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Colin Kavanagh, Joanelle O'Cleirigh, Olivia Mullooly and Bridget McGrath
Arthur Cox

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IRELAND

Law and Practice

Contributed by:
Colin Kavanagh, Joanelle O'Cleirigh, Olivia Mullooly and Bridget McGrath
Arthur Cox see p.20

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1. Regulatory Framework

1.1 Legislation and Regulation

The regulatory framework for pharmaceuticals 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 SI 540/2007 (as amended) (Marketing Regulations).

The regulatory framework for medical devices in Ireland is based on the following directives that have been transposed into Irish law: Directive 93/42/EEC concerning medical devices, Directive 90/385/EEC on active implantable medical devices (as amended) and Directive 98/79/EC on in vitro diagnostic medical devices (the IVD Directive) (as amended). National legislation transposing those Directives (as amended) include the European Communities (Medical Devices) Regulations 1994 (as amended in 2001, 2002 and 2009), the European Communities (Active Implantable Medical Devices) Regulations 1994 (as amended in 2009), the European Communities (In Vitro Diagnostic Medical Devices) Regulations 2001 (as amended in 2012), the European Communities (Medical Devices) (Reclassification of Breast Implants) Regulations 2003, the European Communities (Medical Devices) (Tissues of Animal Origin) Regulations 2003 and the European Communities (Medical Devices) (Reclassification of Hip, Knee and Shoulder Joint Replacements) (Amendment) Regulations 2007, (collectively, the Medical Devices Legislation).

The Health Products Regulatory Authority (HPRA; formerly the IMB) is the Competent Authority responsible for regulating medicinal products, medical devices, cosmetics and other health products in Ireland. The National Standards Authority of Ireland (NSAI) is the Notified Body in Ireland designated by the HPRA to carry out conformity assessment procedures to ensure compliance with the Medical Devices Legislation.

1.2 Challenging Decisions of Regulatory Bodies

Other than in respect of appeal procedures set out in the relevant legislation, decisions of the HPRA, the NSAI, the FSAI or other regulatory bodies may be challenged by way of judicial review to the Irish High Court. In order to bring Judicial Review proceedings, an ex parte application (not on notice to the decision-making body) is made to the High Court for leave, ie, permission to challenge the relevant decision.

An application for leave must be made promptly and in any event within three months from the date when grounds for the application first arose. In the event that leave is granted, the proceedings are served on the relevant public body and they are given an opportunity to defend the matter. When leave is granted by the High Court, the substantive hearing can take place.

Judicial review of a decision of a public body is not an appeal process and the High Court does not substitute its opinion for that of the public authority. The High Court is concerned with how the decision was made rather than whether it was the correct decision to begin with.

1.3 Different Categories

Pharmaceuticals

Pharmaceuticals are generally categorised as either prescription-only or non-prescription products. Prescription-only products are further divided into:

- products for non-renewable supply; and
- products for renewable supply.

Non-prescription products are divided into:

- products which may only be sold from a pharmacy under the supervision of a registered pharmacist; and
- products that may be placed on general sale and therefore without the supervision of a registered pharmacist.

Medical Devices

The classification of medical devices in Ireland is regulated by Directive 93/42/EEC (the Directive) and the Irish implementing legislation, the European Communities (Medical Devices) Regulations 1994 (S.I. No 252 of 1994) (the Regulations).

Medical devices are grouped into different classes under the Directive and Regulations, depending on their perceived risk:

- Class I – Low Risk;
- Class IIa – Medium Risk;
- Class IIb – Higher Risk; and
- Class III – Highest Risk.

2. Clinical Trials

2.1 Regulation of Clinical Trials

Pharmaceuticals

Clinical trials in Ireland are regulated by the European Communities (Clinical Trials on Medicinal Products for Human Use) Regulations 2004 to 2009 (Clinical Trial Regulations), which implement Directive 2001/20/EC on the conduct of clinical trials (Clinical Trials Directive) and Directive 2005/28/EC on good clinical practice for medicinal products for human use (GCP Directive).

The Clinical Trial Regulations apply to clinical trials conducted in human subjects and involving investigational medicinal products (IMP). In April 2014, the new Clinical Trials Regulation (Regulation No 536/2014) was adopted and entered into force on 16 June 2014. However, the timing of its full application depends on the EU Database and single online EU Portal created under the new Regulation being fully functional. Clinical trials will, however, continue to be conducted in accordance with the Clinical Trials Directive (Directive 2001/20/EC) until the new regulation becomes applicable.

Medical Devices
There are two principal pieces of legislation which relate to the conduct of clinical investigations on medical devices in Ireland:

- SI 252 of 1994 (Article 15, Annexes I, VIII, Annex X) which transposes Council Directive 93/42/EEC of 14 June 1993 concerning medical devices; and
- SI 253 of 1994 which transposes Council Directive 90/385/EEC on the approximation of the laws of the Member States relating to active implantable medical devices (hereafter both referred to as the "Applicable Laws").

Clinical assessments may be required before non-CE (Conformité Européenne) marked medical devices enter the Irish market. For any clinical investigation to commence in Ireland, approval from the HPRA is required, with a positive opinion of an ethics committee. Note that certain clinical investigations, such as those using CE-marked devices within their intended purpose, may not require a review by the HPRA. This must be assessed on a case-by-case basis.

2.2 Procedure for Securing Authorisation

Pharmaceuticals
The European Communities (Clinical Trials on Medicinal Products for Human Use) Regulations, 2004, SI No 190 of 2004 as amended by SI 878 of 2004, SI 374 of 2006 and SI 1 of 2009 (the Regulations) govern the procedure for securing authorisation to undertake a clinical trial. The Regulations also implement the Good Clinical Practice (GCP) Directive which governs the standards for GCP.

The conduct of a clinical trial is subject to an authorisation by the HPRA and a favourable opinion from the relevant Ethics Committee. The Sponsor must not commence the clinical trial without obtaining approval from the HPRA and the positive opinion from the Ethics Committee. Before an application may be submitted by the Sponsor to the HPRA for authorisation, the Sponsor must obtain a EudraCT number through the EudraCT data site. A request for authorisation to conduct a clinical trial must (i) be in writing and signed by or on behalf of the Sponsor and (ii) where relevant, be accompanied by the relevant documentation and fee.

Medical Devices
As previously described in **1.1 Legislation and Regulation**, for any clinical investigation to commence in Ireland, approval from the HPRA is required, with a positive opinion of an ethics committee. Applications are typically submitted by a commercial sponsor, such as a medical device manufacturer. By this application, the manufacturer is proposing to conduct an investigation to gather the necessary clinical data to demonstrate the basic safety and performance of their device.

The requirements governing the conduct of clinical investigations are set out in Directive 93/42/EEC and in the IVD Directive, domestic implementing regulations as specified in **1.1 Legislation and Regulation**, as well as various Commission guidance documents (MEDDEVs) and international standards. The HPRA reviews the regulatory, technical and clinical aspects of the application. The HPRA reviews applications to conduct clinical investigations in Ireland in parallel with the appropriate ethics committee review. An initial decision will be issued within 30 days of the application being made, and the final decision will be provided by the HPRA within 60 days of the application.

