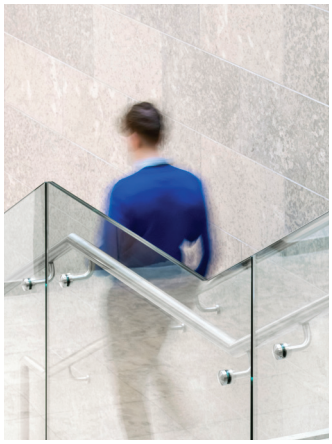
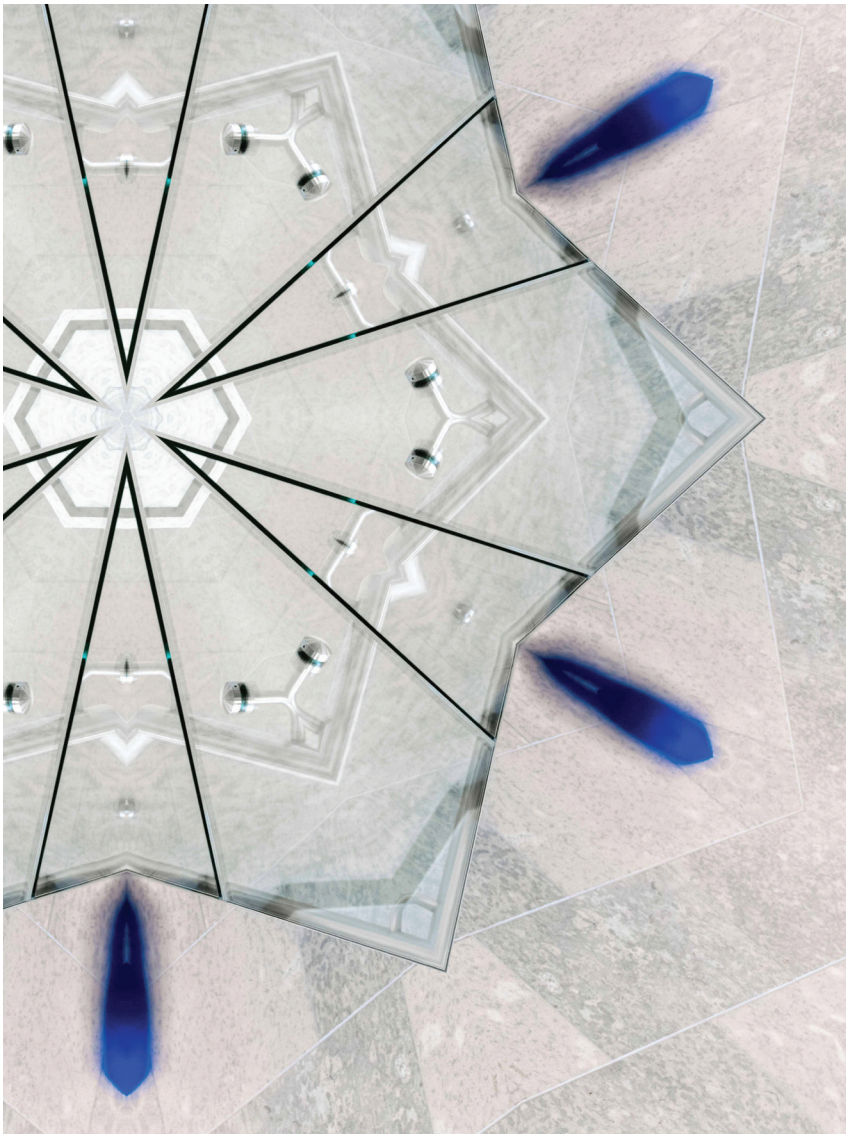
ARTHUR COX





LIFE SCIENCES

Regulatory and Compliance - Our Expertise

As one of the country's leading law firms, we are best placed to advise on all Life Sciences regulatory and compliance matters in Ireland, which has emerged as a global hub for the Life Sciences industry. Our Life Sciences Group offers experienced legal, regulatory, and strategic advice in a competitive and evolving EU and Irish pharmaceutical, biotech, medtech, food and cosmetics market. The Group partners with clients through the lifecycle of products from development right through to marketing, providing specific advice on all aspects of regulatory and compliance.

IP Transactions and Advisory Firm of the Year 2022 (Ireland)
Managing IP Awards

Ireland Law Firm of the Year 2022
IFLR Europe Awards

Green Professional Services Award 2022
The Green Awards

M&A Legal Advisor of the Year 2022
Mergermarket European M&A Awards

International Firm of the Year 2021
Legal Business Awards

Ireland Law Firm of the Year 2021
IFLR Europe Awards

Ireland Corporate Firm of the Year 2021
IFLR Europe Awards

M&A Deal of the Year (AbbVie / Allergan)
IFLR Europe Awards

Accenture Outside Counsel Diversity Awards
2021 Winner

Ireland Firm of the Year 2021
Benchmark Litigation Europe Awards

Ireland Firm of the Year 2021
Women in Business Law Awards

Best National Firm for Minority Lawyers 2021
Women in Business Law Awards

1920
FIRM ESTABLISHED BY ARTHUR COX

740
EMPLOYEES

530
LEGAL STAFF

100
PARTNERS

"It's a great firm for corporate and regulatory life sciences matters."

