Life Sciences Regulation in Ireland: Overview

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

This Q&A provides a high-level overview of key practical issues, including life sciences clinical trials, manufacturing, marketing, abridged procedure, pharmacovigilance, data privacy, packaging and labelling, biological medicines, medical devices, health care IT, combination products, borderlines, and natural health products.

Pharmaceuticals

1. What are the main legislation and regulatory authorities for pharmaceuticals in your jurisdiction?

Legislation

Medicinal products. The regulatory framework for medicinal products in Ireland is based on *Directive 2001/83/EC on the Community code relating to medicinal products for human use*, as amended (Code for Human Medicines Directive). This was implemented in Ireland by 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).

Pricing and reimbursement of medicinal products. Pricing and reimbursement of medicinal products is governed by the *Health (Pricing and Supply of Medical Goods) Act 2013*, as amended (Health Act). In addition, there is a Framework Agreement 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).

Regulatory Authorities

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.

Definition of Medicinal Product

Under the IMB Act, medicinal product has the same definition as that prescribed in the Code for Human Medicines Directive. See Article 1, Code for Human Medicines Directive.

Clinical Trials

2. Outline the regulation of clinical trials.

Legislation and Regulatory Authorities

The *European Union (Clinical Trials on Medicinal Products for Human Use) (Principal) Regulations 2022* (Principal Regulations) came into force in Ireland on 2 March 2022, implementing *Regulation (EU) 536/2014 on clinical trials on medicinal products for human use* (Clinical Trials Regulation (CTR)). Previously, Ireland was regulated by the European Communities (Clinical Trials on Medicinal Products for Human Use) Regulations 2004 to 2009 which implemented Directive 2001/20/EC on the conduct of clinical trials (together, the CTD).

Under the CTR, the application process for conducting clinical trials across the EU has been harmonised through the compilation and implementation of a new *Clinical Trials Information System* database (CTIS). Through the CTIS, the European Medicines Agency (EMA) works closely with national authorities to review applications submitted on CTIS while publicising aspects to the public, patients, and stakeholders.

To support this interaction between the EMA and national authorities in Ireland, the *European Union (Clinical Trials on Medicinal Products for Human Use) (National Research Ethics Committees) Regulations 2022* (National Research Regulations) establish National Research Ethics Committees (RECs) for clinical trials and a national office to administratively support the work of the RECs.

Transitional provisions. A three-year transitional period was introduced, subject to several timelines:

- From 31 January 2023, the submission of all new clinical trial applications is mandatory under the CTR through the CTIS, which serves as the single-entry point for submission by sponsors and for regulatory assessment (from 31 January 2022 to 31 January 2023, initial clinical trial applications could be submitted under the CTD or the CTR).
- Between 31 January 2022 and 31 January 2025: ongoing clinical trials can be previously authorised under the CTD or they can transition to the CTR. By 31 January 2025, all ongoing clinical trials must have transitioned to the CTR and migrated to CTIS.

A sponsor of a clinical trial that received a favourable opinion from an ethics committee in accordance with the 2004 Regulations and, in relation to which trial the HPRA granted an authorisation, must continue to comply with their reporting obligations under the 2004 Regulations until 31 January 2025.

Manufacturer's licences for investigational medicinal products. Any manufacturer's licence granted under the CTD or the *Medicinal Products (Control of Manufacture) Regulations 2007*, as amended (Manufacturing Regulations) for investigational medicinal products will continue in force as if granted under the Principal Regulations. An application for the grant or variation of a manufacturer's authorisation under the Manufacturing Regulations which was not determined before the coming into force of the Principal Regulations is considered as made under the Principal Regulations.

Persons eligible for an exemption from the requirement to hold an authorisation for the manufacture/import of investigational medicinal products, who commenced their activity before 31 January 2022, were required to apply to the HPRA to be listed on the Register of Exemptions by 31 March 2022. The *Medicinal Products (Control of Manufacture) (Amendment) Regulations 2022* amend the Manufacturing Regulations to remove investigational medicinal products from their scope.

Authorisations

An application must be lodged using the CTIS. This EU-wide portal and database is hosted by the EMA and provides information to stakeholders, the public, and patients on various aspects of a particular application. A sponsor or applicant must specify the relevant member states concerned (MSCs) by the proposed clinical trial alongside nominating a reporting member state (RMS). Sponsors can also indicate in the cover letter of their application whether they consider the trial to be low intervention.

The CTIS application process generally has two phases:

- The first phase includes an assessment of the protocol, investigator's brochure, and investigational medicinal product dossier. Assessment of these documents, within EU-mandated timelines, is led by the RMS, with MSCs providing comments.
- The second phase includes assessment of the subject information and informed consent documents, the suitability of the investigator and of the trial site, indemnity, and data protection. This assessment is done at national level by each national ethics committee.

MSCs consider the application in the first phase while ethics committees consider the second phase. In Ireland, the HPRA is responsible for the first phase with input from the RECs on ethical matters. Thereafter, the national office with the RECs is responsible for the phase two assessment.

The sponsor or, where necessary, its legally designated representative must be established in the EU. When the sponsor is not established in the EU, it must appoint a natural or legal person established in the EU as its legal representative, who is responsible for compliance with the sponsor's obligations under the CTR.

Consent

The CTR provides that trial subjects must give informed consent to their participation in the trial. This should be obtained during an interview carried out by a registered medical practitioner, registered dentist, or registered nurse. Further, the Principal Regulations state that the training, experience, and qualification of the interviewer should be assessed by the investigator to determine whether the interviewer has sufficient qualifications to conduct the interview.

In the case of an incapacitated subject, a legally designated representative, such as a family member, or a medical practitioner who is primarily responsible for the treatment of the proposed subject, may provide consent on behalf of that subject.

Where the subject is under the age of 16, they are considered a minor, and informed consent must be given by a guardian on behalf of the minor. However, where a minor is capable of forming an opinion and assessing the information provided to them during the interview, the minor must also assent to their participation in the trial.

In emergency situations, due to sudden life-threatening or serious medical conditions, informed consent may be obtained after the trial has commenced in accordance with Article 35 of the CTR.

