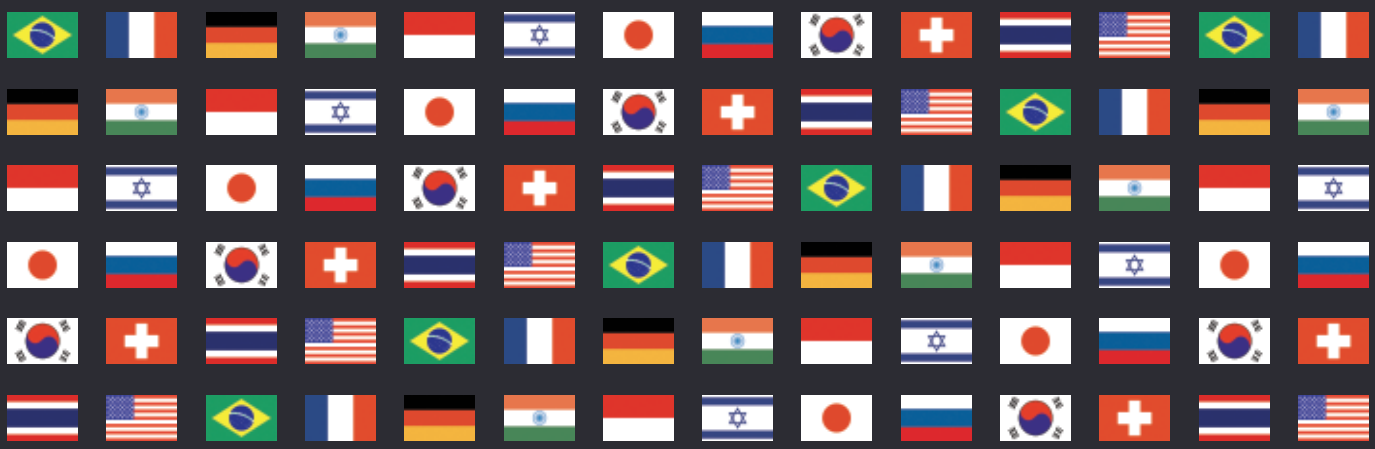
Digital Health
2021



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Ireland

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MARKET OVERVIEW AND TRANSACTIONAL ISSUES

Key market players and innovations

1 | Who are the key players active in your local digital health market and what are the most prominent areas of innovation?

The key players in Ireland's digital health market include:

- 3D4Medical: a software technology company that specialises in the development of medical learning applications and clinical solutions to educate healthcare learners;
- 3rd Pillar Orchestrator: a cloud platform that designs and automates patient support services;
- ICON plc: a global provider of consulting, and outsourced development and commercialisation services to pharmaceutical, biotechnology, medical device and government and public health organisations;
- LetsGetChecked: an at-home health testing start-up with operations in Dublin and New York;
- SilverCloud: a platform that enables healthcare organisations to deliver a broad range of evidence-based clinical content. Its platform is used by over 300 organisations, including the Health Service Executive; and
- government financing and other support initiatives, including Enterprise Ireland and IBEC.

Investment climate

2 | How would you describe the investment climate for digital health technologies in your jurisdiction, including any noteworthy challenges?

The investment climate for digital health technologies in Ireland is incredibly positive, with Ireland having the potential to become a leader in the development of digital health technologies as the sector goes from strength to strength. Ireland is already an attractive jurisdiction for companies given its corporation tax rate of 12.5 per cent.

Investment tends to come from a range of international geographies, as well as from Irish investment houses. The most typical geography of an investor in investment transactions involving Irish digital health companies is the United States. Investment by US private equity and venture capital investors into growing Irish businesses is very common, especially on the larger investment rounds.

Investment into digital health business has gone from strength to strength during the covid-19 pandemic, but in terms of investment rounds in Ireland, smaller rounds involving early stage start-ups have fallen dramatically during this period. Larger fundraising rounds involving developed businesses have increased. This means that early stage digital health businesses may have difficulty attracting initial funding.

Recent deals

3 | What are the most notable recent deals in the digital health sector in your jurisdiction?

Recent deals in the digital health sector in Ireland include the following.

- In May 2020, LetsGetChecked raised US$71 million in a Series C funding round. Prior to this Series C funding round, the company had raised around US$43.7 million in funding, including a US$30 million round in May 2019, backed by Leerink Transformation Partners, Optum Ventures and Qiming Venture Partners USA, and a US$12 million Series A round in 2018.
- In April 2020, SilverCloud confirmed a US$16 million Series B funding round led by MemorialCare Innovation Fund, which included LRVHealth, OSF Ventures and UnityPoint Health Ventures. This elevated the company's total funding to over US$30 million.
- In January 2021, ICON plc acquired PRA Health Sciences in a cash and stock transaction valued at approximately US$12 billion. This acquisition has created a world leader in healthcare intelligence and clinical research.
- In February 2021, Mainstay Medical Holdings plc (Mainstay) announced the closing of an equity financing in which it raised gross proceeds of US$108 million. Mainstay is a medical device company focused on commercialising an innovative implantable restorative neurostimulation system for people with disabling, mechanical chronic low back pain.
- In February 2021, Jazz Pharmaceuticals plc (Jazz) and GW Pharmaceuticals plc (GW) announced that the companies have entered into an agreement for Jazz to acquire GW for a total consideration of US$7.2 billion. The transaction is expected to close in the second quarter of 2021. Upon close of the transaction, the combined company will be a global leader in neuroscience.

Due diligence

4 | What due diligence issues should investors address before acquiring a stake in digital health ventures?

The main due diligence issues that investors should consider are as follows.