European Standard ISO 14155:2011, a harmonising standard which addresses GCP for the design, conduct, recording and reporting of clinical investigations carried out in human subjects to assess the safety or performance of medical devices for regulatory purposes (the ISO 14155: 2011 Standards) and the Declaration adopted by the 18th World Medical Assembly in Helsinki, Finland, in 1964 (as amended) (Declaration of Helsinki), are also relevant.

2.3 Public Availability of Databases

Under the provisions of the Declaration of Helsinki, every research study involving human subjects must be registered in a publicly accessible database before recruitment of the first subject. Researchers, authors, sponsors, editors and publishers all have ethical obligations with regard to the publication and dissemination of the results of research. In particular, researchers have a duty to make publicly available the results of their research on human subjects and are accountable for the completeness and accuracy of their reports. All parties should adhere to accepted guidelines for ethical reporting. Negative and inconclusive as well as positive results must be published or otherwise made publicly available.

An applicant is not required to provide the results of pre-clinical and clinical trials if it can demonstrate 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).

2.4 Restriction for Using Online Tools

All processing must be conducted in accordance with the requirements of the GDPR (eg, processing of special categories of personal data, security requirements, use of third-party processors and the required provisions of contracts with such processors).

Under the provisions of the Data Protection Act 2018 (Section 36(2)) (Health Research) Regulations 2018 (2018 Regulations), which came into force on 8 August 2018, mandatory suitable and specific measures are outlined, protecting the rights of participants, while at the same time promoting and facilitating the conduct of high-quality research in the public interest. The 2018 Regulations also introduce a mechanism which allows for the processing of personal data for health research purposes in exceptional circumstances without the explicit consent of the individual concerned.

Article 28(1) of the GDPR, which provides that where processing is to be carried out on behalf of a controller, the controller shall use only processors providing sufficient guarantees to implement appropriate technical and organisation measures, in such a manner as to ensure that the processing will meet the requirements of the Regulation and ensure the protection of the rights of the data subject.

2.5 Use of Resulting Data

Under Article 9 of the GDPR, data concerning health, biometric and genetic data are considered "special categories" of data.

The data subjects must be made aware of this in accordance with the transparency requirements under Articles 5(1), 13 and 14 of the GDPR. Personal data must be processed lawfully, fairly and in a transparent manner. Data subjects should be informed that their data will be transferred to third parties and ensure there is an appropriate legal basis for the disclosure (eg, explicit consent if required).

Transfers outside the EEA may take place on the basis of an adequacy decision from the European Commission, or where Standard Contractual Clauses or Binding Corporate Rules are in place. There are a number of other derogations for specific situations that allow data transfers even in the absence of appropriate safeguards, for instance if the data subject provides explicit consent, for the performance of a contract, for the exercise of legal claims or for important reasons of public interest

2.6 Further Requirements for the Creation of a Database

As with all processing, there should be consideration of whether a data protection impact assessment is required, noting that such an assessment is required where the processing is likely to result in a high risk to the individuals. All processing of personal data must be done in accordance with the requirements of the GDPR.

Specific rules apply for the processing of special categories of data. Under Article 9(2)(i) of the GDPR, the processing of special categories of data for reasons of public interest in the area of public health is subject to the implementation of suitable and specific measures. Processing for the purposes of scientific research that involves the processing of special categories of data, such as health information, must be i) proportionate to the aim pursued; ii) respect the essence of the right to data protection; and iii) provide for "suitable and specific measures" to protect the fundamental rights and interests of the data subject. The 2018 Regulations outline a list of suitable and specific measures which must be adopted.

3. Marketing Authorisations

3.1 Assessment Process and Criteria

In order to distinguish between pharmaceuticals and medical devices, it is necessary to consider:

- the intended use of the product as assigned by the manufacturer; and
- the demonstrated mode of action by which the intended use is achieved.

Pharmaceuticals

Typically, the classification of a product as a pharmaceutical is clear in that the nature of the substance, its effects on the body, the indications for use/contraindications, its presentation and the manner of marketing are consistent with the definition of the Directives regarding medicinal products, which are set out in **1.3 Different Categories**.

Products for which medicinal claims are made or which contain substances likely to have effects on the body are considered as medicines, and therefore, require a marketing authorisation from the Competent Authority. In Ireland, a national application for a marketing authorisation, ie, an application submitted locally, goes to the HPRA. The marketing authorisation is issued with a Product Authorisation (PA) number which is included on the medicine packaging.

The HPRA are responsible for making classification decisions. The applicant must provide all relevant information with regard to the product, its intended usage and promotional materials to the HPRA. This includes not only labels, leaflets and all advertising materials but also any websites linked to that literature. In the event that the HPRA determines that the product could potentially be a medicinal or other product, the product may be referred to the HPRA Classification Committee, which meets once a month and is responsible for assessing products for which classification is not obvious, including those that are borderline medical devices or medicinal products. Alternatively, classification requests for borderline products may be sent directly to the Classification Committee as opposed to being referred by the HPRA.

Decisions made by the Classification Committee can be appealed to the HPRA Management Committee, which may request the advice of the Advisory Committee on Human Medicines (ACHM) set up under the IMB Act. The decision of the Management Committee is final.

Medical Devices
For a product to be classified as a medical device it must have an intended medical purpose and act primarily by physical means. Medical devices can be considered as Class I (lowest risk), IIa, IIb or III (highest risk).

Factors such as the invasiveness, the part of the body affected, and the duration of use all affect classification. Similarly, in vitro diagnostic devices can be divided into as general category (low risk), List B and List A (high risk). Regulatory requirements (such as registration and route to CE marking) are heavily reliant on the classification of a device.

A manufacturer is responsible for the classification of their product. However, in certain situations it may be difficult to determine if a product qualifies as a medical device and, if so, which class it falls under. In this case, an application for classification may be submitted to the HPRA, together with the relevant fee can be made to the HPRA. The outcome of a formal classification request is generally available within 30 days, and there is an associated fee.

3.2 Granting a Marketing Authorisation

The approval process for originator biologics involves many phases of controlled clinical trials. In terms of biosimilars, the approval process also involves clinical trials for at least one indication of the already licensed reference biologic medicine. All other indications are then considered for approval by extrapolation. In addition to clinical trials, quality, efficacy, patient safety and other factors will be investigated before a biosimilar is authorised. Most biosimilars are approved centrally by the European Medicines Agency (EMA) and only some biosimilars may be approved at national level.

3.3 Period of Validity

Pharmaceuticals
Marketing authorisations are valid for five years from the date of first issue. For the authorisation to remain valid, it should be renewed at the end of this five-year period. Following this renewal, the authorisation remains valid for an indefinite period (unless further renewals are deemed necessary by the HPRA on drug-safety grounds).

Renewal applications should be submitted to the HPRA at least nine months before the expiry of the authorisation, although earlier renewals are acceptable in order to facilitate a common renewal date for a range of products or for products within the Mutual Recognition procedure which may have been authorised at different times in different Member States (the common renewal date should be agreed with the Reference Member State).

An application for authorisation of a generic of a medicinal product or similar biological product can be made to the HPRA eight years after authorisation of the reference product (ie, 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 Community MA, the period is reduced to six years.

Once authorised, a generic or similar biological product cannot be placed on the market for ten years (depending on the exclusivity period available for the reference medicinal 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 in comparison to existing therapies.