Trial Pre-Conditions

A clinical trial may only be authorised if there is an insurance policy or indemnity scheme in place to provide compensation for any damage suffered by a subject participating in the trial. The insurance policy must be appropriate having regard to the nature and the risk of conducting the trial. Proof of this insurance cover must be submitted as part of the trial application.

Procedural Requirements

Sponsors must comply with various reporting obligations set out under the CTR such as annual reports, reports on adverse events, and reports summarising the results of the trial.

The Principal Regulations also provide that sponsors must keep a clinical trial master file that contains sufficient information to show compliance with principles and guidelines of GCP (Annex I and Annex II of CTR), and which is specific to each phase of the trial.

If a sponsor become aware of an issue that requires safety measures to protect the health and safety of subjects, the HPRA must be notified immediately, no later than seven days after such measures were taken. The clinical trial documents must later be amended to reflect the implementation of urgent safety measures. Where a trial is suspended, the restart is treated as a substantial amendment, which requires the sponsor to provide sufficient evidence to the HPRA that it is safe to continue the trial.

Transparency and Reporting Requirements

Where a trial is approved the sponsor must submit the results of the clinical trial via CTIS within one year from the end of the trial in all MSCs. The results should not be submitted to the HPRA.

The results comprise two summaries:

- A summary of the results.
- A summary written in a manner understandable to lay persons.

For limitations on the use or disclosure of participants' data, see *Question 12*.

Manufacturing and Distribution

3. What is the authorisation process for manufacturing and distributing medicinal products?

Manufacturing is regulated by the Manufacturing Regulations.

A Wholesale Distribution Authorisation (WDA) is required to engage in the procurement, holding, supply, or export of pharmaceutical products in Ireland, in accordance with:

- The *Medicinal Products (Control of Wholesale Distribution) Regulations 2007*, as amended (Wholesale Distribution Regulations).
- The Code for Human Medicines Directive.
- The guidelines issued by the HPRA.

Application

A manufacturing authorisation is required for the manufacture, dividing up, packaging, labelling, presentation, and importation of medicinal products from outside the EEA. Applications are made to the HPRA, and must include details of:

- The applicant.
- The relevant medicinal products and pharmaceutical forms.
- The proposed operations.
- The premises, equipment, and facilities.
- The site master file.
- The "qualified person" for batch release, who ensures that each batch complies with law, good manufacturing practice (GMP), the manufacturer's authorisation, and the marketing authorisation (MA) or equivalent. This person must be nominated by the applicant.

Each applicant must give a written undertaking to comply with the conditions of the authorisation, if granted.

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

Conditions

Applicants must have suitable and sufficient premises, equipment, and facilities, and appropriate and sufficient staff, including the qualified person (see above, *Application*). 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.
- Premises.

The manufacturer must not use the premises for any other purpose, and must comply with 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.

The HPRA issues WDAs. To receive a WDA, 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 (maximum of 90 days) and a possible inspection.

Restrictions on Foreign Applicants

There is no restriction on foreign applicants. However, the HPRA only issues manufacturing authorisations for Irish manufacturing or importation sites.

Fees

Application fees are listed on the *HPRA's website* and are typically updated annually.

Authorisations, Variations, and Renewals

Authorisations are valid indefinitely, unless otherwise specified by the HPRA. Renewal applications for authorisations should be submitted three months before the expiry date. Renewals do not carry an expiry date.

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 where:

- The holder is not carrying out the manufacturing or importation operations to which the authorisation relates.
- The matters specified in the application were false or incomplete.
- A material change of circumstances has occurred in relation to any of those matters or particulars.
- The authorisation holder has failed to any material extent to comply with their obligations.
- The holder has manufactured or imported medicinal products otherwise than in accordance with the terms of the authorisation.
- The authorisation holder does not have the staff, premises, equipment, or facilities necessary for carrying out properly the handling, storage, or distribution activities to which the authorisation relates.
- The authorisation holder has failed to carry out an obligation imposed by the HPRA.

A WDA can be suspended by the HPRA in circumstances where:

- The holder is not carrying out the wholesaling operations to which the WDA relates.
- The particulars accompanying the application were false or incomplete.
- A material change of circumstances has occurred in relation to any of those particulars.
- The holder has failed to any material extent to comply with their obligations.
- The holder has sold by wholesale medicinal products otherwise than in accordance with the terms of the WDA.
- The holder does not have the staff, premises, installations, or equipment necessary for carrying out properly the handling, storage, or distribution activities to which the WDA relates.

Monitoring Compliance and Imposing Penalties

The HPRA is responsible for monitoring compliance with manufacturing authorisations, WDAs, GMP, and GDP requirements. The HPRA can:

- Enter and inspect sites.
- Inspect and copy records.
- Conduct tests or examinations at the site.
- Take samples for testing.

The HPRA can investigate whether a manufacturer, importer, or wholesale distributor has:

- Obtained an authorisation and is complying with it.
- 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 EUR2,000 or imprisonment for up to one year, or both.
- On conviction on indictment for a first offence, a fine up to EUR120,000 or imprisonment for up to ten years, or both, and for a subsequent offence, a fine 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.

Marketing

Authorisation Procedure

4. What is the authorisation process for marketing medicinal products?

Application

Placing medicinal products on the market in Ireland is regulated by the Marketing Regulations, which transposes the Code for Human Medicines Directive. Subject to certain exceptions (including the compassionate use exemption and clinical trial supplies), a medicinal product cannot be placed on the market in Ireland unless an MA has been granted for that product through one of the following procedures:

- **National procedure.**An application is submitted to the HPRA and, if granted, the MA entitles the marketing authorisation holder (MAH) to place the medicinal product on the Irish market.
- **Mutual recognition procedure.** If the medicinal product has received an MA in another EEA member state (Reference Member State), the MAH can apply to one or more other member states (Concerned Member State) to recognise that authorisation. If a product has received an MA in another member state, the MAH can apply to the HPRA to mutually recognise that authorisation in Ireland.
- **Decentralised procedure.** This can be used if the product has not yet received an MA in a member state, and the applicant wishes to apply for simultaneous authorisation in two or more member states. The applicant nominates one of the states as the Reference Member State, whose competent authority examines the application in full and prepares a report for the competent authorities of the Concerned Member State(s). The HPRA is the competent authority for these applications in Ireland.
- **Centralised procedure.** A Community MA, which is valid throughout the EEA, can be obtained by applying to the EMA, through the centralised procedure governed by *Regulation EC) 726/2004 laying down EU procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency* (EMA Regulation). Following a positive assessment by the EMA, an MA is granted by the European Commission. The centralised procedure is compulsory for certain medicinal products.