Product: first, the product itself must be analysed. The following should be considered as part of the review:

- whether the product is new to the marketplace;
- the level of disclosure available in relation to the product;
- whether the product raises conflicts of interest issues that have not been addressed;
- for whom the product is intended; and
- the marketing of the product.
- Intellectual property: it is important to assess the extent to which the target has not violated third-party intellectual property rights and has taken the necessary steps to protect its own intellectual

property. It must protect its invention and properly document ownership.
- Contracts: the target's contracts should be carefully reviewed to ascertain how well it has used licensing and service agreements to ensure legislative compliance and increased comfort regarding the opportunities and risks of the target and its digital health products.
- Privacy compliance: it is important to consider whether the target has designed its product to comply with international privacy, data security and data transfer requirements across Europe and elsewhere, which may differ to other countries.
- Regulatory: investors should consider whether a digital product may be regulated as a medical device under the EU Medical Device Regulation.
- Litigation: it is important to consider whether the target is involved or likely to be involved in any claims. If so, confirmation should be sought that the claims are covered by the target's insurance.

Other considerations include assessing whether the terms and conditions surrounding the purchase of the product are adequate; reviewing the shareholder capitalisation table to ensure it is properly documented and to confirm that there are no outstanding rights to any shareholders; and reviewing all loan facilities in respect of the target to ensure that they contain no onerous terms which may affect your investment.

Financing and government support

5 What financing structures are commonly used by digital health ventures in your jurisdiction? Are there any notable government financing or other support initiatives to promote development of the digital health space?

Common financing structures are as follows:
- investment for an equity stake in the target (new shares);
- convertible loan notes; and
- bank debt with security (including traditional and alternative lenders such as Bank of Ireland or Activate Capital).

Enterprise Ireland provides specific sector support in digital healthcare technologies in Ireland, such as:
- Health Innovation Hubs Ireland Scheme, which offers companies the opportunity for pilot and clinical validation studies and the health service access to innovative products and devices that they may not otherwise be exposed to;
- Technology Transfer Offices, which provide an invaluable resource in relation to research, development and innovation; and
- Technology Gateway Programme, which fosters greater cooperation between business and institutes of technology by offering funding rounds for capital expenditure.

In its 2017 Sláintecare strategy, the Irish government outlined its healthcare vision for the next 10 years, including the implementation of connected digital health to facilitate the provision of services in more appropriate care settings closer to a patient's home.

The Irish Business and Employers Confederation's 'Where Digital Health Thrives' campaign is aimed at capitalising on Ireland's existing strengths to help the country realise its potential to become a global hub in this emerging area.

LEGAL AND REGULATORY FRAMEWORK

Legislation

6 What principal legislation governs the digital health sector in your jurisdiction?

The regulatory landscape for digital health products in Ireland is heavily influenced by the EU regime, in particular by the Medical Devices Directive 93/42/EEC (MDD) and the Medical Devices Regulation (EU) 2017/745 (MDR), which apply to medical devices (including software medical devices) and classify those products based on their level of potential risk to users.

The MDD was entirely replaced by the MDR on 26 May 2021. To avoid market disruption, transitional provisions allow for some devices, previously accredited under the MDD prior to 26 May 2021, to continue to be placed on the market until May 2024 and be made available to end users until May 2025, provided certain conditions are met. One of the conditions of this transitional measure is that no significant changes can be made to the intended purpose or design of the relevant device after 26 May 2021.

The regulatory regime for medicines may also be applicable if the digital health product is involved with medicine or medicine delivery. The regulatory regime in relation to medicines is primarily governed by Directive 2001/83/EC on the Community code relating to medicinal products for human use and implemented through various national regulations in Ireland.

Although some digital health products fall within the regulatory framework applicable to medical devices, a number of further or other regimes may be applicable depending on the type of digital health product involved.

The General Product Safety Directive 2001/95/EC is transposed in Ireland by the European Communities (General Product Safety) Regulations 2004 (SI No. 199 of 2004) and may apply to digital health products that are regulated as general consumer products.

There are also further requirements relating to consumer products more generally that may apply to certain digital health products:
- Directive 2012/19/EU, which was transposed in Ireland by the European Union (Waste Electrical and Electronic Equipment) Regulations 2014 (SI No. 149 of 2014);
- Directive 2014/53/EU (RED), which was transposed in Ireland by the European Union (Radio Equipment) Regulations 2017 (SI No. 248 of 2017);
- Directive 2014/35/EU, which was transposed in Ireland by the European Union (Low Voltage Electrical Equipment) Regulations 2016 (SI No. 345 of 2016);
- Directive 2014/30/EU (the EMC Directive), which was transposed in Ireland by the European Communities (Electromagnetic Compatibility) Regulations 2017 (SI No. 69 of 2017);
- Directive 2006/66/EC, which was transposed in Ireland by the European Union (Batteries and Accumulators) Regulations 2014 (SI No. 283 of 2014); and
- Directive 2002/95/EC (the RoHS Directive), which was transposed in Ireland by the European Union (Restriction of Certain Hazardous Substances in Electrical and Electronic Equipment) Regulations 2012 (SI No. 513 of 2012).

A number of those pieces of legislation provide that compliance with their requirements must be demonstrated and recorded as part of technical documentation for the product that is prepared by the manufacturer. This technical documentation provides the basis for a Declaration of Conformity to be made by the manufacturer in respect of the product, which in turn allows for a CE mark to be affixed to the product as required.

The Consumer Protection Act 2007 (the 2007 Act), which implements the EU Directive on Unfair Commercial Practices (Directive 2005/29/EC), may also be applicable to digital health products that are intended for consumer use. The 2007 Act regulates advertising and commercial practices in Ireland. It established a national body, now known as the Competition and Consumer Protection Commission (CCPC), which is responsible for enforcing the 2007 Act.

The use of digital health products by healthcare professionals may also require consideration of legislation providing for the regulation of healthcare professionals in Ireland as well as associated guidance published by the professional regulators. The key pieces of legislation providing for the functions of those regulators are:

- the Medical Practitioners Act 2007 (as amended), which provides for the regulation of the medical profession by the Medical Council;
- the Nurses and Midwives Act 2011 (as amended), which provides for the regulation of nurses and midwives by the Nursing and Midwifery Board of Ireland;
- the Pharmacy Act 2007 (as amended), which provides for the regulation of pharmacists and pharmaceutical assistants by the Pharmaceutical Society of Ireland; and
- the Health and Social Care Professionals Act 2005 (as amended), which provides for the regulation of dietitians, dispensing opticians, medical scientists, occupational therapists, optometrists, physical therapists, physiotherapists, radiographers, radiation therapists, social workers and speech and language therapists by the Health and Social Care Professionals Council.