Withdrawal of an authorisation/certificate may occur during the period of validity of the authorisation or certificate or on renewal, when the holder may decide not to renew it. In each case, the HPRA should be notified of the intention to withdraw.

Medical Devices
A CE mark remains valid until the specifications of the medical device change, in which case, a renewed conformity assessment will be required.

3.4 Procedure for Obtaining a Marketing Authorisation

Pharmaceuticals

The applicant for an MA must be established in an EEA state. Applications (whether to 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; and
- 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 (i) include a list of all of the Concerned Member States and (ii) confirm that the dossier, the SmPC, package leaflet and labelling are identical in each of the Member States involved.

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 is required to process an application for an MA within 210 days from the 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.

Paediatric Population

The Paediatric Regulation 1901/2006, as amended, is directly applicable in Ireland. An applicant may therefore be required to conduct paediatric clinical trials, or to obtain a waiver from this requirement in accordance with Chapter 2 of Regulation 1901/2006.

Variation

After a medicine has been authorised, the terms of the marketing authorisation may subsequently be varied. The procedures around such variations are governed and harmonised throughout the EU by Commission Regulation (EC) No 1234/2008 of 24 November 2008 (the Variations Regulation), which has subsequently been amended by Regulation (EU) 712/2012. Regulation (EU) 712/2012 extends the scope of the Variations Regulation to all marketing authorisations, human and veterinary, whether granted through national, mutual recognition, decentralised or centralised procedures.

Transfer

An MA may be transferred from the existing authorisation or licence-holder to another holder using a transfer procedure. A transfer may 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 receipt of a valid application by the HPRA. Products can be transferred either before authorisation or once authorised. Transfer applications are subject to the national procedure, even if the product has been authorised via the mutual recognition procedure.

Medical Devices

As described above, a CE mark is required in order to place medical devices on the Irish market. Medical devices carrying the CE mark may be freely marketed anywhere in the EEA. Clinical assessments are usually required before non-CE marked medical devices may enter the Irish market. For any clinical investigation to commence in Ireland, approval from the HPRA is required, with a positive opinion of an ethics committee. Certain clinical investigations, such as those using CE-marked devices within their intended purpose, may not require a review by the HPRA. This must be assessed on a case-by-case basis.

Paediatric Population

There is no requirement to conduct clinical assessments of use of the medical device on the paediatric population in order to obtain a CE mark.

Variation

A conformity assessment must be renewed if there is any update or amendment to a device specification, method of manufacture or intended use. The device manufacturer is responsible for submitting a renewed conformity assessment.

Transfer

If ownership of a medical device is transferred to a new entity, that new entity becomes the legal manufacturer of the medical device and is responsible for the medical device's compliance with the CE mark. A change in legal manufacturer should be notified to the relevant Notified Body, depending on the class of medical device.

3.5 Access to Unauthorised Products

Pharmaceuticals

Named-patient programmes

Regulation 2 of Schedule 1 of the Marketing Regulations regulates named-patient programmes in Ireland. Under the Marketing Regulations, a named-patient programme permits the sale or supply of an unauthorised product in response to a bona fide unsolicited order, formulated in accordance with the specifications of a practitioner for use by his or her individual patients on his or her direct personal responsibility, to fulfil the special needs of those patients.

To make use of the programme, the following conditions must be satisfied:

- receipt of an unsolicited order from a registered healthcare professional (HCP);
- the product must be supplied to the order or prescription of the requesting HCP;
- the product is only provided to the HCP's individual patient; and
- the provision of the product is supervised under the direct personal responsibility of the HCP.

There is no formal authorisation for establishing a named-patient programme in Ireland.

Compassionate use

Medicinal products for use in an authorised clinical trial are exempt from the requirement to be subject to an MA. The HPRA does recognise the option of an Expanded Access Programme (EAP) for patients who have been treated with a medicinal product during a clinical trial and wish to continue treatment after the trial is completed. If, however, the EAP fulfils the definition of a clinical trial, it is required to be authorised as such under the applicable Irish legislation. In the event that it does not fulfil the definition of a clinical trial, the medicinal product can only be supplied via a named-patient programme. This essentially means that EAPs for groups of patients at a time are only recognised in Ireland if they are authorised as clinical trials and meet all applicable legislation governing clinical trials.

Medical Devices

The CE marking does not have to be present on medical devices intended for clinical investigations, custom-made devices and in vitro diagnostic medical devices for performance evaluation. The CE marking does not have to be present on medical devices intended for exhibitions, demonstrations, trade fairs, etc. However, these devices must bear a visible marking indicating that they are not intended to be marketed or put into use.

3.6 Ongoing Obligations

Pharmaceuticals

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 concerning pharmacovigilance of medicinal products for human use, and the Code for Human Medicines Directive, as amended by Directive 2010/84/EU. This framework was updated in 2010 by Directive 2012/26/EU and Regulation (EU) No 2012/1027/EU. This updated EU legislation has been transposed in Ireland, in respect of human medicines, by the Medicinal Products (Control of Placing on the Market) (Amendment) Regulations SI 272/2012 and SI 151/2014. In addition, detailed guidance in the form of a number of good pharmacovigilance practice (GVP) modules to facilitate the performance of pharmacovigilance in the EU are available.

In accordance with 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 EU 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 in respect of which an MA has been 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 date is the earlier; and
- operate, and keep updated, a risk-management system for medicinal products in respect of which an MA has been granted on or after 21 July 2012 or, if granted before 21 July 2012, where required by the HPRA.

A post-authorisation safety study (PASS) is defined in Article 1(15) of the Code for Human Medicines Directive as any study relating to an authorised medicinal product conducted with the aim of identifying, characterising or quantifying a safety hazard, confirming the safety profile of the medicinal product, or of measuring the effectiveness of risk-management measures. A PASS may be interventional or non-interventional studies.

Interventional PASSs are clinical trials and are subject to the requirements of Directive 2001/20/EC. The GVP module VIII provides comprehensive guidance on non-interventional PASSs conducted by a MAH, either voluntarily or pursuant to an obligation imposed by a competent authority.

Medical Devices
The medical device vigilance system was established under the Medical Device Directive in order to minimise patient and user safety risks.

In Ireland, the medical device vigilance system operates as follows:

- manufacturers and users submit vigilance reports to the HPRA;
- the HPRA evaluates reported incidents;
- information flowing from these reports is gathered and disseminated; and
- medical devices are updated, modified or recalled from the market in cases where it is necessary to do so.

There is a mandatory requirement for manufacturers to report vigilance issues to the HPRA as outlined in MEDDEV 2.12-1. In relation to user reporting, the HPRA operates a system whereby a user, healthcare professional or any other person who identifies a medical device safety issue can report it to the HPRA.

3.7 Third-Party Access to Pending Applications

Pharmaceuticals
At present, third parties cannot access information about pending applications for marketing authorisations in Ireland. If a marketing authorisation has already been granted, or if it has been refused, it is open to a third party to submit a Freedom of Information (FOI) request to the HPRA under the Freedom of Information Act 2014 to access certain records. However, there are several bases in the Act upon which a public body can rely in refusing to release information. One such basis is the disclosure of commercially confidential information.

Medical Devices
As for pharmaceuticals, a third party may submit an application for access to information to the NSAI under the FOI Act 2014.