An applicant for an MA must be established in an EEA state. Applications (whether to the HPRA or EMA) must be accompanied by the appropriate fee and certain documents and particulars, including:

- A summary of the product characteristics (SmPC).
- A mock-up of the packaging and package leaflet.
- The requisite safety, quality, and efficacy data (including clinical trial results and a description of the proposed pharmacovigilance system).

Applications under the mutual recognition or decentralised procedure must:

- Include a list of all the concerned member states.

- Confirm that the dossier, the SmPC, package leaflet, and labelling are identical in each of the member states involved.

Authorisation Conditions

The application must include certain documents (see above, *Application*) and be approved by the EMA (under the centralised procedure), the HPRA (under the national procedure in Ireland), or other national competent authority.

An MA can be granted to an applicant in the EEA who is responsible for marketing a specific medicinal product. An MA covers the placing on the market, labelling, and packaging of a medicinal product.

Key Stages and Timing

The key stages and timing are determined by the procedure used.

Under the national procedure, the Marketing Regulations do not specify any timescale within which the HPRA must consider the application. In line with the Code for Human Medicines Directive, the HPRA must process an application for an MA within 210 days from submission of a complete application.

If an application is refused, the HPRA must provide the applicant with a notice in writing, detailing the reasons on which it has based its decision. The applicant then has 30 days in which it can give notice of its wish to appeal. The HPRA, after considering the applicant's representations, will decide whether to alter its decision.

If the applicant is unsatisfied with the appeal decision it can, in certain circumstances, seek judicial review of the HPRA's decision-making procedure.

Conditional MAs can be granted where the available data indicates that the benefit of a human medicine outweighs its risks and the applicant should be able to provide comprehensive clinical data in the future. In addition, the relevant competent authority can require, on granting authorisation, that the MAH carries out post-authorisation safety studies and efficacy studies.

Fee

The applicable fees are available on the *HPRA website*.

The fees for the centralised procedure are available on the *EMA website*.

Authorisations, Variations, and Renewals

Unless a shorter time period is specified, an MA is valid for five years. If the product is not placed on the market within three years of authorisation or is not on the market for three consecutive years, the authorisation ceases to be valid.

Renewal applications must be made at least six months before expiry of the current MA. If successfully renewed, the MA remains valid for an indefinite period (unless further renewals are required for pharmacovigilance reasons).

After a medicine has been authorised, the terms of the MA can subsequently be varied. The procedures are governed and harmonised throughout the EU by *Regulation 1234/2008 concerning the examination of variations to the terms of marketing authorisations for medicinal products for human use and veterinary medicinal products* (Variations Regulation), as amended by *Commission Regulation (EU) 712/2012 amending Regulation (EC) 1234/2008 concerning the examination of variations to*

the terms of marketing authorisations for medicinal products for human use and veterinary medicinal products. Regulation (EU) 712/2012 extends the scope of the Variations Regulation to all MAs, human and veterinary, whether granted through national, mutual recognition, decentralised, or centralised procedures.

An MA can be transferred from the existing authorisation or licence holder to another holder using a transfer procedure. A transfer can occur before a product is authorised or after authorisation, to a company related to the existing holder or to an unrelated company. An MA can be transferred within six weeks of the HPRA receiving a valid application. Products can be transferred before authorisation or once authorised. Transfer applications are subject to the national procedure, even if the product has been authorised through the mutual recognition procedure.

The HPRA can revoke a marketing authorisation if the conditions of the authorisation are not met.

Protection of Confidential Information

At present, third parties cannot access information about pending applications for MAs in Ireland. If an MA has been granted or refused, a third party can submit a freedom of information (FOI) request to the HPRA under the *Freedom of Information Act 2014*, to access certain records. However, a public body can rely on several grounds in the Act to refuse to release information, including non-disclosure of commercially confidential information.

Exceptions

5. Are there additional or alternative regulations for special types of medicines or medicines intended for particular types of patients or diseases?

Conditional marketing authorisations may be granted at EU centralised level in particular for special types of medicines where there is less comprehensive clinical data than normally required, for example, orphan medicines.

6. Can products be marketed without a marketing authorisation in certain circumstances?

Activities that promote unlicensed medicinal products are prohibited. Therefore, providing any information about these products that is promotional in tone, content, or approach is a breach of the *Medicinal Products (Control of Advertising) Regulations 2007* (Advertising Regulations) and the Code of Practice for the Pharmaceutical Industry (IPHA Industry Code).

A variety of actions can constitute promotion, including proactively presenting information to someone about an unlicensed medicine in a way that influences or is intended to influence their behaviour.

It is permitted to provide information about unlicensed products in the following circumstances:

- Reacting to an unsolicited enquiry from a health care professional or other relevant decision maker, provided that the information is not promotional in tone or content or provided in a promotional way.
- As part of the legitimate exchange of medical or scientific information, provided the exchange is not promotional.

Monitoring Compliance and Penalties

7. What powers does the regulator have to monitor compliance with marketing authorisations and impose penalties for a breach?

The HPRA is responsible for monitoring compliance with MAs. The HPRA has wide-ranging powers relating to:

- Entry and inspection of sites.
- Inspection and copying of records.
- Conducting tests or examinations at the site.
- Taking samples for subsequent testing.

The HPRA also relies on manufacturers, health care professionals, and the public to report adverse events and misleading information about medicinal products.

The HPRA (or, for centrally authorised medicinal products, the European Commission) can impose an urgent safety restriction for a product on the market. The relevant MAH must implement the safety restriction and apply to vary the MA accordingly immediately, or at the latest within 15 days of imposition of the restriction.

The HPRA can also revoke, withdraw, suspend, refuse to renew, or vary an MA, for a specified period or until further notice.

Breach of the Marketing Regulations is an offence under the IMB Act. Offences can be prosecuted by the HPRA and liability is the same as for breach of the Manufacturing Regulations (see *Question 3, Monitoring Compliance and Imposing Penalties*).