Regulatory and enforcement bodies

7 Which notable regulatory and enforcement bodies have jurisdiction over the digital health sector?

Because of the lack of dedicated legislation and regulatory schemes specific to digital health, IT and e-healthcare in Ireland, a number of different regimes may be applicable, depending on the type of digital health product involved. Depending on the applicable legislation, regulation of digital health products may be overseen by a number of organisations, including those discussed below.

The Health Products Regulatory Authority (HPRA) derives its regulatory authority from the Irish Medicines Board Act 1995 and the Irish Medicines Board (Miscellaneous Provisions) Act 2006. The HPRA is the competent authority in Ireland with responsibility for monitoring and enforcing compliance with regulatory requirements for human and veterinary medicines, human blood, tissues and cells, cosmetic products, medical devices, active pharmaceutical ingredients, and controlled drugs and substances. It has been conferred with broad powers, including the rights of demanding information, investigation, inspection and prosecution, as well as refusal and revocation of licences and ordering the recall of medicinal products and medical devices (including software medical devices).

The independent body eHealth Ireland was set up in 2013 initially as part of the Health Service Executive. It has developed a strategy demonstrating how citizens, the Irish healthcare delivery systems – both public and private – and the economy as a whole will benefit from eHealth. it works closely with all the key business organisations within the health service to drive forward its e-health strategy and ensure that key IT systems are implemented on time and to budget.

The Health and Information Quality Authority (HIQA) was established by the Health Act 2007. It is an independent authority that exists to improve health and social care services for the people of Ireland. In October 2019, HIQA published a guide to its review programme of eHealth services in Ireland. It has also established a new review programme to monitor compliance with National Standards for Safer Better Healthcare for eHealth services within the HSE in Ireland, specifically in respect of patient safety and data quality.

The CCPC is an Irish state agency set up in October 2014 on amalgamation of the Competition Authority and the National Consumer Agency. It has a broad mandate for enforcing competition and consumer protection law in Ireland, including enforcement of product safety regulations and the assessment of mergers.

Additionally, given that a significant number of digital health products contain, store, process or use health data, the DPC will generally investigate any potential data breaches and take appropriate enforcement action where necessary.

Licensing and authorisation

8 What licensing and authorisation requirements and procedures apply to the provision of digital health products and services in your jurisdiction?

There is no specific Irish legislation governing licensing and authorisation requirements and procedures in respect of the provision of digital health products and services; however, depending on the nature of the product, digital health products may be subject to authorisation requirements and procedures under various product-specific frameworks.

Consumer products

Digital health products that are classified as consumer products may be subject to various pieces of EU product safety legislation (eg, the RoHS Directive, the EMC Directive and RED) and may need to be affixed with a CE mark before being placed on the Irish market. To affix a CE mark to a product, under certain legislation, the manufacturer is required to draw up technical documentation for the product demonstrating compliance with the various requirements provided for in the relevant legislation, along with a declaration of conformity in respect of the product.

Medical devices

If a digital health product is a medical device, the manufacturer will be required to demonstrate compliance with stringent requirements provided for under the MDR before being permitted to place the device on the Irish market. The requirements are based on a risk assessment of the device according to classification rules provided for under the MDR (from low to high: Class I, Class IIa, Class IIb and Class III).

Certain types of Class I devices (eg, sterile devices) and devices that are Class IIa or higher require third-party conformity assessment by a notified body, who will assess and certify the device as compliant with the requirements under the MDR before a CE mark may be affixed and the device placed on the market.

Of particular significance in the context of digital health, Rule 11 of the MDR Classification Rules applies specifically to software medical devices. The HPRA also operates a registration system in respect of medical devices placed on the Irish market.

Medicines

Certain digital health products may be involved with or used for the purposes of medicine delivery. In the European Union, all medicines must be authorised before being marketed and made available to patients. This application process will ordinarily involve the preparation and submission of a dossier containing full pharmaceutical, pre-clinical and clinical trial data.

Depending on the nature of the interaction between the medicinal product and the digital health product, the digital health product may be deemed to form part of a drug–device combination, in which case the demonstration of compliance with the relevant requirements under the medical device legislation is required.

Soft law and guidance

9 Is there any notable 'soft' law or guidance governing digital health?

Although there is a lack of 'soft' law or guidance addressed specifically to digital health products in Ireland, there are a number of documents that can be referred to depending on the nature of the digital health product.

Consumer products

The key piece of guidance in respect of the implementation of EU product rules (of which the majority have been transposed directly into Irish law) is the EU Commission's Guide to the implementation of directives based on the New Approach and the Global Approach (the Blue Guide). The Guide to the Radio Equipment Directive 2014/53/EU is also an important guidance document for products that fall under RED.

Medical devices

Various pieces of guidance in relation to digital health products have been published at the EU level by the Medical Device Coordination Group. Additionally, the International Medical Device Regulators Forum provides a range of information documents.

The HPRA, as the relevant competent authority in Ireland, also issues guidelines in respect of the qualification and classification of medical devices and in vitro diagnostic medical devices.

Medical device companies that are members of the Irish Medtech Association, a self-regulatory body, are also subject to the provisions of the Irish Medtech Code. Under the Code, members can be issued with a formal letter of reprimand from of the Irish Medtech Association, who can also recommend suspension (with various conditions) or expulsion of member companies from the Irish Medtech Association.

Medicines

Given the increased involvement of pharmaceutical companies in the development and provision of digital health products, the Codes of Practice issued by the Irish Pharmaceutical Healthcare Association are also relevant in the context of digital health.

