



Life Sciences in Ireland

Ireland is already global leader in the life sciences industry. Continuous international investment since the 1960s has made Ireland the location of choice for international life sciences companies, accounting for 32% of GDP and €140 billion in exports.

Pharmaceuticals and Biotech: Ireland exports pharmaceuticals worth over €45 billion annually, making it the largest net exporter of pharmaceuticals in the world. 85 pharmaceutical companies and 18 of the world's top 20 pharmaceutical companies have substantial operations in Ireland. Six of the world's top 10 selling pharmaceutical products are exclusively produced here and 50 of our manufacturing sites are FDA approved. More than US\$8 billion has been invested in biopharma facilities in Ireland.

Medtech: Nine of the world's top 10 medtech companies have operations in Ireland, with Ireland employing the highest number of medtech personnel per capita in Europe. Ireland exports €12.6 billion in medtech every year, the second largest in Europe.

Research & Development: The development of the Irish Life Sciences manufacturing sector has also fuelled significant Research and Development activity by many multinationals, in collaboration with the Irish SME sector and Irish third level institutions. Ireland currently has five clinical research facilities, which support patient-focused research and is ranked number one globally for the exchange of technology and ideas.

Regulatory Regime: Irish regulation of the manufacture, importation, distribution, sale and marketing of pharmaceuticals, cosmetics, medical devices and food derives primarily from European Directives, transposed into Irish law. The Health Products Regulatory Authority (HPRA), established in 1995, is the competent authority in Ireland responsible regulating medicines, medical devices, cosmetics and other health products. The Food Safety Authority of Ireland (FSAI), established in 1998, performs similar functions in respect of the food industry and coordinates the enforcement of food safety legislation in Ireland in conjunction with the Environmental Health Office of the Health Services Executive.

Commercial Contracts and Licensing: As a common law jurisdiction Irish contract law and forms and their drafting, negotiation and interpretation will be familiar to legal and commercial teams working within the US or Canadian legal systems or who have used English law previously.

Incentives: In addition to an educational system, workforce and financial and legal advisors with decades of experience in the sector, the Irish government offers a range of incentives to life sciences businesses operating in Ireland, including globally competitive tax rates. In addition, Ireland has excellent connectivity with North America and Europe and is now Europe's only English speaking, eurozone country with a common law legal system.

Advanced Manufacturing: Over the past 10 years Ireland has transitioned seamlessly from the manufacturing of API to advanced biotech manufacturing in order to meet fundamental changes such as globalisation, technology and the growth of emerging markets.



Brexit: Ireland is the only European country with a physical border with the United Kingdom and has a long history of working with the United Kingdom in resolving a range of complex issues. Given our geographic location and experience Ireland is uniquely placed to manage the UK-EU Trade and Cooperation Agreement, which has been reflected in the Northern Ireland Protocol. Ireland's proximity to the UK and longstanding cooperation between the MHRA and HPRa has also facilitated the smooth transfer of many regulatory authorisations and functions in the sector to Ireland.

Why Irish Law and Irish lawyers for Life Sciences?

Many years advising leading global life sciences businesses, an active and highly regarded regulator, a collaborative court system and experienced legal professionals has created an expert and competitive legal market and sophisticated legal system to serve the sector.

Predictability of A Common Law Legal System: Ireland is the only fully common law jurisdiction in the EU. As with courts in other common law jurisdictions, like England and North America, Irish courts are bound by the doctrine of precedent, meaning that all courts must follow prior decisions of superior courts and courts of equal jurisdiction. This provides a degree of certainty and predictability which may be absent from other legal systems.

Easy Recognition and Enforcement of Foreign Judgments: Our continued membership of the EU ensures that judgments of the Irish courts will be easily recognised and enforced throughout the EU. Ireland is the only English speaking jurisdiction in the EU in which the Brussels I Regulation, the Recast Regulation and the Lugano Convention 2007 apply.

Dispute Resolution: Since the withdrawal of the United Kingdom from the EU the Irish legal system, courts and arbitral tribunals have become a leading centre for dispute resolution in international litigation and arbitration, capitalising on the technological advancements and improvements made in response to the pandemic.

The Commercial Court: Ireland's Commercial Court, a division of the High Court established to deal with commercial disputes, is recognised internationally for its efficient and effective approach to commercial litigation. Judges assigned to the Commercial Court have extensive experience of and expertise in adjudicating on commercial disputes, and regularly preside over high value disputes with an international dimension. To be admitted to the Commercial Court, cases must, broadly speaking, be "commercial" in nature and have a value of over €1 million. Intellectual property disputes and appeals (or judicial reviews) of regulatory decisions may be admitted regardless of the value of the case.

Intellectual Property Enforcement and Disputes: Protection of IP is vital to the life sciences industry and more information on how Ireland is well placed to assist can be found here <https://www.irelandforlaw.com/enforcement-intellectual-properties>

Legal Technology: The increased use and better integration of technology in the Irish courts in 2020, brought about by the onset of the COVID-19 pandemic, has provided, and will continue to provide, greater access and efficiency for businesses in Ireland and internationally. The Irish Courts Service, working with the legal community, moved swiftly to introduce remote hearings to ensure the continued administration of justice even at the height of the COVID-19 restrictions. This allowed the superior appeal courts, the Court of Appeal



and the Supreme Court, to hear all appeals remotely, and to continue their business without any backlog. At High Court level, while there was an inevitable reduction in the number of cases heard due to social distancing requirements, much of the High Court work, including that of the Commercial Court, continued remotely.

The courts have also moved to direct and facilitate full remote witness hearings. Legislation introduced in 2020 allows judges to direct that hearings proceed remotely, even where one party may object, and to direct the technology that may be used. The legislation also allows the Chief Justice and the Presidents of the various court divisions to direct that certain categories or types of proceedings be heard remotely.

The response of the Irish courts to the challenges posed by the COVID-19 pandemic, and the strong leadership shown by the Chief Justice and the President of the High Court, in particular, demonstrate clearly that the Irish courts and Irish judges are determined to allow the business of the courts to continue, even in the most challenging of circumstances. It is likely that remote hearings will continue to be a feature of the Irish court system, certainly in respect of routine court applications not requiring oral evidence. The continuing development and adoption of electronic alternatives (e.g., predictive coding, technology assisted reviews, paperless hearings) to traditional paper-based practices is increasing, and this reflects credible progress and enthusiasm to ensure that the Irish legal system continues to evolve.

Future Developments: In 2020, a high-level review group, chaired by the former head of the Commercial Court and President of the High Court, established to review the administration of civil justice in Ireland, published a report with over ninety recommendations for reform. The recommendations are aimed at streamlining process, reducing legal costs and shortening the time period involved in civil litigation. The Irish Government has given its commitment to implementing the reforms. Amongst the recommendations is the establishment of a specialist adjunct to the Commercial Court, to hear and determine intellectual property and technology disputes. This will ensure that the courts of Ireland will remain an attractive forum for the resolution of disputes in as timely and cost-effective a manner as possible. The Group also recommended the introduction of an entirely new and more efficient and cost effective discovery regime, the introduction of pre-action protocols in general High Court litigation, more extensive use of case management, limitations on adjournments, increased efficiency around the use of expert evidence, and guidelines in relation to litigation costs.