Data and Marketing Exclusivity Protections

8. What exclusivity does a marketing authorisation holder benefit from?

An application for authorisation of a generic medicinal product or similar biological product can be made to the HPRA eight years after authorisation of the reference product (the original product) when the period of data exclusivity for the reference product expires. If the application for the reference product was made before 30 October 2005 and the application was not in respect of a centralised marketing authorisation, the period is reduced to six years.

Once authorised, a similar generic or biological product cannot be placed on the market for ten years (depending on the exclusivity period available for the reference product) following authorisation of the reference product.

This is extended to 11 years if, during the first eight years after the initial MA for the reference product is granted, the holder of that MA is granted an authorisation for a new therapeutic indication of significant clinical benefit compared to existing therapies.

Abridged Procedure for Marketing Authorisation

9. Outline the abridged procedure for marketing authorisation.

An applicant is not required to provide the results of pre-clinical and clinical trials if it can show that the product is a generic medicinal product, or a similar biological product to a reference medicinal product which has been authorised in the EU for at least eight years (or six years, if the application for the reference product was submitted before 30 October 2005) (see *Question 8*).

An abridged procedure is also available for:

- Applications relying on well-established (ten years) medicinal use of the active substance involved, where the applicant can replace the results of pre-clinical and clinical trials with the appropriate scientific literature.
- Applications relating to new fixed combination products, where the results of new pre-clinical or clinical trials are provided, but scientific references relating to each individual substance are not required.
- Applications where the product has the same qualitative and quantitative composition in terms of active substances as an authorised medicinal product, and the original MAH gives its consent to use of its dossier for examining the application.

Pharmacovigilance and Other Commitments

10. What pharmacovigilance obligations and other commitments apply after a company has obtained marketing authorisation? Are there further conditions on how the medicinal product is distributed and made accessible to patients?

Pharmacovigilance System

The Marketing Regulations require an MAH to comply with certain pharmacovigilance requirements to maintain its MA. The pharmacovigilance framework is based on the EMA Regulation, as amended by *Regulation 1235/2010 amending, as regards pharmacovigilance of medicinal products for human use, Regulation (EC) 726/2004 and Regulation (EC) 1394/2007*, and the Code for Human Medicines Directive, as amended by *Directive 2010/84/EU amending, as regards pharmacovigilance, Directive 2001/83/EC on the Community code relating to medicinal products for human use*, as amended. The pharmacovigilance framework was updated in 2010 by *Directive 2012/26/EU amending Directive 2001/83/EC as regards pharmacovigilance*) and *Regulation (EU) 2012/1027/EU amending Regulation (EC) No 726/2004 as regards pharmacovigilance*. This updated EU legislation has been transposed in Ireland, for human medicines, by the *Medicinal Products (Control of Placing on the Market) (Amendment) Regulations 2012* and *Medicinal Products (Control of Placing on the Market) (Amendment) Regulations 2014*.

Under this updated legislation, the MAH must, among other things:

- Have permanently and continuously available an appropriately qualified person (the nominated person) for pharmacovigilance in the EEA, who is responsible for the establishment and maintenance of a pharmacovigilance system.
- Maintain, and make available on request, a pharmacovigilance system master file, for medicinal products for which an MA is granted on or after 21 July 2012 (or, if granted before 21 July 2012, from the date on which the MA is next renewed or 21 July 2015, whichever is earlier).
- Operate, and keep updated, a risk management system for medicinal products for which an MA is granted on or after 21 July 2012 (or, if granted before 21 July 2012, where required by the HPRA).

In the case of suspected adverse reactions, the MAH must, among other things:

- Keep a detailed record of all suspected adverse reactions to the relevant medicinal product which are brought to the MAH's attention. This includes suspected adverse reactions occurring in and outside the EU.
- Report all serious suspected adverse reactions no later than 15 days following the day on which the MAH gained knowledge of the event.
- For a suspected adverse reaction to a biological medicinal product prescribed, dispensed, or sold in Ireland, record the brand name and batch number of the product. Reports of serious suspected adverse reactions, non-serious suspected adverse reactions, and updates on suspected adverse reactions must be submitted to the *EudraVigilance database*.

The MAH must also submit Periodic Safety Update Reports (PSURs) to the HPRA or EMA at specified intervals. PSURs must include certain safety information, resulting in an evaluation of the impact of the reports on the risk-benefit balance of a medicinal product.

Other post-marketing commitments of the MAH required by the Marketing Regulations include:

- Informing the HPRA of certain information, including the date that the medicinal product is placed on, or removed from, the market, and any new information which may influence the evaluation of the benefits and risks of the medicinal product.
- If relevant, complying with any post-marketing obligations and conditions imposed on the MAH by HPRA or the European Commission in the grant of the relevant MA.
- Ensuring that sufficient supplies of the product are provided to pharmacies on an ongoing basis.
- Ensuring that the product information is kept up to date with current scientific knowledge.

Other Commitments

The *Marketing* Regulations impose an obligation on marketing authorisation holders to ensure that sufficient and continuous supplies of the relevant medicinal product are made available to meet the needs of patients in Ireland.

Further, the continuity of supply is recognised as an important principle for the parties under the IPHA Agreement. Suppliers who become aware of foreseeable or prolonged shortages must notify the HSE and HPRA as soon as they become aware of such a shortage. The supplier must then try to source an alternative supply within the notice period.

In addition, the HPRA operates a *multi-stakeholder framework* which provides guidance to all operators in the supply chain on their respective responsibilities and steps required to avoid potential shortages from occurring, and to manage and reduce the impact of shortages.

Foreign Marketing Authorisations

11. Are foreign marketing authorisations recognised in your jurisdiction?

An MA issued by, or an application for an MA submitted to, the competent authority of another EEA state, can be recognised in Ireland under the mutual recognition or decentralised procedure. MAs issued by countries outside the EEA are not automatically recognised in Ireland.

Data Privacy

12. Do privacy and data protection laws impact on pharmaceutical regulation in your jurisdiction?

The processing of personal data relating to a person's physical or mental health or condition, or sexual life, constitutes special category data within the meaning of the *General Data Protection Regulation ((EU) 2016/679)* (GDPR) and the *Data Protection Act 2018* (DPA).