Eudamed, the European Database for Medical Devices, which is only accessible by Competent Authorities and the European Commission, contains data on medical devices that have been entered by Competent Authorities and the European Commission, including data on authorised representatives, certifications, information on any modifications, suspensions or withdrawals of certifications and data relating to the medical device vigilance system.

3.8 Rules Against Illegal Medicines and/or Medical Devices

The European Union Falsified Medicines Directive, implemented into Irish law by the Medicinal Products (Control of Placing on the Market) (Amendment) Regulations 2013 (S.I. No 162/2013), 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 regulate the supply chain more rigorously. 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;
- to introduce more robust rules regarding the control on starting materials and inspection of producers of active substances and excipients contained in medicines;
- to introduce more robust controls on the wholesale distribution of medicines, including introducing controls for the first time on entities involved in brokering medicines; and
- to introduce a common, EU-wide logo to identify legal online pharmacies and to establish a notification system for entities offering to supply medicines to the public over the internet.

In addition to the Falsified Medicines Directive, the Commission Delegated Regulation (EU) 2016/161, that 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", was adopted in 2016 and has applied in Ireland since 9 February 2019.

The repositories referred in Commission Delegated Regulation (EU) 2016/161 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.

3.9 Border Measures

Pharmaceuticals
The HPRA, the Irish Revenue Commissioner's Customs Service and An Garda Síochána, the Irish national police force, monitor the Irish market for the importation and online sale of counterfeit and illegal medicines. The HPRA uses a range of enforcement powers to tackle this activity, including seizing products and taking prosecutions.

The HPRA, the Irish Revenue Commissioner's Customs Service and An Garda Síochána, took part in Operation Pangea, which is an international week that targets the sale of falsified medicines online.

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

4. Manufacturing of Pharmaceutical and Medical Devices

4.1 Manufacturing Plants

Pharmaceuticals
Manufacturing is regulated by the Medicinal Products (Control of Manufacture) Regulations 2007 (as amended).

Manufacturers of pharmaceuticals in Ireland are required to hold a manufacturer's authorisation if a company is involved in any of the following manufacturing activities:

- processing of a dosage form;
- primary packaging;
- secondary packaging;
- batch certification; and
- importation of medicinal products from a third country and/or quality control testing.

Marketing authorisations are valid for five years from the date of first issue. For the authorisation to remain valid, it should be renewed at the end of this five-year period. Following this renewal, the authorisation remains valid for an indefinite period (unless further renewals are deemed necessary by the HPRA on drug safety grounds).

The manufacture and importation of medicinal products is subject to the holding of a manufacturing import authorisation (MIA). To obtain an MIA, an application is made to the HPRA. The manufacturer is required to provide certain documentation as part of the application that will be verified for accuracy by the HPRA, which may include an inspection of the site where the activities take place. There is no restriction on foreign applicants applying for an MIA. However, the HPRA only issues manufacturing authorisations for Irish manufacturing or importation sites. Applications must be granted or refused by the HPRA within 90 days.

The requirements governing the information to be submitted as part of the application and those required to ensure the validity of the authorisation (eg, a qualified person and the principles of GMP) are discussed in the European Union chapter.

Medical Devices
The Medical Device Regulations require that certain persons placing devices on the market must register their contact details and details of their devices with the HPRA. This requirement applies if that person has a registered place of business in Ireland and if that person:

- manufactures Class I or custom-made medical devices and places them on the market under his or her own name or trading name;
- manufactures custom-made, active, implantable medical devices and places them on the market under his or her own name or trading name;
- manufactures in vitro diagnostic medical devices and places them on the market under his or her own name or trading name;
- fully refurbishes Class I devices or labels one or more ready-made devices, with a view to placing these on the market under his or her own name;
- places medical devices bearing the CE marking on the market, in a system or a procedure pack;
- sterilises, for the purpose of placing on the market, systems or procedure packs or other CE-marked medical devices designed by the manufacturers to be sterilised before use; or
- is the designated European authorised representative for a manufacturer that does not have a registered place of business in the European community, and that places on the market devices within the above-listed categories.

5. Distribution of Pharmaceutical and Medical Devices

5.1 Wholesale of Pharmaceutical and Medical Devices

Pharmaceuticals
A Wholesale Distribution Authorisation (WDA) issued by the HPRA is required in order 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 to 2013, Code for Human Medicines Directive (as amended) and guidelines issued by the HPRA. The HPRA has emphasised that the definition of wholesaling includes reference to procurement and supply, both of which may not necessarily involve the physical handling of medicines and may only relate to financial transactions carried out at an office (eg, purchasing medicinal products from the manufacturer and selling them on to the primary wholesaler or outsourcing the storage of medicinal product on a consignment basis to a wholesaler).

The purpose of authorisation of wholesalers is to ensure that the standards of medicinal product quality, safety and traceability that exist within the manufacturing sector are also maintained within the distribution chain. In order 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 (a maximum of 90 days) and a possible inspection.

Medical Devices
Distributors of medical devices are not required to obtain an authorisation to engage in wholesale trade. Distributors with a registered place of business in Ireland should, however, register with the HPRA to be listed on the Register of Medical Device Economic Operators by completing an online form. Annual registration fees are based on annual turnover. Ideally, registration is effected prior to engaging in distribution activities.

5.2 Different Classifications
Pharmaceuticals
Activities which are approved are the distribution to consumers of drugs which require a prescription, and those which may be sold without a prescription. Prescription-only drugs can be further sub-divided into two sub-categories: i) drugs for non-renewable supply; and ii) drugs for renewable supply. Non-prescription drugs can also be further subdivided into: i) drugs which may only be sold from a pharmacy under the supervision of a registered pharmacist, and ii) drugs that may be placed on general sale and therefore without the supervision of a registered pharmacist.

6. Import and Export of Pharmaceuticals and Medical Devices

6.1 Governing Law and Enforcement Bodies
Pharmaceuticals
The Irish rules governing the import and export of medicinal products and medical devices generally reflect those at EU level.

As previously set out, an MIA is required for the importation of medicinal products from outside the EEA into Ireland.

In order to export pharmaceuticals, there must be a "qualified person" for batch release, who ensures that each batch complies with the Code for Human Medicines Directive, as implemented in Ireland by the Medicinal Products (Control of Manufacture) Regulations 2007 (S.I. No 539/2007), the GMP, the manufacturer's authorisation and the MA or equivalent. The qualified person must be nominated by the applicant. Each applicant must give a written undertaking to comply with the conditions of the authorisation, if granted.

Medicinal products may only be exported by authorised manufacturers or distributors who have obtained an MIA for these export activities.

Medical Devices
As previously noted, the Irish rules governing the import and export of medical devices generally reflect those at EU level. A Manufacturer, Authorised Representative or Legal Manufacturer may apply for a certificate of free sale provided they are located in Ireland.

The content of each certificate will vary, depending on whether the devices are CE-marked or non-CE-marked and whether the applicant is a manufacturer, authorised representative or legal manufacturer. Certificates of free sale have a validity period of five years from the date of issue. However, it is important to note that where a certificate of free sale has been issued and where device registration is not continued, for whatever reason, the potential remains for the free sale certificate to be used in non-EU markets up to its expiry date. It is the responsibility of the organisation to which the certificate is issued to have in place a system to withdraw from circulation certificates which list such devices.

The Revenue Commissioners in Ireland are responsible for applying and enforcing import regulations at the point of entry.