Professional guidelines

As members of professions that are statutorily regulated, registered healthcare practitioners must ensure that their practice is in compliance with governing legislation that provides for various obligations and regulations, including profession-specific codes of professional conduct and ethical guides. Given the impact that the use of digital health products may have on patient safety, some healthcare regulators have published guidance for healthcare practitioners providing care using digital health products. For example, the Medical Council has published a guide for doctors on the use of telemedicine to be used in conjunction with its Guide to Professional Conduct and Ethics for Registered Medical Practitioners.

Liability regimes

10 What are the key liability regimes applicable to digital health products and services in your jurisdiction? How do these apply to the cross-border provision of digital health products and services?

In Ireland, liability applicable to digital health products and services falls under four main headings.

Contract

Contracts for the sale of goods are governed by the Sale of Goods Act 1893, as amended by the Sale of Goods and Supply of Services Act 1980 (the Sale of Goods Acts). The Sale of Goods Acts imply a number of terms into contracts for the sale of goods, including that the goods must be of 'merchantable quality' (ie, they are as fit for the purpose or purposes for which goods of that kind are commonly bought and as durable as it is reasonable to expect, having regard to any description applied to them, the price and all other relevant circumstances). If the product sold is subsequently found not to be of merchantable quality, the seller will be deemed to have breached this implied term of the contract.

The European Communities (Certain Aspects of the Sale of Consumer Goods and Associated Guarantees) Regulations 2003 also apply to contracts for the sale of goods to consumers and require that goods delivered to the consumer under a contract of sale must be in conformity with that contract.

Contractual liability can also arise through various other contractual relations entered into by parties involved in the supply and use of digital health products (eg, hospitals, clinicians, pharmaceutical and device manufacturers and software manufacturers) and parties to those agreements must be highly conscious of their respective liability positions as provided for in those agreements.

Tort

Liability in tort is fault-based, and the common law duty of care principles apply. In general, the burden of proof is on the claimant to prove, on the balance of probabilities, that the defendant (in this case usually a manufacturer or seller of a product) was negligent and that this negligence caused him or her injury or damage.

Statutory liability

The key piece of legislation in this regard is the Liability for Defective Products Act 1991 (the 1991 Act), which transposed into Irish law Council Directive 85/374/EEC on liability for defective products. The 1991 Act imposes strict liability on the producer of a product in the event that it is found liable for damage caused wholly or partly by a defect in its product.

The limitation period for an action under the 1991 Act is three years from the date on which the cause of action accrued or the claimant's date of knowledge (if later). A claimant's right of action under the 1991 Act is extinguished on the expiration of 10 years from the date on which the product that allegedly caused the damage was first put into circulation, unless the claimant has instituted proceedings in the meantime.

In Ireland, it is common for claimants to pursue a claim under the statutory product liability regime in tandem with a claim of negligence; therefore, the extinguishment of a claimant's rights under the 1991 Act may not necessarily preclude the pursuit of a claim in negligence.

Criminal liability

Another important piece of legislation in this area is the General Product Safety Regulations 2004 (the 2004 Regulations), which transposed into Irish law Directive 2001/95/EC on general product safety. The 2004 Regulations set out the duties of producers and distributors in this regard and make the placing of unsafe products on the market a criminal offence.

The Competition and Consumer Protection Commission (CCPC) has a range of investigative and enforcement powers, including the power to order a product recall, in order to monitor and enforce compliance with the 2004 Regulations. Distributors and producers must cooperate with and inform the CCPC about any unsafe products placed on the market, and the 2004 Regulations also provide that a failure by a producer or distributor to inform the CCPC where they know or ought to know that a product that has been placed on the market by them is incompatible with relevant safety requirements is a criminal offence.

There is currently no Irish legislation providing for the offence of corporate manslaughter. Although published by the Irish government in 2016, the Corporate Manslaughter Bill has not been passed into law.

Medical devices

Some digital health products will be medical devices that are, therefore, subject to liability and offences under the MDD and the MDR. For example, it is an offence to place a non-CE marked medical device on the market.

Clinical negligence

Because digital health products are frequently used by medical practitioners while delivering healthcare services, the issue of clinical negligence may also be relevant. In Ireland, clinical negligence claims place the burden of proof on the claimant (in this case a patient) to prove, on the balance of probabilities, that the medical practitioner owed the patient a duty of care; that duty of care was breached (by the standard of care falling short of that expected); and the breach caused him or her injury.

DATA PROTECTION AND MANAGEMENT

Definition of `health data'

11 What constitutes 'health data'? Is there a definition of 'anonymised' health data?

Health data (or 'data concerning health' as it is termed in the General Data Protection Regulation (GDPR)) is defined as 'personal data related to the physical or mental health of a natural person, including the provision of health care services, which reveal information about his or her health status'.

Recital 35 of the GDPR provides further guidance noting:

> *[p]ersonal data concerning health should include all data pertaining to the health status of a data subject which reveal information relating to the past, current or future physical or mental health status of the data subject. This includes information about the natural person collected in the course of the registration for, or the provision of, health care services as referred to in Directive 2011/24/EU of the European Parliament and of the Council to that natural person; a number, symbol or particular assigned to a natural person to uniquely identify the natural person for health purposes; information derived from the testing or examination of a body part or bodily substance, including from genetic data and biological samples; and any information on, for example, a disease, disability, disease risk, medical history, clinical treatment or the physiological or biomedical state of the data subject independent of its source, for example from a physician or other health professional, a hospital, a medical device or an in vitro diagnostic test.*

Health data is, therefore, a broad concept and one that is broader than medical data. It is also not necessary that the data reveals poor health or illness. A test result revealing good health also constitutes health data.

Although heath data is a broad concept, it would generally not extend to data generated by lifestyle and wellness apps where conclusions cannot be reasonably drawn from the data about the health status of the individual.

The GDPR also defines genetic data as 'personal data relating to the inherited or acquired genetic characteristics of a natural person which give unique information about the physiology or the health of that natural person and which result, in particular, from an analysis of a biological sample from the natural person in question.'

Anonymous information is described in the GDPR as 'information which does not relate to an identified or identifiable natural person or to personal data rendered anonymous in such a manner that the data subject is not or no longer identifiable'.

