TRADE AND DISTRIBUTION OF THERAPEUTIC PRODUCTS (PHARMACEUTICALS/BIOLOGICS AND MEDICAL DEVICES

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REGULATORY FRAMEWORK AND COMPETENT AUTHORITIES

1. What are the principal statutes, regulations, and competent authorities that govern the import, wholesale distribution, retail sale, and export of therapeutic products (ie, for pharmaceuticals/biologics and medical devices, noting any separate or overlapping regimes)? In the case of a federal state, what is the division of powers between the federal government and the states?

Medicinal products

The regulatory framework for medicinal products in the Republic of Ireland (Ireland) is currently based on Directive 2001/83/EC on the Community code relating to medicinal products for human use, as amended (Code for Human Medicines Directive). The Irish Medicines Board Act 1995, as amended (IMB Act) and domestic regulations, most notably the Medicinal Products (Control of Placing on the Market) Regulations 2007, as amended (Marketing Regulations) implement this Directive in Ireland. Due to agreement reached at the end of 2025 on the EU Pharma Package, the regulatory framework will change in the next few years.

Pricing and reimbursement of medicinal products is governed by the Health (Pricing and Supply of Medical Goods) Act 2013, as amended (Health Act 2013). In addition, there is a Framework Agreement, which operates on a five-year cycle, between the Irish Pharmaceutical Healthcare Association (IPHA), representing the international research-based pharmaceutical industry in Ireland, the Department of Health, and the Health Services Executive (HSE) (IPHA Agreement).

The most recent IPHA Agreement was signed in 2021 (2021 IPHA Agreement) and expired on 30 September 2025. On 29 September, the Minister for Health announced that, following preliminary engagement, formal negotiations had commenced between the State and IPHA on a successor agreement. To date, the outcome of those negotiations is uncertain.

A parallel agreement was entered into by the State in 2021 with Medicines for Ireland (MFI), the body who represent the generic and biosimilar medicines sector in Ireland. The State is expected to engage separately with MFI to negotiate a potential successor agreement.

The Health Products Regulatory Authority (HPRA) (formerly the Irish Medicines Board) (IMB) is the competent authority responsible for regulating medicines, medical devices, and other health products in Ireland. The National Standards Authority of Ireland (NSAI) is the notified body in

Ireland approved by the HPRA to carry out conformity assessment procedures to ensure compliance with medical devices legislation.

The HPRA's main areas of responsibility are:

- Ensuring the quality, safety, and efficacy of medicines (including veterinary medicines) available in Ireland, participating in systems designed to do so throughout the EU, and monitoring the quality of medicines and their manufacturing and distribution processes.
- Acting as a competent authority for the implementation of EU and national legislation relating to blood, blood components, tissues, cells and medical clinical research, and cosmetics.
- Regulating medical devices on the Irish market.
- Regulating the protection of animals used for scientific purposes.
- Regulatory functions in respect of organs intended for transplantation.

Medical devices

Two EU regulations govern medical devices in the EU: (1) Regulation (EU) 2017/745 on medical devices (MDR), applicable since 26 May 2021; and (2) Regulation (EU) 2017/746 on in vitro diagnostic medical devices (IVDR), applicable since 26 May 2022.

The MDR and the IVDR are implemented into Irish law by way of several statutory instruments and medical devices on the Irish market are classified per the MDR and IVDR.

In December 2025, legislative proposals to revise both the MDR and the IVDR were published by the European Commission.

The HPRA is the competent authority responsible for regulating medical devices in Ireland. The NSAI is the notified body designated by the HPRA to carry out conformity assessment procedures to ensure compliance with medical devices legislation.

The Office of the Revenue Commissioners (Revenue) is responsible for implementing all applicable taxes, duties and customs controls, in Ireland.

Further, to note the position post Brexit, regarding the HPRA, the movement of medicines from the Republic of Ireland to Northern Ireland is not considered export from the EU.[1]

2. How are therapeutic products classified for regulatory purposes (eg, prescription-only, over-the-counter, hospital-use, risk classes for devices, etc.) and what legal consequences attach to each classification with respect to trade and distribution? In particular, is premarket review and approval required by a competent authority?