6.2 Importer of Record
Pharmaceuticals
Either the importer appointed by the marketing authorisation-holder of the product on the Irish market or any person or entity that imports medicinal products into Ireland from a third country and is the holder of a MIA can act as the importer of record. Businesses that are established in the EU, actively involved in customs operations and international trade and have an Economic Operator Registration and Identification (EORI) number may register with the Revenue Commissioners of Ireland as Authorised Economic Operators (AEO). Companies that meet the requirements may take advantage of simplified customs procedures for the security and safety of their imports in transit. This is therefore preferable when acting as the importer of record.

Medical Devices
As with pharmaceuticals, for customs purposes, AEOs are subject to simplified procedures on the basis of meeting specific criteria. On the basis of Article 39 of the Union Customs Code (UCC), the AEO status can be granted to any economic operator meeting the following common criteria:

- compliance with customs' legislation and taxation rules and absence of criminal offences related to the economic activity;
- appropriate record-keeping;
- financial solvency;
- proven practical standards of competence or professional qualifications, and appropriate security and safety measures.

The AEO status granted by one Member State is recognised by the customs authorities in all Member States (Article 38 (4) UCC).

6.3 Prior Authorisations

Pharmaceuticals

Parallel-importation is the importation from within the EU or EEA of a medicinal product which is essentially similar to a product already authorised in Ireland, by an importer who is someone other than the importer appointed by the marketing authorisation-holder of the product on the Irish market. The parallel trade of medicinal products is based on the principle of the free movement of goods within the internal market of the EU (Articles 28-30 of the EC Treaty).

The HPRA grants authorisations for parallel-imported products pursuant to the general framework set out in the European Commission Communication on Parallel Imports of Proprietary Medicinal Products for which Marketing Authorisations have already been granted. Once an authorisation is obtained from the HPRA, the imported product may then be parallel-distributed in Ireland. A parallel product authorisation is identified by the letters "PPA" in front of the authorisation number.

Where the product to be imported is identical in all respects (including identical packaging, labels and leaflets) to the product on the Irish market, the reduced requirements of the Dual Pack Registration (DPR) scheme apply.

Medical Devices

Importers of medical devices from outside the EU are not required to obtain an import authorisation, but will instead become legally responsible under the medical devices legislation for those devices. They may choose either to sell under the name of the actual manufacturer as its local authorised representative, or to sell under the importer's name (but will then require agreement with the actual manufacturer to ensure access to the technical documentation relating to the CE marking).

6.4 Non-tariff Regulations and Restrictions

A common customs tariff is charged across all EU countries on goods imported from outside the EU. An importer or exporter is responsible for the correct tariff classification of goods.

6.5 Provisions on Trade/Regulatory Facilitation

Ireland participates in the free trade arrangements of the EU and European Free Trade Association (EFTA), and is a member of the World Trade Organization (WTO).

7. Pharmaceutical and Medical Device Pricing and Reimbursement

7.1 Price Control

Pharmaceuticals

The Health (Pricing and Supply of Medical Goods) Act 2013 (as amended) (the 2013 Act) and the Irish Pharmaceutical Healthcare Association (IPHA) Framework Agreement 2016 between the IPHA on behalf of its member companies, the Health Service Executive (HSE) and the Department of Health (IPHA Agreement) are the key documents controlling the prices of medicinal products in Ireland.

The HSE is required under the 2013 Act, to maintain a publicly accessible "Reimbursement List" in respect of medicinal products, medical and surgical appliances. Ireland operates a positive Reimbursement List. If the product is not on the Reimbursement List, the supplier may make an application to have the product added to the list in order to be eligible for reimbursement. The reimbursement price of pharmaceuticals included on the HSE's Reimbursement List has two components:

- the ex-factory price; and
- the wholesale mark-up.

Ex-factory price

The ex-factory price, ie, the price to wholesaler of any medicinal product introduced to Ireland following the commencement of the IPHA Agreement shall be the currency-adjusted average price to the wholesaler in the nominated EU Member States.

Wholesale mark-up

Once pricing approval has been granted for a product, a further 8% mark-up for room-temperature medicines and 12% mark-up for medicines which require refrigeration is applied to the price for the wholesaler or distributer.

Reductions and Rebates also apply.

Medical Devices

The Health Act 1970 and the 2013 Act regulate the pricing and reimbursement of medical devices.

7.2 Price Comparison

Pharmaceuticals

If the product is to be included in the Reimbursement List, the product must be priced at the currency-adjusted average ex-factory price in the 14 reference EU Member States. If the product is not available in all 14 EU reference Member States on the date the application for reimbursement is submitted to the HSE, the product is priced at the currency-adjusted average ex-factory price in those Member States in which the product is available. If the product is not available in any of the reference Member States, the supplier must propose a price to the HSE.

Medical Devices

If the device is to be reimbursed by the HSE, the price level of a pharmaceutical or medical device will depend on the prices for the same product in other countries. The 2013 Act provides for the assessment of the applicant's proposed price and the relevant factors to take into consideration. One such factor is the equivalent price, if practicably available, of the item in all other Member States where the item is marketed.

7.3 Reimbursement from Public Funds

Pharmaceuticals

Medicinal products dispensed in the community are funded by the State, through reimbursement of the pharmacist, where the patient in question is eligible under a reimbursement scheme, and where the medicinal product being dispensed is eligible for reimbursement.

A medicinal product is eligible for reimbursement if it:

- has a current MA;
- is approved for reimbursement by the HSE;
- is prescribed by a doctor; and
- is dispensed by a doctor or pharmacist

Medical Devices

See Section **1. Regulatory Framework**.

7.4 Cost Benefit Analysis

Pharmaceuticals

The HSE may subject products to an HTA on a case-by-case basis. An HTA may be applicable to products that are expensive or that have a significant budget impact on the Irish healthcare system. Ireland uses a Quality Adjusted Life Year (QALY) system which refers to the number of years an individual's life is prolonged as a result of a particular intervention, incorporating adjustments for the quality of that life. For the purposes of the HTA, the QALY threshold is EUR45,000. Medicinal products that are below the QALY threshold generally receive a positive decision on an HTA unless the product has a high budget impact. Determination of a high budget impact in this context is not defined. Products that receive a positive HTA outcome will obtain pricing approval at the lower of the price submitted for HTA or the price as calculated per the average of the 14 nominated EU Member States. Orphan medicinal products generally exceed the QALY threshold.

Exceptional products which fail to satisfy the EUR45,000 QALY threshold for a variety of reasons may still be approved, subject to negotiations between the Corporate Pharmaceutical Unit of the HSE (CPU), the Department of Health, clinicians and the marketing authorisation-holder. This procedure is governed by Section 18 of the Health Act. The first body with which such negotiations take place is an expert Drugs Group whose members evaluate the product in question. Following the evaluation of the Drugs Group, certain members of the senior leadership team of the HSE will either approve or reject the Drugs Group's decision.

Medical Devices

The scope of the HSE's HTA Group (HTAG) is confined to the area of medical devices. The HTAG is responsible for assessing the effectiveness and cost-effectiveness of new and innovative medical technologies or existing medical technologies with new and/or innovative indication based on a mini-HTA. If a full HTA is deemed necessary, the assessment is referred to the HIQA.