Data controllers are subject to the following obligations in relation to personal data under Article 5 of GDPR and the DPA:

- Obtain and process the personal data in a lawful, fair, and transparent manner.
- Collect the personal data for specified, explicit, and legitimate purposes and do not further process in a manner that is incompatible with those purposes.
- Ensure that the personal data is adequate, relevant, and limited to what is necessary in relation to the purposes for which it is processed.
- Keep the personal data accurate and up to date and take every reasonable step to ensure that inaccurate data is erased or rectified without delay.
- Retain the personal data for no longer than is necessary for the specified purpose or purposes.
- Process the personal data in a manner that ensures appropriate security of the personal data, in particular:
    - protect against unauthorised or unlawful processing; and
    - protect against accidental loss, destruction or damage, using appropriate technical and organisational measures.

As a basic principle, processing data generated in relation to the health of patients is prohibited. The GDPR does, however, provide some exceptions. One exception concerns explicit informed consent granted by patients to the processing of their personal health data (Article 9(2)(a), GDPR). It is necessary to be able to prove consent is given.

Article 9 (Processing of special categories of personal data) of the GDPR imposes the following special obligations on the data controller when processing special category data:

- The data must be fairly obtained (see above).
- The data subject, a parent, or legal guardian (where required) must give explicit consent, having been informed of the purpose of the processing.

If consent is not obtained, a data controller can still process the special category personal data under certain circumstances, for example:

- Processing is necessary for the purposes of carrying out the obligations and exercising specific rights of the controller of the data subject in the field of employment and social security and social protection law.
- To otherwise protect the vital interests of the data subject or of another natural person, where the data subject is physically or legally incapable of giving consent.
- Where the personal data has been made manifestly public by the data subject.
- Where processing of the data is necessary for the purposes of preventative or occupational medicine, for the assessment of the working capacity of the employee, medical diagnosis, the provision of health or social care or treatment, or the management of health or social care systems and services on the basis of EU or member state law, or under a contract with a health professional and subject to the conditions and safeguards referred to in Article 9(3) of the GDPR. Processing on this ground is subject to the requirement in the DPA that it must be subject to suitable and specific measures to safeguard the rights and freedoms of the data subject.

For the processing of personal data to be fair, the data subject must be informed of the following:

- The identity and contact details of the controller and, where applicable, the identity and details of the controller's representative.
- The contact details of the data protection officer, where applicable.
- The purposes of the processing for which the personal data are intended, and the legal basis for the processing.
- Where the processing is based on point (f) of Article 6(1), the legitimate interests pursued by the controller or by a third party.
- The recipients or categories of recipients of the personal data (if any).
- Transfers of personal data to a third country and the existence or absence of an adequacy decision by the European Commission, or in specific circumstances as set out in the GDPR, reference to the appropriate safeguards and the means by which to obtain a copy of them or where they have been made available.

(Article 13(1), GDPR.)

In addition, Article 13(2) GDPR requires the data controller to provide the data subject with the following further information at the time when personal data are obtained:

- The period for which the personal data will be stored.
- The existence of data subject rights (including the right to withdraw consent).
- Where the processing is based on consent, the existence of the right to withdraw consent at any time, without affecting the lawfulness of processing based on consent before its withdrawal.
- The right to complain to a supervisory authority.
- Whether the provision of personal data is a statutory or contractual requirement, or a requirement necessary to enter into a contract, and whether the data subject is obliged to provide the personal data and the possible consequences of a failure to provide such data.

- The existence of automated decision-making (including profiling), meaningful information about the logic involved, and the significance and envisaged consequences of that processing for the data subject.

Under the GDPR, the rules governing the lawful processing of health data and genetic data may be further restricted by national laws in each EU member state.

Where personal data is processed based on the consent of a particular patient, the consent must be:

- Freely given, specific, informed, and an unambiguous indication of the patient's wishes by which the patient, by a statement or by a clear affirmative action, signifies agreement to the processing of personal data relating to the patient.
- Clearly distinguishable from other matters or information (if the consent is in writing).
- Capable of being withdrawn at any time by the patient.
- As easy for the patient to revoke as it is to grant.

To comply with the GDPR, data controllers must also:

- Maintain records of their data processing activities and be able to show compliance with the GDPR.
- Put in place data processing agreements with any processors that process personal data on their behalf (that contain extended provisions compared to those legally required under the DPA).
- Meet transparency obligations by providing patients with certain information (in addition to that required under the DPA), either when the controller collects the information from the patient itself or obtains it from another source.
- Carry out a Data Protection Impact Assessment if they intend to process on a large scale special categories of data, as referred to in Article 9(1).

In addition to rights such as data access, rectification, and deletion, patients, or other data subjects, or both have data protection rights under the GDPR in certain circumstances, including to:

- Restrict the processing of personal data relating to them.
- Erasure (the right to be forgotten).
- Data portability.

The *Data Protection Act 2018 (Section 36(2)) (Health Research) Regulations 2018* to *Data Protection Act 2018 (Section 36(2)) (Health Research) (Amendment) Regulations 2021* (Health Research Regulations) introduced material changes to the rules governing how health research can be conducted in Ireland, including the following:

- A new statutory definition of health research.
- Prescribing a list of mandatory suitable and specific measures when processing personal data for health research purposes, including a general requirement that explicit consent is obtained from data subjects.
- Imposing obligations on data controllers to obtain data subjects' explicit consent to use their personal data for scientific purposes in accordance with international best practice on the ethical conduct of health research. This includes

providing data subjects with information regarding the scientific research and providing an option for consent to be withdrawn.

- Where a patient is mentally or physically incapacitated and therefore cannot consent to the processing of their personal data, the Health Research Regulations introduce the concept of deferred consent, where personal data can be processed without consent. This is only permissible in circumstances where the processing is connected to the provision of health care to the data subject and is necessary to protect their vital interests.
- Permitting the processing of patient records for pre-screening purposes (to determine whether the individual is suitable or eligible for inclusion in a study) without the data subject's explicit consent and without the ethical approval of a research ethics committee.

Where the health research was commenced before 8 August 2018, but the controller processes or further processes personal data after this date, the controller must apply to the Health Research Consent Declaration Committee (appointed by the Minister for Health) for a declaration that explicit consent from the data subject is not required. The controller must convince the Committee that the public interest is significantly weighted in favour of proceeding with the health research over requiring the explicit consent of the data subject.