All medicines for human use must be approved, and medicinal products must have a marketing authorisation. Medicines are permitted to be sold as either 'prescription only' or 'over the counter'.

[1] HPRA, 'Questions and Answers on the Windsor Framework and medicines for human use', www.hpra.ie/regulation/human-medicine/marketing-authorisation-holders/post-licensing/windsor-framework accessed 17 May 2026.

Prescription-only medication

The Medicinal Products (Prescription and Control of Supply) Regulations 2003 (SI No 540/2003) (Prescription and Control of Supply Regulations 2003) provide that a medicinal product must only be supplied under prescription if it meets any of the following criteria:

1. it contains a substance listed in Column 1 of the First Schedule, unless exempted by specified strength, form, pack size, labelling, or treatment period conditions listed in subsequent columns;
2. it is intended for parenteral administration; or
3. it contains a new chemical molecule, unless three years have passed since its marketing authorisation.

Prescription medicinal products can only 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.

Over-the-counter medication

Certain non-prescription drugs (as set out in the Prescription and Control of Supply Regulations 2003, as amended) can only be sold from a pharmacy under the supervision of a registered pharmacist. These products are known as over-the-counter medications.

General sale products can be sold in a pharmacy and any other outlet which is not a pharmacy, for example, a supermarket. The HPRA determines which category a particular medicine falls into based on several criteria, including safety considerations.

Extemporaneous preparation is permitted in Ireland in limited circumstances. Exemption from holding an authorisation provided certain criteria are met ((Medicinal Products (Control of Manufacture) Regulations, 2007. s 5 – S.I. No. 539 of 2007) and supply is under the Marketing Regulations.[2]

Classification of medical devices

Medical devices in Ireland are classified under the MDR and the IVDR and must comply with the conformity assessment and CE marking processes which apply thereunder.

Exceptions to the requirements for medical devices

The HPRA has issued a form on its website for use by manufacturers in respect of compassionate use of medical devices which have not been CE marked for use in one patient. The form requires the manufacturer to have: discussed the proposed use of the non-CE marked device with the medical/surgical consultant intending to use it; and, made available to the consultant all relevant data relating to the use of the device in the manner proposed, with specific attention to the risk/benefit analysis.

[2] PSI, 'Guidance for Pharmacists on Extemporaneous Dispensing', www.psi.ie/practice-supports/guidance-and-guidelines-pharmacists-and-pharmacies/guidance-pharmacists, 1 June 2015, accessed 17 May 2026.

It is required as part of compassionate use that the device has been designed, manufactured, and tested with due consideration for the relevant General Safety and Performance Requirements and other relevant legislative requirements of the MDR/IVDR and national implementing legislation.

LICENSING, AUTHORISATIONS, AND DISTRIBUTION CHANNELS

3. Which licences, authorisations, registrations, or other official permissions are required for businesses to engage in wholesale distribution of therapeutic products, and what key conditions (such as Good Distribution Practice, facility standards, personnel, insurance, or financial guarantees) attach to them?

Medicinal products

The Medicinal Products (Control of Wholesale Distribution) Regulations 2007 and the Medicinal Products (Control of Wholesale Distribution) (Amendment) Regulations 2013 (Wholesale Regulations) regulate the wholesale distribution of medicines.

Any business seeking to engage in the wholesale distribution of pharmaceutical products in Ireland must hold a Wholesale Distribution Authorisation (WDA). These authorisations are governed by the Wholesale Distribution Regulations, the Code for Human Medicines Directive and the guidelines issued by the HPRA.

The HPRA issues WDAs subject to a number of conditions.

Medical devices

There is no wholesale licence required in Ireland for distributing medical devices. Entities seeking to engage in the distribution of medical devices must however register with the HPRA as a distributor before placing products on the market. Wholesalers of medical devices must pay an annual maintenance fee as part of their registration.

4. Are there distinct licensing or notification requirements for businesses that provide therapeutic products directly to consumers (including community pharmacies, internet pharmacies, or other retailers), and what key conditions attach to them?