The HTAG provides assistance to stakeholders when considering various health technologies and innovation in the medical devices field. The key stakeholders are the Primary Care Reimbursement Service (PCRS), Procurement, other internal HSE divisions (Clinical Programmes, etc) and the device manufacturing industry.

The HTAG is supported by and reports to the HTA Expert Group. Device companies must demonstrate evidence of compliance with minimum safety standards, that there is a clinician who supports the application and that the device is of potential benefit to patients.

7.5 Prescriptions and Dispensing

The Health Act introduced generic substitution and reference pricing for groups of interchangeable medicinal products, in order to reduce healthcare expenditure in Ireland. The introduction of generic substitution allows pharmacists to dispense a less costly medicine than that which has been prescribed, provided that the less costly medicine falls within the same group of interchangeable medicinal products. The HPRA is responsible for drawing up the list of groups of interchangeable medicinal products.

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

In setting the reference price, the HSE is required to take into account the:

- ability of suppliers of the relevant items to meet patient demand;
- value for money provided by the relevant items;
- equivalent relevant prices (if practicably available) of the relevant items in all other Member States where one or more than one of the relevant items is marketed;
- relevant prices of therapeutically similar items;
- resources available to the HSE; and
- terms of any agreement in place (whether entered into before, on or after the commencement of the Health Act) between the HSE and any representative body of the suppliers of drugs, medicines or medical or surgical appliances where the agreement relates, whether directly or indirectly, to the price of one or more of those items.

8. Digital Healthcare

8.1 Rules for Medical Apps

In Ireland, there are no specific legal rules which deal with medical apps and there is no specific regulation as distinct from the regulation of medical services generally.

8.2 Rules for Telemedicine

As previously stated, there is no legislation which deals specifically with this area. However, the current Medical Council Guide to Professional Conduct and Ethics for Registered Medical Practitioners Guide states that telemedicine services can be provided in Ireland, but requires the following:

- strong security measures;
- patients have given their consent to conduct the consultation through telemedicine and consent to any treatment provided;
- information policies are clear to users;
- services are safe and suitable for patients;
- the patient's general practitioner is informed of the consultation; and
- intra-jurisdictional transfers of personal patient information comply with data protection principles.

In addition, healthcare providers of telemedicine services to patients within Ireland must be registered with the Medical Council. While the Medical Council Guide has no statutory effect, derogations from it may constitute a breach of professional duty by medical doctors.

8.3 Promoting and/or Advertising on an Online Platform

There are no specific restrictions on advertising and promoting telemedicine services in Ireland other than standard commercial advertising rules under the Consumer Protection Act 2007 and/or the European Communities (Misleading and Comparative Marketing Communications) Regulations 2007.

The promotion of medical devices online is regulated by the general rules governing the promotion of medical devices. Other limitations and rules regarding e-commerce and data privacy, amongst others, apply. There is no explicit prohibition on online promotional tools. However, if the company wants to set up discussion forums or other social media tools, it is recommended that monitoring measures be implemented.

The Medical Council Guide provides that medical practitioners may advertise telemedicine services but must include their Medical Council registration numbers. All information published must:

- be true and verifiable;
- not make false claims; or
- not have the potential to raise unrealistic expectations.

Doctors must include information about any risks associated with the services (eg, explain to patients that there are aspects of telemedicine that are different from traditional medical practice, ie, a consultation through telemedicine does not involve a physical examination).

8.4 Electronic Prescriptions

The issuing of electronic prescriptions is not permitted in Ireland. The Medicinal Products (Prescription and Control of Supply) Regulations 2003 (as amended) (the Prescription Regulations) detail the format to which a prescription must adhere for it to be legally valid. A registered medical practitioner (meaning a doctor registered with the Irish Medical Council) (RMP) may not issue prescriptions in electronic form (Regulation 7(1)(a) of the Prescription Regulations). However, a doctor who is registered in Ireland but practises in another EEA state may issue a prescription in electronic format, which could then be dispensed by a pharmacist in Ireland.

8.5 Online Sales

The supply of medicinal products by mail order is prohibited in Ireland under Regulation 19(1) of the Prescription Regulations.

8.6 Electronic Health Records

Electronic health records are not specifically regulated under domestic legislation but any processing or use of electronic health records must comply with the provisions of the Data Protection Acts in Ireland and the GDPR, in consultation with the Office of the Data Protection Commissioner (ODPC). One hospital in Ireland recently pioneered the entire digitisation of in-patient electronic health records. Privacy Impact Assessments (PIAs) were conducted to facilitate the transition.

9. Licensing

9.1 Customary Deal Structures

As Ireland is a common-law jurisdiction, a wide variety of deal structures are employed, depending on the nature and stage of development of the products, the value of the products and cost of getting them to market, the stage of regulatory development, the potential market and relative bargaining strengths of the entities involved. Such structures include options for licences based on the generation of satisfactory data, co-development and licence, co-commercialisation agreements, split territories, split fields and achievement of sales targets.

9.2 Dispute Resolution Provisions

Reference to arbitration is commonplace in commercial contracts. However, as arbitration becomes increasingly formalised and more akin to traditional adversarial proceedings, there is a shift in Ireland towards consent-based non-binding forms of alternative dispute resolution, including mediation, expert determination and adjudication as more flexible and cost-efficient dispute resolution mechanisms. Other provisions that need to be considered from a dispute resolution perspective in commercial contracts include, amongst others, jurisdiction and choice of law, service of documents and preservation of documents.

Under the Mediation Act 2017, there is a statutory requirement on solicitors to advise clients in relation to mediation prior to instituting proceedings. Solicitors must swear a Statutory Declaration confirming that they have provided the relevant advice and information to their client regarding mediation.

9.3 Diligence Obligations Provisions

"Reasonable efforts", all "reasonable efforts" or "commercially reasonable efforts" would typically be used to define a parties' diligence obligations in Irish licences. While the expression "commercially reasonable" endeavours is regularly used in contracts, it has yet to be interpreted by the Irish courts. One view is that there may be no material difference between "reasonable endeavours" and "commercially reasonable endeavours" as the former already involves consideration of commercial factors. "Best" endeavours obligations would be unusual.

Typically, regulatory and/or sales milestones linked to agreed timelines are included and each parties' respective obligations in relation to achieving such milestones are agreed.

9.4 Change of Control

Protection for licensees and licensors in a change of control situation will typically be agreed between the parties. "Control" may not be defined. However, where this term is defined, it is often defined in reference to Section 432 of the Taxes Consolidation Act 1997 (as amended).

9.5 Termination

Any rights in clinical data generated during the term of a licence agreement or during a clinical trial, for example, will be governed by the terms of that agreement. It is typical for all IP and any know-how owned or licensed to the licensee prior to the date of the agreement to remain the property of the licensor.

It is possible for the licensee to be permitted to use any IP or clinical data generated under the terms of a licence agreement for the furtherance of its normal business activities, to the extent that such use does not result in the disclosure or misuse of confidential information or the infringement of any data protection laws.

On termination of a licence agreement, it is common for the agreement to require the licensee to discontinue all exercise of any IP licensed under the agreement and to provide that the licensee shall have no further right, title or interest in any of the IP. This can be varied by way of agreement between the parties, subject always to compliance with data protection laws.