Data protection law

12 What legal protection is afforded to health data in your jurisdiction? Is the level of protection greater than that afforded to other personal data?

Health data and genetic data are afforded a higher level of protection than ordinary personal data. The GDPR and the Irish Data Protection Act 2018 impose additional restrictions on the circumstances in which such data can be lawfully processed by a controller. Typically, a data subject's explicit consent will be required to process such data unless one of the narrow statutory derogations apply.

The processing of health or genetic data can also trigger other obligations for a controller. For example, if a controller processes health or genetic data on a large scale, it may need to appoint a data protection officer and carry out a data impact assessment for any proposed processing.

In the event of a personal data breach, a controller is more likely to need to notify a supervisory authority and data subjects where health or genetic data has been impacted.

The Data Protection Act 2018 (Section 36(2)) (Health Research) (Amendment) Regulations 2018, as amended, impose additional obligations and restrictions on the processing of personal data in relation to health research, which includes any of the following for the purpose of human health:

- research with the goal of understanding normal and abnormal functioning at the molecular, cellular, organ system and whole body levels;
- research that is specifically concerned with innovative strategies, devices, products or services for the diagnosis, treatment or prevention of human disease or injury;
- research with the goal of improving the diagnosis and treatment (including the rehabilitation and palliation) of human disease and injury and of improving the health and quality of life of individuals;
- research with the goal of improving the efficiency and effectiveness of health professionals and the healthcare system; and
- research with the goal of improving the health of the population as a whole or any part of the population through a better understanding of the ways in which social, cultural, environmental, occupational and economic factors determine health status.

Anonymised health data

13 Is anonymised health data subject to specific regulations or guidelines?

No. Anonymous data is not subject to regulation under the GDPR and the Irish Data Protection Act 2018.

Anonymisation is a difficult to achieve in practice. De-identified or depersonalised data may still constitute personal data where it relates to an identifiable individual. To determine whether a person is identifiable, account should be taken of 'all the means reasonably likely to be used, such as singling out, either by the controller or by another person to identify the natural person directly or indirectly'.

The Data Protection Commission has published guidance on the anonymisation of data. It notes that 'to determine when data are rendered anonymous for data protection purposes, you have to examine what means and available datasets might be used to reidentify a data subject.'

It also notes '[o]rganisations don't have to be able to prove that it is impossible for any data subject to be identified in order for an anonymisation technique to be considered successful. Rather, if it can be shown that it is unlikely that a data subject will be identified given the circumstances of the individual case and the state of technology, the data can be considered anonymous.'

This guidance also states that 'in some cases, it is not possible to effectively anonymise data, either because of the nature or context of the data, or because of the use for which the data is collected and retained' and that 'even where effective anonymisation can be carried out, any release of a dataset may have residual privacy implications, and the expectations of the concerned individuals should be accounted for.'

Companies should also be aware that the act of anonymising personal data is considered an act of processing of personal data. The activity must comply with the provisions of the GDPR and the Irish Data Protection Act 2018, including the principles of ensuring transparency and having a legal basis for processing.

Enforcement

14 How are the data protection laws in your jurisdiction enforced in relation to health data? Have there been any notable regulatory or private enforcement actions in relation to digital healthcare technologies?

The GDPR and the Data Protection Act 2018 are enforced by the Data Protection Commissioner (DPC) in Ireland. The DPC is an active regulator and identifies key enforcement activities in its annual reports. However, there have been no public reports on specific enforcement action in relation to digital healthcare companies to date.

There have been no private enforcement actions in relation to digital healthcare companies to date, and private claims under GDPR and Data Protection Act 2018 remain somewhat limited in Ireland, although such action is likely to increase in the coming years.

Cybersecurity

15 What cybersecurity laws and best practices are relevant for digital health offerings?

The EU cybersecurity law is set out in the Directive on Security of Network and Information Systems, and it has been transposed in Irish law by SI No. 360/2018 – European Union (Measures for a High Common Level of Security of Network and Information Systems) Regulations 2018.

The law applies only to two categories of entity:

- operators and essential services: private businesses or public entities with an important role to provide security in healthcare, transport, energy, banking and financial market infrastructure, digital infrastructure and water supply; and
- online marketplaces (that allow businesses to make their products and services available online), cloud computing services and search engines.

Generally speaking, the law gives rise to obligations regarding the maintenance of appropriate levels of security and notification obligations to competent authorities in Ireland.

In our experience, those in the digital health industry are not within the scope of those laws. Those entities will, however, be subject to the GDPR and the Data Protection Act 2018, which require companies to put in place appropriate security measures to protect the data processes from risk.

The cyber-insurance market in Ireland continues to develop, and market practice continues to evolve. A key consideration in this respect is that it remains unclear to what extent fines under GDPR are insurable.

Best practices and practical tips

16 What best practices and practical tips would you recommend to effectively manage the ownership, use and sharing of users' raw and anonymised data, as well as the output of digital health solutions?

The following are key GDPR principles that apply to any use of personal data.

- Legal basis: companies should ensure they have a legal basis for any processing. Using health or genetic data often requires the explicit consent of the individual. This must be obtained up front.
- Transparency: companies should endeavour to adopt a 'no surprises' policy. Companies should be clear with individuals about what information is being collected, for what purposes, who it will be shared with and how long it will be retained.
- Data minimisation: companies should only collect the information they need. Collecting information because it might be useful or valuable at a later date creates risks of non-compliance. Holding unnecessary information creates unnecessary risk, especially where it is sensitive.
- Purpose limitation: companies should use information for the purpose for which it has been collected. For example, if a company collects information to provide a health service, it should not be later used for unrelated marketing purposes without the customer's permission.
- Retention: once data is no longer required, it should be deleted. Data should not be kept 'just in case'.
- Security: companies should ensure that appropriate security measures are in place, regular reviews are undertaken of the measures in place and access to the information is restricted to a 'need to know' basis only.

Finally, if a company seeks to rely on the fact that data is anonymous, it should ensure it has put in place robust processes to ensure it satisfies the high standard set by the GDPR.