CHAMBERS EUROPE: EUROPE'S LEADING LAWYERS FOR BUSINESS, 2020

Sources are "extremely impressed with their commercial, practical and creative approach."

CHAMBERS EUROPE: EUROPE'S LEADING LAWYERS FOR BUSINESS, 2019

FOCUS ON IRISH LIFE SCIENCES

Ireland has secured a global leadership position in the life sciences industry and four decades of continuous investment has made Ireland the location of choice for international life sciences companies.

This industry now employs over 50,000 people directly and exports over €45 billion annually making Ireland the largest net exporter of pharmaceuticals in the world. Eighteen of the world's top 20 pharmaceutical companies have substantial operations in Ireland and six of the world's top 10 selling pharmaceutical products are exclusively produced here. Ireland is also home to Europe's leading medical technologies cluster and now has the highest per capita employment of medical technologies personnel across Europe.[1]

EXPERIENCE

Our team advises on all aspects of life sciences compliance and regulation including:

Clinical Trials and Investigations

- Advising on requirements for approval of clinical trials by ethics committees and competent authorities;
- Advising on all aspects of transparency and data privacy of trial data;
- Drafting and negotiation of clinical trial, principal investigator and research development for collaboration agreements or multi-centre trials.

Authorisation and life cycle management

- Advising on issues related to post-marketing vigilance activities including adverse event reporting and product recalls;
- Assisting in the establishment of regulatory pathways to market medicinal products, combination products, medical devices and borderline products;
- Assisting clients with challenges to decisions by the Irish Health Products Regulatory Authority (HPRA) and the NSAI concerning the classification, regulation and promotion of products, as well as the Department of Health and Agriculture and the Health Service Executive (HSE) with regard to pricing;
- Advising on EU orphan drug designation, data and market exclusivity and supplementary protection certificates;
- Preparing and reviewing supply, distribution, manufacturing, packaging and pharmacovigilance agreements.

Compliance with anti-bribery and transparency requirements

- Assisting in negotiating and drafting agreements with physicians and other healthcare professionals;
- Advising clients on hospitality arrangements and gifts provided to healthcare professionals;
- Providing advice in relation to transparency requirements, including disclosure of transfers of value and other benefits to healthcare professionals and healthcare organisations.

Promotion and marketing

- Advising on advertising and promotion of products, including experience as a member of the promotional review team of a global pharma company;
- Assisting in developing EU-wide and Irish-specific promotional and marketing policies;
- Advising on development of product-related and disease awareness websites with regard to EU and Irish rules on marketing of medicinal products.

Transactional

- Conducting due diligence in connection with commercial transactions in the pharmaceutical sector.

OUR TRACK RECORD

Recent work completed by our Life Sciences Group includes:

Clinical Trials and Investigations

- Advising a leading Irish healthcare institution on establishing a multi-jurisdiction framework for conducting clinical trials and investigations of medicinal products and medical devices
- Advising hospitals, sponsors and CRO's on the regulatory aspects of conducting clinical trials and investigations in Ireland

Authorisation and life cycle management

- Assisting clients in challenging a medical device classification decision by HPRA
- Advising manufacturers, brokers and wholesalers of medicinal products on their registration requirements, the Falsified Medicines Directive and their obligations in relation to the licensing, importation and distribution of medicinal products
- Advising a market-leading medical devices company on the regulation, including the CE marking, of medical devices in Ireland, and on the packaging and labelling requirements

Compliance

- Providing advice in relation to disclosure of payments to healthcare professionals and healthcare organisations and other related transparency requirements
- Advising a multinational pharmaceutical company on preparation for Competent Authority inspections
- Advising healthcare clients on all aspects of regulatory compliance and interaction with HIQA/HPRA

Promotion and Marketing

- Advising US pharmaceutical companies on the promotion of prescription medication in Ireland and the EU
- Advising food supplemental manufacturers on the promotion of food substances in Ireland and the EU

Transactional

- Advising a major pharmaceutical manufacturer on the regulatory aspects of the disposal of a manufacturing plant in Ireland
- Advising a multinational pharmaceutical company and the regulatory aspects of the restructuring of its Irish subsidiaries and related marketing and manufacturing authorisations

1 As reported by Enterprise Ireland's *Life Sciences Directory*.

Our team

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