To operate a pharmacy in Ireland, a business must comply with the Pharmaceutical Society of Ireland (PSI) (Retail Pharmacy Businesses) (Registration) Rules 2008 (S.I. No. 495 of 2008). These rules set out the requirements for registering as a pharmacy under the PSI. Section 17 of the Pharmacy Act 2007 (Pharmacy Act) governs the changes in the ownership of a retail pharmacy business.

Sections 27(c), 28(b) and 29(c) of the Pharmacy Act require a Supervising Pharmacist (a registered pharmacist who has a three-year minimum post-registration experience in whole time in charge of the carrying on of the business) to be at the premises where a retail pharmacy business is carried on. Sections 27(b), 28(a) and 29(b) of the Pharmacy Act require a retail

pharmacy business to be under the control of a registered pharmacist who has a three-year minimum post-registration training.[3]

5. What rules govern the sale of therapeutic products to consumers over the internet (including social-media and marketplace platforms)?

Medicinal products cannot be sold in Ireland without a marketing authorisation, and medical devices cannot be sold unless they are correctly CE marked.

Online advertising

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 the IPHA Code of Practice for the Pharmaceutical Industry (for IPHA members only, see more below).

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 advertising of medical devices is regulated by the provisions of the MDR and the IVDR, and the various statutory instruments that give effect to these regulations in Irish law. The MDR and IVDR provide that devices cannot be presented or advertised in a manner which may mislead the user or the patient as to the device's intended purpose, safety and performance.

Online sale

The Control of Placing on the Market Regulations 2007 govern the sale of medicinal products, under the Code for Human Medicines Directive, as amended.

The supply of prescription-only medicines in Ireland by mail order is not permitted. Supply by mail order is defined as both: (1) any supply made, after solicitation of custom by the supplier, or by another person in the supply chain inside or outside Ireland; (2) 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.

Anyone who seeks to sell non-prescription medicines over the internet in Ireland must register with the PSI. The PSI keep record of all online suppliers of non-prescription medication on the Internet Supply List. Part A of the Internet Supply List includes retail pharmacy businesses that

[3] PSI, 'First Time Registration', www.psi.ie/registration/pharmacies/first-time-registration accessed 17 May 2026.

also sell non-prescription medicines online and Part B of the Internet Supply List includes non-retail pharmacy businesses. All registered websites must display the EU common logo on every web page offering non-prescription medicines for sale.[4]

Non-EU based manufacturers that wish to import medical devices must use an importer based in the EU. The importer is then responsible for making sure that the devices they place on the market bear the CE marking, are accompanied by the required information, labelled correctly, and have been assigned a Unique Device Identification (UDI) where applicable in accordance with the relevant medical devices regulation.

The broader regulatory setting

The advertising and sale of therapeutic products is also informed by general laws concerning advertising and commercial practices in Ireland, including the Consumer Protection Act 2007 (as amended) (CPA) and the European Communities (Misleading and Comparative Marketing Communications) Regulations 2007 (Misleading Advertising Regulations).

The Consumer Rights Act 2022 also amends and consolidates the law relating to rights and remedies in contracts between traders and consumers. The Ethics in Public Office Acts, 1995 and 2001 (as amended) (Ethics Acts), apply to promotional practices involving healthcare professionals who also hold certain designated public positions or directorships. The Criminal Justice (Corruption Offences) Act 2018 (as amended) (2018 Act) may also apply in circumstances where promotional practices are found to be corrupt.

The HPRA is the body responsible for monitoring the advertising of medicinal products and enforcing the Regulations. The Competition and Consumer Protection Commission (CCPC) is the regulatory body with oversight of general consumer law. *Coimisiún na Meán* (CnM) was established pursuant to the provisions of the Online Safety and Media Regulation Act 2022 (amending the Broadcasting Act 2009).

The law is also supplemented by a number of codes of practice. The Irish Pharmaceutical Healthcare Association (the IPHA) has published two relevant codes of practice: (1) the IPHA Code of Practice for the Pharmaceutical Industry (Version 8.6) (Pharmaceutical Code); and (2) the IPHA Self-Care Advertising Code (Version 6) (Self-Care Code) (together the Codes). These Codes apply only to those pharmaceutical companies that have voluntarily agreed to be members of the IPHA. The Advertising Standards Authority for Ireland (ASAI) has issued a 'Code of Standards for Advertising and Marketing Communications in Ireland' (7th edition) (ASAI Code).