INTELLECTUAL PROPERTY

Patentability and inventorship

17 What are the most noteworthy rules and considerations relating to the patentability and inventorship of digital health-related inventions?

Ireland is part of the European patent system and the European Patent Convention. Patents are generally used to protect the hardware components of digital health products and services, assuming that those components meet the patentability requirements (ie, they solve a technical problem in a novel and non-obvious manner).

Methods and protocols associated with using the digital health product may also be patentable; therefore, patents can be used to protect aspects of the functionality of the digital health product.

Specifically excluded from patentability under Irish law are the items in the following non-exhaustive list:

- a mathematical method (ie, an algorithm);
- a computer program (ie, software code but excluding computer-implemented inventions);
- a method for treatment of the human or animal body by surgery or therapy;
- a diagnostic method practised on the human or animal body; and
- data and databases.

The ownership of employer and employee inventions is governed by Irish common law. An invention made by an employee belongs to an employer, where:

- it was made in the course of the normal duties of the employee or in the course of duties falling outside the employee's normal duties, but specifically assigned to the employee, and the circumstances in either case were such that an invention might reasonably be expected to result from the carrying out of his or her duties; or
- the invention was made in the course of the duties of the employee and, at the time of making the invention, because of the nature of his or her duties and the particular responsibilities arising from the nature of his or her duties, he or she had a special obligation to further the interests of the employer's undertaking.

Patent prosecution

18 What is the patent application and registration procedure for digital health technologies in your jurisdiction?

From the inventors and digital technology owner's perspective, the patent process can be broken down into three distinct stages: preparation pre-filing, application and grant. Once granted, an Irish patent lasts for 20 years from the filing date.

It is also possible to obtain a patent without a substantive examination process. Those patents are known as short-term patents, and they generally have a lower requirement for inventive step, as well as having a shorter term of protection. They tend not to be used for digital heath technologies.

A single application in Ireland (or another country) is sometimes filed in the first instance so that the commercial prospects of the invention can be tested. The applicant will have 12 months to commercialise the invention and file further patent applications in other jurisdictions claiming priority from the Irish application. If filed within 12 months, the subsequently filed applications in other jurisdictions are afforded the same filing date as the Irish application as such disclosures of the invention are not held against the patentability of subsequent applications for the same invention.

Alternatively, inventors may decide to bypass the preliminary application stage and file either a Patent Cooperation Treaty application covering over 140 countries or file complete applications in certain jurisdictions, for example the United States and Canada, straight away. The latter is the more common route for established applicants for patents covering digital health technologies, given their international reach and market.

Other IP rights

19 Are any other IP rights relevant in the context of digital health offerings? How are these rights secured?

In respect of copyright in the programs, code and databases (whether original or sui generis) used by the digital health devices, the owner of original works of copyright or the maker or a database will be the creator and, as such, it is vital to appropriately document arrangements with third-party contractors to allow for the transfer of ownership to the commissioning party. Copyright is not registrable in Ireland, and rights are generally secured and verified by refence to code files.

Digital health devices can be subject to both registered and unregistered design rights. Registered designs are used to protect aspects of the appearance of digital health devices (eg, the shape and any contours or ornamentation of the device). Registered design protection can be obtained in Ireland by filing an application for an Irish-registered design or a registered Community design at the EU level. Unregistered designs are an EU law right that arises on creation of the design and lasts three years from the date on which the design was first made available to the public within the European Union. It is necessary to demonstrate copying in order to prove infringement.

Inventions in digital health products can also be protected as trade secrets. In Ireland, trade secrets are protected under common law, as well as by the European Union (Protection of Trade Secrets) Regulations 2018 (Regulations). A trade secret is one that:

- is secret in the sense that it is not, as a body or in the precise configuration and assembly of its components, generally known among or readily accessible to persons within the circles that normally deal with the kind of information in question;
- has commercial value because it is secret; and
- has been subject to reasonable steps under the circumstances, by the person lawfully in control of the information, to keep it secret.

Finally, branding and trademarks are key in the competitive digital health market. Distinctive brand names and logos are used to distinguish a digital health product from its competitors. Trademark protection can be obtained in Ireland by filing an application for an Irish trademark or an EU trademark at the EU level. Applications for shape and colour marks are becoming more and more challenging to register.

Licensing

20 What practical considerations are relevant when licensing IP rights in digital health technologies?

A licensor of IP rights in digital health technology should at least consider the following:

- the scope of the grant, having regard to global licensing plans and opportunities (excusive, sole or non-exclusive);
- whether the technology has more than one use and if the rights should be divided on the basis of those uses or fields to optimise opportunities;
- remuneration model (ie, license fee and royalties based on devices and also consider similar issues for software and platforms);
- efficiency planning (ie, where to locate the IP to develop and exploit it most efficiently);
- the scope of warranties to be provided, having regard to maturity of the IP, whether it is all propriety or a mix of propriety, third party and open source;
- how to deal with IP in improvements that are made by the licensor, the licensee or jointly;
- the ownership and licensing of data related to the device; and
- the strategic shaping of termination provisions to allow for exits where the licensee is underperforming.

Enforcement

21 What procedures govern the enforcement of IP rights in digital health technologies? Have there been any notable enforcement actions involving digital health technologies in your jurisdiction?

Enforcement strategy and procedures depend on the digital health technology rights being infringed. In the vast majority of cases, infringement will likely be pursued through an action before the High Court or the Commercial Court because of the nature and quantum of the damage.

However, recent amendments to Irish IP legislation (the Copyright and Other Intellectual Property Law Provisions Act 2019) now permit the District Court and the Circuit Court to hear and determine certain intellectual property claims, including certain claims under the Patents Act 1992, the Trade Marks Act 1996 and Industrial Designs Act 2001 (ie, claims of a lower quantum, which makes IP claims accessible to a broader class of claimants).

Procedural Office actions before the Intellectual Property Office of Ireland and the European Union Intellectual Property Office are also available to the owners of trademarks and designs who wish to pursue new market entrants with the same or similar brands or designs.