10. Patents

10.1 Applicable Laws

The relevant legislation includes the Patents Acts 1992 to 2012 (the Patents Act). Patents granted under the Patents Act can be for 20 years (full-term patent) or ten years (short-term patent). To obtain protection under a long-term patent, an invention must:

- be new;
- involve an inventive step; and
- be capable of industrial application.

The invention must not fall within any excluded categories (for example, a mathematical method or scientific theory).

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

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

The European Communities (Supplementary Protection Certificate) Regulations 2008 also applies in relation to certain medicinal and plant protection products. The Regulations provide for Supplementary Protection Certificates (SPCs), which extend the protection conferred by a full-term patent for an additional period of up to five years. SPCs for medicinal products for paediatric use may be extended for a further six months.

Medical Devices

Software which runs on the device is typically protected by copyright unless, as per EPO practice, they constitute "computer implemented inventions" which could render them eligible for patent protection if they meet the required standard for patentability. In addition, it must be shown that it is not "a method for treatment of the human or animal body by surgery or therapy and a diagnostic method practised on the human or animal body" which is excluded from patentability, and instead is a product… for use in any such method".

Section 9(1) of the Patents Act provides that an invention in all fields of technology shall be patentable if it is susceptible of industrial application, is new and involves an inventive step.

Pharmaceuticals

Pursuant to Section 10 of the Patents Act, methods for treatment of the human body or animal by surgery or therapy, and diagnostic methods practised on the human or animal body are not capable of being patented, but products (in particular substances or compositions) used in such methods are.

10.2 Second and Subsequent Medical Uses

Second and subsequent medical uses of a known product are regarded as patentable provided they are novel (ie, not prior art). Section 11(4) of the Patents Act provides that the patentability of any substance or composition comprised in the state of the art for use in any method for treatment of the human or animal body by surgery, or therapy or diagnostic method practised on a human or animal body, is not excluded, provided that its use for any such method is not comprised in the state of the art.

New Dosage Regimes

The Enlarged Board of Appeal of the European Patent Office held in "G2/08 Dosage Regime/Abbott Respiratory" that it is possible to obtain a patent over new and inventive dosage regimes. In order to be patentable (noting the requirements above) it would need to be shown that the regimen is not obvious, such that it lacks an inventive step (in that it is not obvious to a person skilled in the art).

New or Selected Patient Populations

If, with respect to the class of patients to be treated, it can be shown to be patentable (having particular regard to the requirement of novelty (ie, not prior art)).

Apart from the general activities that can constitute patent infringement, case law from the UK suggests that contributory infringement will arise from the supply of a product where the supplier has the requisite knowledge that at least some of the product will be used for the particular treatment in contravention of the second and subsequent patent.

10.3 Patent Term Extension

The term of full-term and short-term patents can be extended, for a maximum of five years, by the granting of an SPC.

SPCs are granted for medicinal products or plant production products when the patent's commercial exploitation period is reduced by the process of obtaining a marketing authorisation. Once an SPC has been granted, it does not take effect until the end of the term of the basic patent and extends protection only to the specific product which was the subject of the marketing authorisation, rather than the patent as a whole. A holder of an SPC can apply for a further extension of six months if the protected product has been tested for paediatric use and the relevant studies have complied with an agreed paediatric investigation plan. The granting of an SPC is governed by the European Communities (Supplementary Protection Certificate) Regulations 2008 (S.I. No 307/2008).

Pursuant to Paragraph 10 of SI No 307 of 2008, an application for a declaration of invalidity of an SPC can be made to the Controller of Patents or to the High Court.

10.4 Patent Infringement

Section 40 of the Patents Act provides that if a third party uses the patented invention without the owner's consent, the owner can take action to enforce his or her rights, including by preventing any other party from making, offering, putting on the

market or using a product which is the subject of a patent or importing or stocking the product for those purposes;

- using a process which is the subject of a patent; and
- offering, putting on the market, using or importing, or stocking for those purposes, the product obtained directly by a process which is the subject-matter of a patent.

Section 41 of the Patents Act provides that a patent can also be indirectly infringed by a person who supplies or offers to supply any of the means which relate to an essential element of the invention for putting the invention into effect.

The "Bolar exemption" is contained in Sections 42(g) and (h) of the Patents Act and provides that, in relation to pharmaceutical products, any necessary studies, experiments, tests and trials (including clinical trials and field trials) required to obtain a marketing authorisation in any jurisdiction will not amount to patent infringement.

Section 47 of the Patents Act 1992 allows for a quia timet injunction to be granted where there is an apprehended act of infringement. However, in practice, these are rarely awarded. Any remedy granted must be proportionate and dissuasive. Their purpose must be to prevent barriers to legitimate trade and freedom of speech. This is a high barrier to relief.

Proceedings for patent infringement can be brought before the Commercial Court, a division of the High Court, which deals with certain specified matters, including intellectual property infringement. An injunction is generally sought in the first instance to prevent continued infringement, pending the full hearing of the action. Applicants for injunctive relief must demonstrate that damages are not an adequate remedy. Applicants at the early stage in proceedings often face difficulty in discharging this test. Available remedies at the full hearing include:

- damages or an account of profits;
- order for delivery up or destruction of any infringing product; and
- declaration of validity of the patent and of infringement by the defendant.

The Commercial Court offers a faster litigation process through case-management conferences, stringent filing and documentation requirements and compliance obligations in respect of pre-trial judicial directions. Applications for admission to the Commercial List can be made by either party to a dispute.

10.5 Defences to Patent Infringement

Section 42 of the Patents Act governs the acts which do not come within the scope of a patent (that is, the specific acts that a third party can carry out without infringing the patent rights of a patent-holder). Section 42 confirms that acts done privately for non-commercial purposes and acts done for experimental purposes relating to the subject-matter of the relevant patented invention do not come within the protection offered by a patent. The extemporaneous preparation for individual cases in a pharmacy of a medicine in accordance with a medical prescription issued by a registered medical practitioner or acts concerning the medicine so prepared are also exempt.

As previously discussed, the "Bolar exemption" is contained in Sections 42(g) and (h) of the Patents Act.

Compulsory licences are only available if the patentee is not meeting demand for the patent either by manufacture in Ireland or importation from a WTO country or if the establishment or development of commercial or industrial activities in the State is unfairly prejudiced. Applications may only be made three years after publication of the grant of the patent. S73(1) of the Patents Act provides that the applicants must show evidence that they sought to obtain a licence from the patent-holder but were unable to obtain the licence on reasonable terms and within a reasonable time. This requirement may be dispensed with in the event of a national emergency or other circumstances of extreme urgency, or in the case of an application for a licence for public non-commercial use.

10.6 Bringing Proceedings

Proceedings for infringement may be brought by the proprietor of the patent, co-owners of patents and exclusive licensees.

Proceedings for patent infringement can be brought before the Commercial Court, a division of the High Court, which deals with certain specified matters, including intellectual property infringement. An injunction is generally sought in the first instance to prevent continued infringement, pending the full hearing of the action. Applicants for injunctive relief must demonstrate that damages are not an adequate remedy. Applicants at the early stage in proceedings often face difficulty in discharging this test. The Commercial Court offers a faster litigation process through case-management conferences, stringent filing and documentation requirements and compliance obligations in respect of pre-trial judicial directions. Applications for admission to the Commercial List can be made by either party to a dispute.