IMPORT

6. What is the import-control framework for therapeutic products (eg, import licences, product registration or listing prerequisites, customs classification, tariff rates, national or regional exemptions, and routine or risk-based border inspections)?

Medicinal products

[4] PSI, 'Internet Supply – Overview', www.psi.ie/registration/internet-supply/internet-supply-overview accessed 17 May 2026.

A manufacturing authorisation is required for the importation of medicinal products from outside the EEA. Applications for a manufacturing authorisation are made to the HPRA. Each applicant must give a written undertaking to comply with the conditions of the authorisations, if granted.

Companies require a controlled drug licence, renewable annually, from the HPRA on behalf of the Department of Health, if they want to import any controlled drug in the schedules to the Misuse of Drugs Regulations 2017, as amended.

Applicants must have suitable and sufficient premises, equipment, and facilities, and appropriate and sufficient staff, including the qualified person. The HPRA can grant, refuse, or conditionally grant an authorisation.

An authorisation only applies to the following, specified in the application and in relation to which it has been granted:

- medicinal products and pharmaceutical forms;
- manufacturing or importation operations; and
- premises.

The manufacturer must not use the premises for any other purpose and must comply with good manufacturing practices (GMP) requirements and the terms of the authorisation. The HPRA must be informed of any change in qualified person or any particulars supplied in the application. As noted above in the response to Question 3, businesses who distribute medicinal products in Ireland must be issued with a WDA from the HPRA.

The HPRA can vary an authorisation at any time. The HPRA can suspend authorisations on certain grounds. A manufacturing authorisation can be suspended by the HPRA.

Medical devices

CE marked devices can be freely marketed anywhere in the EU, provided the requirements of the relevant medical devices regulations are met. See previous response to Question 5 above.
All medicinal products and medical devices must meet all relevant import and customs requirements, as enforced by Revenue.

7. To what extent may consumers import therapeutic products for personal use (whether by taking the products across the border or receiving them by mail), and what quantitative limits, prescription requirements, customs declarations, duties, or other restrictions apply?

The Control of Placing on the Market Regulations 2007, as amended, govern the importation of medicinal products in Ireland. These regulations prohibit the importation of medicinal products which do not have a marketing authorisation issued by the HPRA, a community marketing authorisation granted by the European Medicines Agency (EMA), a certificate of registration or a certificate of traditional use registration.

There is an exemption as to importation of unapproved medicines for personal use when individuals enter the state from outside the Schengen Area with such medication in their baggage or on their person, providing that it is a reasonable amount of such medication. If travelling into

the State from within the Schengen Area while carrying such unauthorised medications, then travellers are required to produce an Article 75 Certificate for prescribed narcotics/psychoactive substances containing active substances (controlled drugs) found in Schedule 2 and 3 of the Misuse of Drugs Regulations 2017 (S.I. 173/2017). An Article 75 Certificate covers a maximum of a 30-day supply of the prescribed products for personal use.

8. May foreign suppliers ship therapeutic products directly to consumers via e-commerce or mail order, and what local presence, platform registration, verification, or labelling obligations – if any – must they satisfy?

As noted above in the response to Question 5, prescription only medications cannot be sold directly to consumers via e-commerce or mail order. Foreign suppliers can only ship non-prescription medicines directly to consumers via e-commerce if the product supplied has been authorised for use in Ireland by the HPRA.

As also noted in the response to Question 5, foreign suppliers may ship medical devices directly to consumers in Ireland via e-commerce, provided they are fully in compliance with the provisions of the MDR and the IVDR and the broader regulatory framework as set out in response to that question.

9. How is parallel importation (ie, of products licensed and sold in other jurisdictions) of therapeutic products by businesses regulated, particularly with respect to intellectual property rights, product re-labelling or re-packaging, and requirements to maintain original quality, safety, and traceability?

Nationally authorised products that are parallel imported from another EU or EEA Member State and distributed on the Irish market require a parallel import licence. There are two types of parallel import licence: (1) Parallel product authorisation (PPA) – required where the product being imported differs in any respect from those on the Irish market; (2) Dual pack import registration (DPR) – required where the product being imported is identical in all respects (including identical packaging, labels, and leaflets) to those on the Irish market.

