutical, medical device and healthcare companies on competition law issues.
- Advising CapVest Partners on Irish merger control aspects of its sale of Mater Private Healthcare Group to Infravia.
- Advising Ryanair on High Court proceedings issued against Skyscanner, Vola, Ypsilon and others in relation to screenscraping.
- Advising CRH plc on a successful challenge before the High Court and the Supreme Court to the scope of documentation seized by the CCPC during a dawn raid, which led to a landmark Supreme Court decision on the scope of the search and seizure powers of the CCPC.
- Advising Insurance Ireland on a European Commission investigation into the database, InsuranceLink, including advising on a dawn raid. The investigation closed with a commitments decision and no finding of infringement.
- Advising Insurance Ireland on a separate CCPC investigation into private motor insurance in Ireland. The investigation was closed against Insurance Ireland with no finding of infringement.
- Advising Volvo Trucks and Renault Trucks on defending follow-on actions for damages in Ireland arising from the European Commission' s decision to fine truck manufacturers EUR2.93 billion for participating in a cartel.
- Advising Permanent TSB on Irish merger control aspects of its EUR7.6 billion acquisition of certain assets and liabilities of Ulster Bank from NatWest.
- Advising Glanbia plc on Irish merger control aspects of the EUR307 million disposal of 40% of Glanbia Ireland.
- Advising KBC Group NV on Irish merger control aspects of the EUR5 billion sale of certain assets and liabilities to Bank of Ireland.
- Advised KBC Bank Ireland plc on Irish merger control aspects of the formation of Synch Payments, a payments joint venture involving the other main retail banks in Ireland.
- Advising Flutter Entertainment plc on merger control aspects of its EUR1.9 billion acquisition of Sisal SPA.
- Advising the Department of Housing, Planning and Local Government on the establishment and operation of the Land Development Agency, one of the key initiatives to address the housing shortage in Ireland.

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- Advising public research organisations in relation to funding and performance of research and the management of intellectual property.
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