Section 61 of the Patents Act provides that validity of a patent may be put in issue by way of defence in proceedings for infringement under Sections 47 or 56. The validity of the patent may only be put in issue on a ground specified in Section 58. The grounds set out in Section 58 include the subject-matter of the patent not being patentable and the specification of the

patent not disclosing the invention in a sufficiently clear and complete manner.

10.7 Available Procedures

Section 54 of the Patents Act provides for the power of the court to make a declaration that the use or sale of any process or product does not and would not constitute an act of patent infringement. The court may exercise this power in proceedings between the person and the patent-holder or holder of an exclusive licence, notwithstanding the fact that no assertion to the contrary has been made by the proprietor or licensee. The plaintiff must show i) that they applied to the rights-holder for a written acknowledgement that the act would not amount to infringement and ii) that the rights-holder had refused to provide that written acknowledgement.

Clearing the way is not a requirement for market entry. Pharmaceutical manufacturers may also use the Bolar exemption.

Patent linkage is considered unlawful under the provisions of Regulation (EC) No 726/2004 and the Code for Human Medicines Directive.

11. IP Other Than Patents

11.1 Counterfeit Pharmaceuticals and Medical Devices

Apart from the Patents Act, there is a suite of legislative measures which protect intellectual property rights in Ireland, including the Trade Marks Act 1996 (as amended) (the Trade Marks Act), the Irish Trade Secrets Regulations, which implements the EU Trade Secrets Directive and the Misleading and Comparative Marketing Regulations 2007.

There are various remedies available under Irish law for infringement of intellectual property rights, including damages, injunctive relief, account of profits and delivery-up and destruction of infringing property. The Revenue Commissioners are empowered under Regulation EU 608/2013 and under the Irish Customs Enforcement of Intellectual Property Rights Regulations to take action against the infringement of intellectual property rights at points of importation to the State. The Trade Marks Act also entitles trade mark-owners to prevent goods (and their packaging) that infringe their trade marks from being imported into Ireland from outside the EU. The importer must prove that the trade mark-owner is not entitled to prohibit the placing of the goods on the market in the country of final destination.

11.2 Restrictions on Trade Marks

Section 6 of the Trade Marks Act provides that trade marks are signs which are capable of distinguishing the goods or services of one undertaking from those of other undertakings. Any sign can be registered as a trade mark, provided it complies with the conditions for registration and is not prevented from registration by sections 8 to 10 of the Trade Marks Act. Prohibited signs include those that have a lack of distinctiveness, those that use the national flag, or marks that are identical to an earlier trade mark.

Restrictions under the Trade Marks Act include Section 14(4A). The section allows a trade mark-holder prevent the use of signs identical or similar to their trade mark on packaging. It also allows a trade mark-holder prevent the importation or exportation of packaging with a similar or identical mark.

11.3 IP Protection for Trade Dress or Design

Trade dress and design rights are protected by the tort of passing-off and under the provisions of the Industrial Design Act 2001 (the Design Act).

The doctrine of passing-off allows rights-holders to prevent misrepresentations made by a trader in the course of trade to prospective customers or ultimate consumers of goods or services. The misrepresentations must be calculated to injure the business or goodwill of another trade and must cause actual damages to a business or goodwill of the rights-holder.

Section 2 of the Designs Act defines "Design" as "the appearance of the whole or a part of a product resulting from the features of, in particular, the lines, contours, colour, shape, texture or materials of the product itself or its ornamentation". "Product" is defined in Section 2 as "any industrial or handicraft item, including parts intended to be assembled into a complex product, packaging, get-up, graphic symbols and typographical typefaces, but not including computer programs".

For a design to be registrable, it must have new and individual character. Registration lasts for five years and is renewable up to a period of 25 years. Section 51 of the Design Act provides that a design right is infringed by a person who, without the licence of the registered proprietor of the design and while the design right is in force, undertakes or authorises another to undertake any act which is the exclusive right of the proprietor of the design.

11.4 Data Exclusivity

Pharmaceuticals

Medicinal products for human use which have been authorised in accordance with the provisions of Regulation (EC) 726/2004 enjoy an eight-year period of data protection pursuant to Article 14 of the Regulation.

Medical Devices

There is no specific regulatory exclusivity for medical devices in Ireland.

Arthur Cox is a leading Irish law firm. The firm is a market leader in the provision of legal services to the life sciences industry, with a multi-disciplinary practice group combining the very best of the firm's corporate, commercial, transactional, regulatory, competition and intellectual property expertise to serve Ireland's pharmaceutical, biotechnology, medical devices, food and cosmetics industries. The firm's clients include many of the major multinational and domestic pharmaceutical, diagnostic and medical device companies, ranging from start-ups and university spin-outs to large multinationals and industry leaders. Combining legal skill with solid industry knowledge, Arthur Cox represents many of Ireland and the world's major pharmaceutical, medical devices and agribusiness companies.

Authors

Colin Kavanagh is a partner of the firm and head of its life sciences department. He provides corporate, commercial, regulatory and intellectual property advice in the life sciences industry, as well as food and beverage, agribusiness, media, sports, entertainment and technology. His work includes mergers, acquisitions and investments, cross-border tax and IP re-organisations, post-acquisition integrations and corporate treasury activities. He also advises on the drafting and negotiation of commercial contracts and arrangements and related disputes across a range of sectors, with a particular focus on IP-based industries, as well as on the regulation of the life sciences and media industries in Ireland. Colin is an affiliate member of the Irish Pharmaceutical Healthcare Association, the Irish Medical Devices Association and the council of IBEC's Audio Visual Federation.

Joanelle O'Cleirigh is a partner in the firm's litigation, disputes and investigations group. Joanelle works for a broad range of clients, particularly those in the healthcare, life sciences and regulated sectors. Joanelle also advises clients in relation to inquiries and investigations. Joanelle's corporate crime experience includes advising in relation to the conduct of investigations and inquiries, some of Ireland's most significant tribunals of inquiry and commissions of investigation and on some of the most complex and sensitive statutory and corporate investigations. Her healthcare/life sciences expertise includes advising on contractual issues, the Health Information and Quality Authority (HIQA) regulations, the Health Products Regulatory Authority (HPRA) and compliance, cross-border healthcare, privacy and data issues, medical negligence and investigations/reviews/look-backs and product recalls.

Olivia Mullooly is a partner in the technology group, advising on intellectual property, data protection and information technology matters and a key contact in the firm for intellectual property. Olivia advises clients across a range of sectors, including the pharmaceutical, biotechnology and medtech industries, third-level education and research institutions on IP matters and data protection compliance, including on clinical and collaborative research projects and the licensing and protection of intellectual property. Olivia speaks regularly on IP, data protection and related areas in Ireland, Europe and the US. Olivia also advises on the negotiation of IT and commercial contracts.

Bridget McGrath is an associate in the firm's litigation group and regularly advises on healthcare, life sciences and regulatory and compliance matters, product liability and dispute resolution. Bridget advises pharmaceutical, biotech and medical device companies on clinical trials, promotional and compliance issues, pricing and reimbursement and transactional matters.

Arthur Cox

Ten Earlsfort Terrace
Dublin 2
D02 T380
Ireland

Tel: +353 1920 1196
Email: colin.kavanagh@arthurcox.com
Web: www.arthurcox.com