EXPORT

10. Are there quantitative quotas, permits, or other measures that restrict or condition the export of therapeutic products (eg, to mitigate shortages or address public health emergencies), and how are such measures administered and enforced?

A WDA is required to engage in the export of pharmaceuticals in Ireland, in accordance with the Control of Wholesale Distribution Regulations 2007, the Code for Human Medicines Directive and the guidelines issue by the HPRA. For medical devices, once they are CE marked, they can be marketed anywhere in the EU, provided that the relevant requirements of the MDR and IVDR are met. If a device is being exported outside of the EU it is necessary to apply to the HPRA for a certificate of free sale.

As we understand it, there is no Irish specific or EU legislation that permits the implementation of quantitative quotas or restrictions on the export of therapeutic products.

11. Is there any form of 'export-only' or 'dual-labelling' authorisation that permits the manufacture and export of therapeutic products not approved for domestic marketing, and if so, what standards, labelling, or record-keeping obligations apply?

Manufacturers in Ireland can produce medicines solely for export, even if they are not approved for domestic marketing in Ireland, under specific 'export only' certificates issued by the HPRA. To apply for such a certificate, a manufacturer must in addition to the application, complete a declaration signed by the Qualified Person/Head of Registration stating why the product is not the subject of a Marketing Authorisation or a Veterinary Product Authorisation (VPA).

As we understand it, there is no export only authorisation specifically for the manufacture and export of therapeutic products not approved for domestic marketing.

LABELLING, TRACEBILITY, AND PRODUCT INFORMATION

12. What local language labelling, patient information, unique device identification, serialisation, anti-counterfeiting, or traceability requirements must be met before imported therapeutic products may circulate domestically or before therapeutic products may be exported?

All medicines must include a patient information leaflet written in clear, understandable English. This information must include all requirements specified under Title V of the Code for Human Medicines Directive, including amongst other requirements, the name of the product, the active substances, contents by weight, volume or number of doses, method of administration and expiry date.

Medical devices must be accompanied by labelling and instructions for use in English. Each device must contain a UDI, in accordance with the MDR and the IVDR and be registered with the European Database on Medical Devices (EUDAMED).

CE marked devices can be freely marketed anywhere in the EU, provided the requirements of the MDR and IVDR are met. If a device is to be marketed outside the EU, it is necessary to apply to the HPRA for a certificate of free sale. The importer of non-EU based manufactured devices is also responsible for making sure the device they place on the market bears the CE marking.

PRICING, REIMBURSEMENT, AND MARKET ACCESS

13. Are there any price-control, reimbursement, public procurement, or stock/supply-obligation regimes that (while not trade measures per se) materially influence the distribution channels or availability of therapeutic products?

The Health Act 2013 and the IPHA Agreement are the primary documents governing the pricing of medicinal products in Ireland, produced by originators. There is a similar agreement in place for the generics industry. As mentioned in our response to Question 1, above, the 2021 IPHA Agreement expired on the 30 September 2025. Formal negotiations have now commenced between the State and IPHA on a successor agreement.

Ireland maintains a positive reimbursement list. If a product is not included, the supplier can apply to have it added for reimbursement eligibility. Pricing and reimbursement applications for

medicinal products can only be submitted after marketing authorisations are granted. The HSE is responsible for drug reimbursement.

Under the Health Act 2013, in reaching its reimbursement decision the HSE must consider several factors including but not limited to:

- the cost-effectiveness of meeting health needs by supplying the product concerned instead of an alternative product;
- the health needs of the public; and
- the resources available to the HSE.

Application and process

On receiving a reimbursement application, the National Centre for Pharmacoeconomics (the NCPE) will evaluate certain of the criteria set out in Schedule 3, Part 3 of the Health Act 2013 with the balance being assessed by the HSE. The price proposed by the supplier is set based on the 2021 IPHA Agreement using the average, currency-adjusted, ex-factory price of 14 nominated countries, on the date of the application.