Packaging, Labelling, and Tracking

13. Outline the regulation of the packaging and labelling of medicinal products.

Legislation and Regulatory Authority

The packaging and labelling of medicinal products is regulated by the Marketing Regulations and Title V of the Code for Human Medicines Directive. A mock-up of the label text and artwork design of the outer and immediate packaging together with the package leaflet and SmPC must be submitted to the HPRA for approval as part of the MA application. Any subsequent changes must also be submitted for approval.

If there is a breach of labelling and packaging requirements, the HPRA can suspend the MA until the breach is remedied. Criminal sanctions can also apply.

Information Requirements

The packaging must contain certain information, including:

- The invented name (which must also be expressed in Braille format), strength, and pharmaceutical form (expressed in Braille where a risk of confusion occurs) of the product.
- The active substances using their international non-proprietary names or common names.
- The contents by weight, volume, or number of doses of the product.

- The method and, if necessary, route of administration.
- The expiry date (month/year).
- Any special storage or other instructions.
- A special warning that the medicinal product must be stored out of the reach and sight of children.
- The name and address of the MAH and, where applicable, its representative.
- The authorisation number and the manufacturer's batch number.
- For non-prescription medicinal products, instructions for use.

For medicinal products other than radiopharmaceuticals, the following should be included:

- Information relating to safety features enabling wholesale distributors and persons authorised to supply medicinal products to the public to verify the authenticity of the medicinal product and identify individual packs.
- A device allowing verification of whether the outer packaging has been tampered with.

Serialisation

The *Falsified Medicines Directive (2011/62/EU)*, implemented into Irish law by the *Medicinal Products (Control of Placing on the Market) (Amendment) Regulations 2013*, amends the Code for Human Medicines Directive to safeguard public health by protecting the pharmaceutical supply chain from infiltration by falsified (or counterfeit) medicines and introduces new rules to more rigorously regulate the supply chain. The main provisions of the Falsified Medicines Directive are to introduce:

- A new safety feature which must appear on the outer packaging of designated medicines.
- More robust rules on the control of starting materials and inspection of producers of active substances and excipients in medicines.
- More robust controls on the wholesale distribution of medicines, including introducing controls for the first time on entities involved in brokering medicines.
- A common, EU-wide logo to identify legal online pharmacies, and a notification system for entities offering to supply medicines to the public over the internet.

In addition to the Falsified Medicines Directive, *Commission Delegated Regulation on Safety Features ((EU) 2016/161)* supplements the Code for Human Medicines Directive, with detailed rules for the safety features appearing on the packaging of medicinal products for human use and requirements for unique identifiers and national databases or repositories.

These repositories must be set up and managed by not-for-profit organisations funded by pharmaceutical manufacturers. The Irish Medicines Verification Organisation (IMVO) has been established by the key players in the medicines supply chain in Ireland (pharmaceutical manufacturers, wholesalers, parallel distributors, and community pharmacists) to establish and manage the Irish medicines verification system.

Suppliers of pharmaceuticals in Ireland (pharmacies, hospitals, and pharmaceutical wholesalers) must connect their software systems to the IMVO repository (via an internet connection) to enable them to check that packs are genuine before they

are supplied to patients. Manufacturers add a barcode to each pack containing the unique identifiers and send details of the information in the barcode to the IMVO database via the EU hub. When the pharmacist or wholesaler scans the barcode on a pack, if the details are not found in IMVO's or the wider European database, an alert will be generated, leading to an investigation to find out if the pack is fake.

Other Conditions

A package leaflet must also be included if certain further information (including therapeutic indications, duration of treatment, and action in case of emergency) is not included on the packaging. This information must appear in English, or in both Irish and English. This information can also appear in other languages, provided that the same information is given in all of the languages used.

In addition, a form of the package information leaflet suitable for people with visual impairment must be available to the patient promptly on request, and must not be abridged in any way.

Child resistant packaging in the form of blister packs or comparable individually package dosage units may be required, depending on the medicinal product.

There are separate specific labelling requirements for homeopathic products and traditional herbal medicinal products.

Biological Medicines

14. What is the definition of biological medicines in your jurisdiction? Are there any additional or alternative regulations that apply specifically to them?

Definition of Biological Medicines

Under the Code for Human Medicines Directive, biological medicines are those medicines containing substances produced by, or extracted from, a biological source. Examples of biological medicines include the use of insulin for the treatment of diabetes, or vaccines.

Regulation of Biological Medicines

While, in principle, the regulatory framework mentioned in *Question 1* applies to biological products, in some instances, specific requirements and guidelines have been established for these products. All medicinal products for human use derived from certain biotechnology processes and other advanced technology processes must be approved by the European Commission, following an assessment by the EMA.

Medical Devices

Legislation and Regulatory Authorities

15. What are the main legislation and regulatory authorities for medical devices in your jurisdiction?

Two new EU regulations govern medical devices in the EU:

- *Regulation (EU) 2017/745 on medical devices* (MDR), applicable since 26 May 2021.
- *Regulation (EU) 2017/746 on in vitro diagnostic medical devices* (IVDR), applicable since 26 May 2022.

The HPRA is the competent authority responsible for regulating medical devices in Ireland. The National Standards Authority of Ireland (NSAI) is the notified body designated by the HPRA to carry out conformity assessment procedures to ensure compliance with medical devices legislation. The NSAI is not yet designated as a notified body for the purposes of the IVDR.

Transitional Provisions

Until recently, certificates issued by notified bodies under the previous regime would remain valid until the date of expiration, or at the latest 26 May 2024, with some minor exceptions contained in Article 120(2) of the MDR.

However, *Regulation (EU) 2023/607* entered force on 20 March 2023 and extends the transitional provisions of the MDR, based on risk classification of devices, so that certificates issued by notified bodies under the previous regime will remain valid until:

- 26 May 2026 for class III custom made devices.
- 31 December 2027 for class III and class IIb implantable devices.
- 31 December 2028 for other class IIb, class IIa, class Is, and class Im devices.

Similarly, *Regulation (EU) 2022/112* entered force in January 2022 and extended the transitional deadlines of the IVDR so that devices placed on the market in accordance with previous regime will remain valid until:

- 26 May 2025 for class D devices.
- 26 May 2026 for class C devices.
- 26 May 2027 for Class A and B devices.

