

## Life Sciences & BioTech



Ireland is home to an unrivalled number of the world's leading life sciences and BioTech companies operating in areas such as Pharmaceuticals, Biotechnology, Medical Devices and Diagnostics across the R&D, production and distribution sectors.

This includes ten of the top ten global biopharma companies and fifteen of the top twenty-five medical technology companies. It also includes a number of companies born in Ireland, such as ICON plc, as well as leading multinationals, such as Medtronic, Jazz Pharmaceuticals and Alkermes plc, who have in recent years chosen Ireland as their global base. The continued growth and future success of this sector in Ireland is supported by the continued focus and investment of the Irish Government, State agencies (in particular IDA Ireland), academic and research institutions and the investment community.

### Regulatory Regime

The supply and manufacture of medical products and devices in Ireland is largely regulated by EU Directives, which have been transposed and supplemented in Ireland by national legislation. Depending on the type of activity being carried on by a life sciences company in Ireland, prior regulatory authorization may be required. The principal regulator for the life sciences and biotech industry in Ireland is the Health Products Regulatory Authority (the **HPRA**). The HPRA boasts an international reputation for regulatory compliance and works closely with businesses and other certification agencies to achieve trouble-free compliance for life sciences companies doing business in Ireland.

### Manufacturing Medicinal Products

A manufacturer's/importer's authorisation (**MIA**) is required in order to manufacture medicinal products for use by humans or animals in Ireland. Manufacturing activities in this context includes manufacturing, processing, primary or secondary packaging, batch certification, quality control, as well as importation of a medicinal product from outside the EEA.

In Ireland, applications for an MIA are submitted to the HPRA. An MIA will only be granted if the applicant has at its disposal suitable and sufficient premises, equipment, facilities, staff, manufacturing operations and arrangements for quality control, record keeping, handling, storage and distribution. The applicant must have permanently and continuously at its disposal the services of at least one "Qualified Person". A Qualified Person must have certain minimum qualifications defined in law and this person is responsible for ensuring that each release of medicinal products complies with the law and applicable regulatory requirements.

A wholesale/distribution license may be required in addition to a MIA in certain circumstances depending on the activities being carried on. Wholesale/distribution activities include procuring, holding, supplying medicinal products within the EEA or exporting products outside the EEA.

### Marketing Medicinal Products

A marketing authorisation (**MA**) is required before a medicinal product is placed on the market in Ireland. An application for a MA must be made to the HPRA or, where appropriate, the European Medicines Agency (**EMA**). There are a number of different application procedures for obtaining an MA and the applicable procedure will depend in each case on the type of medicinal product in question and the countries in which it will be marketed.

### Compliance with Post-Marketing Obligations

Irish and EU legislation require an MA holder to comply with pharmacovigilance obligations. These obligations require an MA holder to:

- employ a qualified person to establish and maintain the system of pharmacovigilance, maintain a

pharmacovigilance system master file and operate a risk management system;

- maintain a detailed record of all suspected adverse reactions to a medicinal product and report such reactions to the EudraVigilance database within 15 days in cases of serious suspected adverse reactions or 90 days in cases of non-serious suspected adverse reaction;
- submit periodic safety update reports to the HPRA or EMA containing information regarding the risk-benefit balance of a medicinal product;
- ensure that sufficient supplies of a product are provided to pharmacies; and
- ensure a product's information contains the most current scientific knowledge.

### Packaging, Labelling & Advertising of Medicinal Products

EU rules, which have been incorporated in to Irish law, regulate the packaging and labelling of medicinal products in Ireland. These rules requires certain information, such as storage instructions, expiry dates and method of administration, to be contained on the packaging of a product. The proposed labels and packaging for a product must be submitted to the HPRA for approval when applying for an MA.

Advertising prescription-only medicines or controlled drugs to the general public is prohibited in Ireland. The advertising of medicinal products that are not the subject of a marketing authorisation is also prohibited.

Advertising authorised medicinal products to healthcare professionals is permitted where certain essential information is included in the advertising regarding the product and the MA holder.

The IPHA's Code of Practice for the Pharmaceutical Industry prohibits its members from supplying, offering or promising any gift, pecuniary advantage or benefit-in-kind to a person qualified to prescribe or supply medicinal products, unless it is relevant to the

practice of medicine or pharmacy and it is inexpensive. Pharmaceutical companies may give free samples to healthcare professionals. However, samples must be provided on an exceptional basis and must not exceed four per year. Since 1 January 2015, the IPHA Industry Code has promoted greater transparency in this area by requiring that direct and indirect transfers of value from pharmaceutical companies to healthcare professionals and organisations are documented and publicly disclosed by pharmaceutical companies.

### Medical Devices

The supply and manufacture of medical devices in Ireland is largely regulated by EU Directives, which have been transposed and supplemented by national legislation. The HPRA is the competent authority in Ireland for medical devices. Its role is to regulate medical devices on the Irish market to ensure that they meet the safety requirements of the national and EU legislation. The National Standards Authority of Ireland is the notified body in Ireland responsible for carrying out conformity assessments for the purposes of CE and other certifications applicable to medical devices. Its role is to develop and promote standards for the medical device industry.

The European Parliament formally adopted new regulations in April 2017 which, once effective, will modernize and replace the existing medical devices regime. The aim of these new regulations is to establish a modernised and more robust EU legislative framework to ensure better protection of public health and patient safety. The new rules will impose tighter controls on high-risk devices, requiring a pool of experts at the EU level to be consulted before placing the device on the market. They will also make vital information regarding medical devices more easily available.

### Clinical Trials

The conduct of clinical trials in Ireland is governed primarily by EU Directives, which have been incorporated into Irish law.

A new clinical trials regulation (the **Clinical Trials Regulation**) was adopted by the European Commission in July 2012, the aim of which is to simplify and harmonise the way in which clinical trials are authorised and regulated in the EU. This is expected to replace the existing clinical trials regime in October 2021, following a three year transitional period (commencing in October 2018).

#### Defective or Inadequate Products

Suppliers of medicinal products and devices are also subject to general Irish and EU laws regarding product safety.

The European Communities (General Product Safety) Regulations 2004 (the **2004 Regulations**) (which

implement a related EU Directive) impose a duty on manufacturers to ensure that products placed on the market are safe and do not pose a risk to the health or safety of consumers. A supplier of goods also has obligations under the Sale of Goods Act 1893 and the Sale of Goods and Supply of Services Act 1980, including a duty to ensure that goods are of merchantable quality.

The Liability for Defective Products Act 1991 (which also implements an EU Directive) provides for strict liability if a product is found to be defective. The producer, importer or any party that holds itself out as a producer by placing their name or trade mark on a defective product, may be liable for damage or injury caused.

#### Brexit: What Does it Mean for Life Sciences Companies?



Following the UK's exit from the EU, unless special arrangements are agreed between the UK and the EU:

- The EU pharmaceuticals regulatory regime will no longer apply to the UK. The movement of pharmaceuticals and related products and services, as well as people between the EU and the UK will become more difficult.
- EU funding of Research & Development in UK universities and institutions will likely be cut.
- EU research programmes will likely no longer involve UK institutions.
- The European Medicines Agency will leave the UK.

As a committed member of the EU and eurozone, Ireland offers an unrivalled value proposition for life sciences companies doing business in the EU in a post-Brexit marketplace. In addition to the attractive incentives outlined at Chapter 1, Ireland has made a compelling bid to host the European Medicines Agency in the aftermath of Brexit. A favorable decision in this regard will further bolster Ireland's position as the location of choice for life sciences companies seeking access to the EU single market.

## Life Sciences Companies in Ireland