The NCPE conducts its assessment using its Rapid Review procedure, which typically takes about four weeks. All medicines undergo Rapid Review. For high-cost products or those with significant budget impacts, a more detailed pharmacoeconomic analysis (Health Technology Assessment) will be carried out by the NCPE, which takes approximately 18 weeks with the extension of that time possible when further information is sought from the applicant.

If a medicinal product is deemed not cost-effective, the HSE seeks a recommendation from its Drug Group. During the Drug Group review, the HSE's Corporate Pharmaceutical Unit may engage in commercial discussions with the applicant.

The HSE, generally speaking, will insist that the terms of the IPHA Agreement are followed by most suppliers and therefore the supply of almost all products follows the terms of the IPHA Agreement.

Per the 2021 IPHA Agreement, medicinal products undergo an annual price adjustment to match the average ex-factory price of 14 nominated countries, with only downward adjustments allowed. Suppliers must pay the HSE rebates of the ex-factory price, which increase in stages from 5.5 per cent in 2021 to nine per cent in October 2024.

The Health Act 2013 mandates that the HSE must provide the applicant with formal notice of its proposed reimbursement decision. Applicants can appeal the HSE's decision to the Irish High Court.

Reference pricing

For certain groups of products under the Health Act 2013, the HSE has established a common reimbursement price, known as the 'reference price', for relevant groups of interchangeable medicinal products. If a supplier charges more than the reference price, the patient must pay the difference, as the HSE will only reimburse up to the reference price.

The HPRA draws up the list of groups of interchangeable medicinal products. Under the 2021 IPHA Agreement, a decision on an application as to whether a product should be added to the list of interchangeable products should be made no later than 180 days from when the application is received. A time extension is possible if further information is sought from the applicant.

ENFORCEMENT, COMPLIANCE, AND RECENT DEVELOPMENTS

14. What investigative powers, sanctions, and remedial measures (administrative, civil, or criminal) are available to regulators when they detect non-compliance with trade and distribution rules for therapeutic products, and how are these powers used in practice?

The HPRA is responsible for monitoring compliance with manufacturing authorisations, WDAs, GMP, and GDP requirements. The HPRA's powers derive from several legislative sources, as referred to throughout this survey. The HPRA can:

- enter and inspect sites;
- inspect and copy records;
- conduct tests or examinations at the site; and
- take samples for testing.

The HPRA can investigate whether a manufacturer, importer, or wholesale distributor has obtained an authorisation and is complying with it and at their disposal the qualified person approved by the HPRA who meets the requirements and is fulfilling their obligations.

Breach of the Manufacturing Regulations or Wholesale Distribution Regulations is an offence under the IMB Act, resulting in:

- On summary conviction, a fine up to €2,000 or imprisonment for up to one year, or both.
- On conviction on indictment for a first offence, a fine up to €120,000 or imprisonment for up to ten years, or both, and for a subsequent offence, a fine up to €300,000 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 or connivance of, 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.

If there is a breach of labelling and packaging requirements, the HPRA can suspend the product's manufacturing authorisation until the breach is remedied.

Those supplying therapeutic products within the Irish market will also need to be cognisant of the broader regulatory commerce setting as explained in response to Question 5.

15. Is there recent case law, legislative or policy developments, noteworthy enforcement trends, or anticipated reforms that may significantly alter the regulation of trade, distribution, or cross-border movement of therapeutic products in the future?

IPHA framework agreement

As stated above, we would expect to see a successor agreement to the 2021 IPHA Agreement and this will shape the position on pricing and reimbursement as between the HSE and the innovator industry.

US tariffs

Irish pharmaceutical and medical technology companies are closely monitoring the evolving U.S. tariff environment. Notwithstanding the ongoing Section 232 investigations, under national security grounds, the position has stabilised somewhat since the summer of 2025.

The EU/US deal reached in Scotland has been confirmed as all-inclusive in terms of EU pharma exports and pharma will be capped at a ceiling of 15 per cent following the outcome of the Section 232 investigation. The position on medtech is still under negotiation.

National Life Sciences Strategy

In January 2025 the Irish government announced their intention to develop a new National Life Sciences Strategy. This strategy is intended to ensure that the life sciences sector remains competitive and to provide coherent and ambitious framework to future opportunities. It is expected to be published in 2026.