ADVERTISING, MARKETING AND E-COMMERCE

Advertising and marketing

22 What rules and restrictions govern the advertising and marketing of digital health products and services in your jurisdiction?

The Consumer Protection Acts 2007 (CPA) prohibits false or misleading advertising. Sections 43 to 47 of the CPA is a criminal offence for a digital health provider to engage in an unfair or misleading commercial practice in relation to a range of matters, including the existence or nature of a product, its benefits or fitness for purposes, the results to be expected from it, etc.

To be a misleading commercial practice, the marketing communication must be likely to cause the average consumer to make a transactional decision they would not otherwise make. A person who is found guilty of an offence under the CPA is liable on summary conviction to a fine of up to €3,000 or up to six months imprisonment, or both. On conviction on indictment, a person is liable to a fine up to €60,000 or imprisonment for up to 18 months, or both.

There are also general advertising guidelines under the Advertising Standards Authority of Ireland's Code of Standards for Advertising and Marketing Communications in Ireland (the ASAI Code). This is a voluntary industry code for advertisers in Ireland. It applies to marketing communications in TV, radio, print and social media.

Section 3 of the ASAI Code requires advertisements to:

- be legal, decent, honest and truthful;
- be prepared with a sense of responsibility to consumers and to society; and
- respect the principles of fair competition generally accepted in business.

Further, section 11 of the ASAI Code applies specifically to marketing communications for medicines, medical devices, treatments, health-related products and beauty products. It requires the following:

- claims about health and beauty products and treatments should be backed by substantiation;
- medicinal or medical claims and indications may be made for a medicinal product that is authorised by the Health Products Regulatory Authority or the European Medicines Agency for a CE-marked medical device;
- any scientific information in a marketing communication should be presented in an accurate manner;
- no reference should be made to tests, trials or endorsements by any college, hospital, clinic, laboratory or similar establishment, unless there is a bona fide establishment corresponding to the description used and it is under the effective supervision of a registered medical practitioner or other appropriate professional;
- marketing communications for health and beauty products or treatments should not include representations of individuals that give the impression of professional advice or recommendations, unless those persons are suitably qualified and have relevant and recognised qualifications;
- advertisers should not discourage essential treatment for conditions for which medical supervision should be sought;
- marketing communications for medical services should not cause unwarranted or disproportionate anxiety or suggest that any product or treatment is necessary for the maintenance of health; and
- advertisers inviting consumers to diagnose their own minor ailments should not make claims that might lead to a mistaken diagnosis.

A breach of the ASAI Code carries no criminal sanction for the advertisers, but the ASAI can: require the advertisement to be withdrawn; publish details of the defaulter (adverse reputational damage for the advertiser); or sanction advertisers who ignore ASAI decisions by suspending them from membership of the ASAI.

In a business-to-business context, the European Communities (Misleading and Comparative Marketing Communications) Regulations 2007 regulate comparative advertising between traders. This is defined as any form of communication that explicitly or implicitly identifies a competitor or a product of a competitor. Such communications are prohibited if they:

- are misleading;
- do not compare products or services that meet the same need or purpose;
- discredit trademarks or present goods or services as imitations of those bearing a protected trademark; or
- create confusion between the trader and the competitor or between trademarks.

This allows traders may apply to the Circuit Court or the High Court for an order prohibiting the marketing communication of a competitor.

e-Commerce

23 What rules governing e-commerce are relevant for digital health offerings in your jurisdictions?

The Sale of Goods Act 1893 and the Sale of Goods and Supply of Services Act 1980 set out statutory implied warranties that apply to a contract for the supply of goods or services, such as correspondence to description, fitness for purpose and merchantable quality. Digital health providers can potentially exclude most of the warranties in its commercial contracts (although more restrictive rules apply to the exclusion of statutory warranties when contracting with consumers).

In a consumer-facing contract, the Sale of Goods and Supply of Services Act 1980 (as amended) requires a supplier of services (acting in the course of a business) to provide the service using a reasonable level of care and skill, within a reasonable time frame and at a reasonable cost. The Sale of Goods Act 1893 requires that goods or services sold or supplied by traders to their customers be of merchantable quality, fit for purpose they were bought for and as described. Consumer redress may include a right to get a repair, replacement, reduction in price or refund and, in the case of a major fault, they may be entitled to rescind the contract.

The European Communities (Unfair Terms in Consumer Contracts) Regulations 1995 provide that consumers will not be bound by terms imposed by the trader if they are deemed unfair to them. For the particular term or terms to be unenforceable, it must be contrary to the requirement of good faith or cause a significant imbalance of power to the detriment of the consumer.

The Schedule to the Regulations sets out a non-exhaustive 'grey list' of contract terms that may be found to be unfair. The Competition and Consumer Protection Commission (CCPC) may investigate complaints by consumers about unfair terms and has the power to go to the Circuit Court or the High Court to obtain a declaration that a particular term is unfair on the consumer and should be binding on them.

The Consumer Protection Act 2007 makes it a criminal offence for a merchant to make a false or misleading claim about goods, services and prices. It also protects consumers against misleading, unfair, prohibited and aggressive commercial practices.

If merchants engage in those practices and their customers make a complaint to the CCPC, it has the power to issue fines or imprisonment, or both. A range of serious enforcement actions can be taken in line with the Consumer Protection Act 2007, including prohibition orders, fixed payment notices and requiring the merchant to give an undertaking. The CCPC may issue a compliance notice where the merchant is committing or engaging in a prohibited act or practice and require them to comply with directions.

The European Union (Consumer Information, Cancellation and Other Rights) Regulations 2013 introduced additional consumer rights, and there are also pre-contractual information obligations with which traders must comply. Consumers are provided with a cooling-off period of 14 days from the date on which they receive the goods. In the case of a contract for services, the cooling-off period expires 14 days after the contract starts.

There are some statutory exceptions when cooling-off periods will not apply in the context of digital products where the consumers expressly waive their cooling-off rights and acknowledge that they understand this at the time of commencement of the digital service.