Regulation (EU) 2023/607 removes the deadline under the MDR and IVDR for the "sell off" of products lawfully placed on the market under the previous regulatory regime. This means that devices already placed on the market can continue to be made available or put into service until the revised expiry of the certificate or until the shelf life of the device.

Medical Devices Definition

16. What is the definition of a medical device (or equivalent) in your jurisdiction?

A general medical device is considered to be any instrument intended to be used on human beings, either on its own or in combination, for a medical purpose (Article 2, MDR). The concept of medical purpose is construed broadly to include diagnosis, treatment, or alleviation of any disease, injury, or disability. These range from standard products, for example, plasters or bandages to more complex devices, for example, contact lenses.

Active implantable medical devices are those medical devices supported by an energy source that may be partially or wholly implanted in the human body, for example, pacemakers or ventricular assist systems and are also governed under the MDR.

In vitro diagnostic medical devices are those medical devices used to test biological samples, for example, blood or urine to assess a person's health status. The IVDR implements a broad definition to include any piece of equipment, used either on its own or in combination, for the purpose of assessing a person's predisposition to a disease, exposure to congenital physical and mental impairments, or used to assess a person's physiological state.

Classification of Medical Devices

17. Briefly outline any classification system and the main classifications of regulated medical devices.

The MDR has four main classifications, along with several sub-classifications:

- Class I (lowest risk):
    - Class Is: Class I product delivered sterile;
    - Class Im: Class I product with a measuring function; and
    - Class Ir: Class I products that are reprocessed.
- Class IIa.
- Class IIb.
- Class III (highest risk).

Factors including the degree of invasiveness, the part of the body affected, the duration of use, and whether or not the device is active are used to determine the classification. Special rules apply for certain devices, for example, contraceptives, substance-

based devices, or those which contain a medicinal product. Additionally, depending on the classification, a notified body can carry out product conformity assessments to ensure the device meets relevant safety criteria before it can be placed on the market.

The IVDR creates a classification system whereby IVDs are divided into categories based on patient and public health risks, ranging from Class A (low risk) to Class D (high risk):

- Class A: IVDs that present a low risk to patients and public health, for example, specimen receptacles, laboratory instruments, and buffer solutions.
- Class B: IVDs that are intended for self-testing which pose a lesser risk to the patient than those in Class C. It includes products such as pregnancy tests and cholesterol tests. Class B is also the catch-all category for IVDs which do not fall into another class.
- Class C: IVDs that are intended to be used to detect an infectious agent without a high risk of propagation, or to detect the presence of an infectious agent with the potential to cause death or severe disability in the case of an erroneous result.
- Class D: IVDs that detect or are exposed to life-threatening transmissible agents or transmissible agents and infectious diseases with a high risk of propagation. This includes antigen tests.

The IVDR contains seven rules which determine the classification of an IVD. Where an IVD falls into Class A, generally it can be marketed in the EU with the self-certification of its manufacturer. However, it is anticipated that the vast majority of IVDs will fall into Class B, C, or D. Where a device falls into any of these three classes, it must undergo an independent audit of its compliance with safety and performance requirements, carried out by a notified body.

Requirements to Manufacture and Market Medical Devices

18. What are the requirements to manufacture and market medical devices?

Manufacturers must comply with the obligations outlined in the MDR, IVDR, and national implementing legislation. These include:

- Implementing a system of risk management (RMS) to ensure medical devices are designed and manufactured in a way that does not compromise patient safety and complies with the MDR.
- Conducting clinical evaluations on certain classifications of products. Clinical evaluations are critical assessments of product safety based on available scientific literature and clinical investigations.
- Ensuring the performance of conformity assessments conducted by notified bodies where applicable to the classification of the medical device.
- Retaining technical documentation linked to the manufacture of custom-made devices (that is, devices prescribed by a medical professional and tailored to a specific patient's needs).

- Implementation of a quality management system (QMS) that outlines how a manufacturer is dealing with the quality of processes and procedures. Additionally, the QMS should outline the structure, responsibilities, procedures, processes, and management resources required to comply with the regulations.
- Compliance with the unique device identification (UDI) system. The UDI system facilitates the traceability of medical devices in the EU by assigning them with a unique numeric or alphabetic code. The UDI system comprises a device identifier (UDI-DI) which provides access to certificates, declaration of conformity, technical documents, and summary of safety and clinical performance. The second UDI is the production identifier (UDI-PI), which identifies the unit of device production and, where applicable, the packaged devices. The UDI is submitted to the European database on medical devices, which will be available to the public and contain information on UDIs along with information relating to the registration of economic operators and devices, certificates, clinical and performance investigations, and post-market surveillance.
- Compliance with the obligation not to use misleading labelling or packaging practices.

Manufacturers that are located outside the EU must nominate an authorised representative (AR) within the EU who will be responsible for ensuring compliance with the obligations set out in the MDR and IVDR. ARs will be responsible for ensuring, among other things, that technical documents are completed and any applicable conformity assessments are carried out by the manufacturer.

Medical devices under both the IVDR and MDR that comply with the relevant legislative requirements will be allocated a CE marking that will permit the marketing and sale of the product within the EEA. Both regulations set out obligations for both manufacturers and regulatory authorities in respect of post-market surveillance of medical devices.

19. Are there exceptions to the requirements (for example, for clinical studies, special individual patient use, custom devices, and compassionate use)?

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 that the manufacturer has discussed the proposed use of the non-CE marked device with the medical/surgical consultant intending to use it and has 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. 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.

20. Are there fewer or different requirements for medical devices that have already been licensed or approved in another jurisdiction?

Medical devices that are authorised in other jurisdictions must obtain a CE marking certification and be in conformity with all relevant legal and regulatory requirements.

21. What are the main requirements to import medical devices from or export medical devices to other jurisdictions?

CE marked devices can be freely marketed anywhere in the EU, provided the requirements of the relevant medical devices regulations are met.

If a device will be exported outside the EU, it is necessary to apply to the HPRA for a certificate of free sale.

Non-EU based manufactures 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 UDI where applicable in accordance with the relevant medical devices regulation.

Health Care IT

22. Is there any specific regulation of medical software, health care IT, or e-health products (such as mobile health apps)?