The European Communities (Certain Aspects of the Sale of Consumer Goods and Associated Guarantees) Regulations 2003 require goods to be in conformity with the contract.

The European Communities E-Commerce Regulations 2003 (the E-Commerce Regulations) require that in e-commerce, the following information must be on a digital health provider's website:

- name;
- address;
- contact details (email address);
- company registration number (or equivalent registration number in relevant jurisdiction); and
- VAT number.

To comply with the E-Commerce Regulations, digital health providers should:

- ensure commercial communications are clearly identified as such;
- ensure any unsolicited commercial communications are clearly identified as such;
- supply certain information prior to an order being placed and a contract being concluded electronically; and
- provide a receipt of the order without undue delay and by electronic means.

Digital health providers must have standard e-commerce documentation in place, such as applicable terms and conditions, a privacy policy and a cookie policy in place for the cookies dropped on its website.

The upcoming Digital Services Act will be implemented as an EU Regulation and will largely uphold the current liability regime under the E-Commerce Directive. It contains new obligations in relation to digital services that connect consumers to goods, services and content, as well as new procedures for faster removal of illegal content and measures for protecting users' fundamental rights online.

There are specific measures set out for intermediary service providers of a mere conduit service, a caching service or a hosting service. There will also be reporting obligations for removing and disabling information that is illegal or contrary to providers' terms and conditions, as well as mechanisms to allow third parties to notify the presence of illegal content.

There is a specific exception for micro or small enterprises, which employ fewer than 50 persons and whose annual turnover does not exceed €10 million. All other platforms will be required to have an internal complaint-handling system and to make decisions about illegal content or information violating the provider's terms and conditions. Very large platforms, which are those that reach 45 million users or more, will be required to:

- carry out risk assessments on the use and functioning of their services; and
- put mitigating measures in place to protect users from illegal content, goods and services.

The Proposed text for the Digital Services Act is still at draft stage and has yet to be discussed with the European Parliament and the European Council.

PAYMENT AND REIMBURSEMENT

Coverage

24 Are digital health products and services covered or reimbursed by the national healthcare system and private insurers?

In Ireland, the HSE has statutory responsibility for medicine and non-drug (medical device) pricing and reimbursement under the Health (Pricing and Supply of Medical Goods) Act 2013 (the 2013 Act). There is a standard application procedure (other than for cancer drugs) to have products included on a reimbursement list through which suppliers can make reimbursement applications to the HSE. Ireland does not have a distinct approval procedure for reimbursements for rare disease medicines or hi-tech products.

The 2013 Act outlines the criteria for decisions regarding the reimbursement of medicines and non-drug products (medical devices). The decisions made by the HSE are made objectively, and they are advised by the National Centre for Pharmacoeconomics, which makes recommendations on which medicines are to be reimbursed by the taxpayer.

UPDATES AND TRENDS

Recent developments

25 What have been the most significant recent developments affecting the digital health sector in your jurisdiction, including any notable regulatory actions or legislative changes?

Other jurisdictions have witnessed a rise in product liability claims in relation to fitness trackers and wearables. Although this trend has yet to be seen before the Irish courts, this may not remain the case for long.

The Multi-Party Actions Bill, which is currently making its way through Irish parliament, will (if enacted) legislate for multi-plaintiff or group actions, including in respect of product liability claims. To date, multi-plaintiff litigation in Ireland generally progresses by way of a lead or pathfinder case. However, plans for the introduction of this piece of national legislation may have been overtaken by the adoption and coming into force of Directive (EU) 2020/1828 on representative actions for the protection of the collective interests of consumers.

Once implemented, this legislation will enable collective redress actions to be brought on behalf of Irish consumers, which is a development that could have a profound effect on the legal landscape in this jurisdiction, given that qualified entities, such as consumer organisations, will be able to seek both injunctive relief and collective redress measures on either a preventative or prohibitive basis against traders that infringe consumers rights across a wide range of EU legislation.

Coronavirus

26 What emergency legislation, relief programmes and other initiatives specific to your practice area has your state implemented to address the pandemic? Have any existing government programs, laws or regulations been amended to address these concerns? What best practices are advisable for clients?

In response to the covid-19 pandemic, the government enacted the Health (Preservation and Protection and other Emergency Measures in the Public Interest) Act 2020 (signed on 20 March 2020) and the Emergency Measures in the Public Interest (Covid-19) Act 2020 (signed on 27 March 2020).

A number of statutory instruments have also been enacted since March 2020 to make temporary amendments to the Health Act 1947 (Section 31A Temporary Requirements). This includes measures such as mandatory face coverings on public transport. In 2021 this was extended to include the following as relevant premises: credit unions, post offices and banks (SI No. 20/2021 Health Act 1947 (Section 31A Temporary Restrictions) (Covid-19) (Face Coverings in Certain Premises and Businesses) (Amendment) Regulations 2021).

Specific to product liability, a number of initiatives were commenced to get products and devices to the market as urgently as possible. For example, the European Communities (In Vitro diagnostic medical devices) (amendment) Regulations 2020 (SI No. 145 of 2020) gave the Minister of Health the power to authorise non-CE marked in vitro diagnostic medical devices and the European Communities (medical devices) (amendment) Regulations 2020 (SI No. 144 of 2020) gave the Minister of Health the power to authorise particular non-CE marked medical devices so that those could be urgently used on the Irish market where required.

The Health Products Regulatory Authority (HPRA) is responsible for the regulation of medical devices and the Health and Safety Authority is responsible for the regulation of personal protective equipment (PPE). If a manufacturer wishes to supply a product that could assist in the fight against the covid-19 pandemic, it must consider relevant industry guidance and notifications from the industry-specific competent authority as there are a number of guidance documents and expedited ways of getting those products or devices to the market.

The latest updates on covid-19 guidance can be found of the HPRA's website.

The National Standards Authority of Ireland and SAI Global have also developed the COVID-19 Response Package, which provides access at no cost to a series of Irish, American, European and International standards for medical devices and PPE to organisations involved in the fight against covid-19.

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