The MDR applies to mobile medical apps. Standalone software (including apps) may be considered a medical device if it is intended for a medical purpose meeting the definition of a medical device, as defined in the MDR.

Of particular importance to manufacturers in this area is Ireland's data protection legislation, namely the DPA and, where health research is being conducted, the Data Protection Act 2018 (section 36(2) (Health Research) Regulations 2018. Operators in the health care sector must be particularly vigilant with respect to the data they collect, process, and maintain, given its sensitive nature. The GDPR has overhauled the EU data protection regime, and has implications for the processing of personal data, including sensitive health data by health care operators (see *Question 12*).

The *Health Identifiers Act 2014* provides the legal basis for the introduction of unique health identifiers for health service users, and also unique identifiers for health service providers to be used across the Irish health service. The Act has also established the National Register of Individual Health Identifiers.

Combination Products and Borderlines

23. Does your jurisdiction recognise combination products? Are there any additional or alternative regulations that apply specifically to them?

Combination products are recognised in Ireland, and their regulatory treatment will depend on the mode of use and functionality. As a general rule, a combination product can be regulated under medical devices or medicinal product legislation. The MA and the conformity assessment procedures do not apply cumulatively. For certain defined features, however, some cross-references are made within one regime to specific provisions of the other regime.

Borderlines

24. What product type determinations are relevant and are there specific mechanisms for determining which regulatory regime applies to a borderline product?

In all cases, determining the applicable legal framework depends on the mode of action and functionality of both the medical device and medicinal product. For example, a drug delivery product involving a device intended to administer a medicinal product, where the device and the medicinal product form a single integral product intended exclusively for use in the given combination and is not reusable is governed by the medicinal products legislation. However, the relevant essential requirements of the medical device legislation apply to the safety and performance-related device features.

Alternatively, medical devices incorporating, as an integral part, a medicinal substance which, if used separately, may be considered to be a medicinal product, are assessed and authorised under the medical devices legislation.

Combination products may be subject to high levels of compliance assessment. Similar to all medical devices, these devices must bear a CE mark, following the conduct of a positive conformity assessment procedure. During this, where required, the NSAI audits the conformity of the medical device and the manufacturer with the relevant requirements of the medical devices legislation. The specific procedure to affix the CE mark depends on the classification of the medical device.

Natural Health Products

25. Is there a separate regulatory regime for natural health products (or equivalent) (for example, traditional medicines, homeopathic medicines, supplements, vitamins, and minerals)?

Natural health products are regulated under several regimes in Ireland:

- Herbal medicines and homeopathic medicines are regulated as medicinal products.
- Supplements, vitamins, and minerals are considered as food supplements and regulated under food legislation.

26. Which authorities regulate the manufacture and marketing of natural health products?

The HPRA regulates the manufacturing and marketing of homeopathic and herbal medicines.

The Food Standards Authority Ireland (FSAI) regulates the manufacture and marketing of health supplements, vitamins, and minerals. The *European Communities (Food Supplements) Regulations 2007* (Food Supplement Regulations) define food supplements as "foodstuffs the purpose of which is to supplement the normal diet and which are concentrated sources of nutrients or other substances with a nutritional or physiological effect, alone or in combination, marketed in dose form, namely forms such as capsules, pastilles, tablets, pills and other similar forms, sachets of powder, ampoules of liquids, drop dispensing bottles, and other similar forms of liquids and powders designed to be taken in measured small unit quantities."

27. What notifications, registrations, approvals, and licences are required to manufacture and market natural health products?

Manufacturing

The main requirements under the Manufacturing Regulations also apply to herbal and homeopathic medicines. However, these products are subject to separate registration/licensing regimes, as set out below.

Schedule 2 of the Food Supplements Regulations list the vitamins and minerals and their chemical forms permitted for use in the manufacture of food supplements.

Marketing

The Marketing Regulations provide for a herbal medicine registration scheme. Where herbal medicines are suitable for use without medical supervision, rather than obtaining a full MA from the HPRA (see *Question 4*), a simplified registration scheme is available.

The simplified registration procedure, also known as traditional-use registration, requires the applicant to apply in writing to the HPRA. The details of the documents required to be submitted include, for example, a summary of product characteristics, summaries of the dossier, and quality data. The application must be made electronically using the EU electronic application form. Notably, the applicant must show that the product has been in medicinal use for at least 30 years in order to be classified as a traditional use medicine. This must be proven with bibliographic or expert evidence. Alternatively, applicants must show that the medicinal product complies with an EU listed entry.

Further information on the herbal medicines regime is on the *HPRA website*.

Homeopathic medicines must be licensed by the HPRA before being placed on the market (see *Question 4*). Two registration schemes apply, depending on whether the product has indications.

Further information on the homeopathic medicines regime is on the *HPRA website*.

There is an obligation to notify the FSAI when placing a vitamin, mineral, or supplement on the Irish market for the first time but an MA is not required.

28. Are there fewer or different requirements for natural health products that have already been licensed or approved in another jurisdiction?

For herbal and homeopathic medicines, the medicinal products regulatory regime applies (see *Question 1*).

For vitamins, supplements, and minerals, provided the product falls within the legislative definition (see *Question 26*), the Food Supplement Regulations regulatory regime applies.

29. Is it possible to sell natural health products to or buy natural health products from other jurisdictions?

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:

- Parallel product authorisation (PPA). This is required where the product being imported differs in any respect from those on the Irish market.

- Dual pack import registration (DPR). This is required where the product being imported is identical in all respects (including identical packaging, labels, and leaflets) to those on the Irish market.

For the export of herbal and homeopathic medicines, the HPRA can issue the following export certificates:

- Certificate of a pharmaceutical product.
- GMP certificate for manufacturers of finished products or active ingredients.
- Certificate of free sale.
- Certificate of manufacture and free sale.
- Price certificate.

To the extent that any vitamins, mineral, or food supplements fall within the medicinal products regime, the same requirements will apply.

Recent Developments and Reform Proposals

30. Have there been any significant recent developments or proposals for reform?

The most significant recent development was the implementation of the CTR that came into effect in 2022 (see *Question 2*) and the revised transitional periods for the implementation of the MDR and IVDR (see *Question 15*).

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- Advising a wide range of pharmaceutical, medical device, and healthcare companies on competition law issues.
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- 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.

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- 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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