

C/M/S/ Cameron McKenna

# Lifesciences

Market leading legal solutions

At CMS Cameron McKenna we work hard to be a truly client focused law firm. This means understanding the unique needs and challenges of each market sector, and providing a service that is tailored to the particular concerns and requirements of each client.



*“The experience of the people involved in the transaction counts, there’s no substitute for that.”*

*Chief financial officer, leading biopharmaceutical company*

## Client-based solutions

Anyone can claim to be truly client focused. At CMS Cameron McKenna, we’ve launched one of the legal sector’s most comprehensive client feedback programmes to measure just how focused we are. Here are some of the findings:

**We build strong, long term relationships** – clients recognise that our approach is very different to some other firms that focus primarily on transactions.

**Our partners are ‘hands on’** – our clients tell us we are often more approachable and accessible than many other organisations.

**We’re pro-active** – clients praise our approach to alerting them to issues. Our unique online information service, Law-Now, is consistently praised for its ‘first to market’ approach to addressing legal developments and news.

**We’re flexible** – with clients ranging from multinationals to smaller, privately-owned companies, we have learned to be flexible in our approach and in managing our resources.

All of which goes to show why so many businesses choose to work with us. Time and time again.

Our track record of advising on a wide range of issues in the lifesciences sector, coupled with our insight developed through many long-term relationships with the industry's key players, means that our clients benefit from working with a team that really understands the sector and its issues.



**"The firm's expertise in product liability, product safety, medical device regulation is not only formidable, but in some cases unique."**

*Group Managing Director, medical equipment manufacturer*

## Our know-how, your benefit

Using our know-how for the benefit of our clients is what CMS Cameron McKenna is all about. We have been involved in the lifesciences sector from the very beginning, often helping to establish businesses that have grown to become global players.

Our approach is based upon multi-disciplinary teamwork and specialisation. Several members of the team are medically or scientifically qualified in addition to being lawyers. Many of them have experience working within pharmaceutical companies. All team members devote time to maintaining their knowledge of the sector to keep abreast of developments, whilst building an extensive network of useful relationships throughout the world.

## The Lifesciences team

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## Our range of services

Our lifesciences team advises on a wide range of legal issues. Our clients range from entrepreneurs and SMEs to major institutions and the largest multinationals.

### Regulatory

We have extensive experience in the licensing of medicinal products and pre-market approval procedures for other medical products (including devices, diagnostics and human engineering), both at UK and EU level, appeals against licensing decisions and on pricing and reimbursement issues in the UK.

We also advise on the application of all relevant regulations and codes of practice governing labelling, advertising, prescriber and patient information, legal status, post-marketing surveillance, adverse reaction reporting and parallel imports. (We also provide similar advice in relation to cosmetics, novel and other foods - especially those claiming specific health benefits and pesticides). We have a wealth of experience in considering and advising on 'borderline' issues, especially in the context of marketing and labelling requirements of such products.

Many of the issues concerning medicinal products apply irrespective of whether the product is derived from conventional technology, high-technology or biotechnology processes. We also advise on the wide range of issues arising from the rules and guidelines specific to high-technology and biotechnology products and the use of human tissue.

### Pre-clinical and clinical research

We advise on both the regulatory aspects of research and development, and on relevant commercial control. We have extensive experience in the application and implementation of international guidelines relating to good laboratory practice and good clinical practice.

We have considerable experience of approval of research proposals by Ethics Committees (Institutional Review Boards) and a number of our team are or have been members of Ethics Committees. We have also been involved in the preparation and negotiation of specific insurance policies for clinical research.

### Collaboration and licensing

We advise companies on the commercial arrangements associated with research and development, including collaborative R&D agreements and agreements between clinical trial investigators and contract research organisations. We also regularly advise clients on licensing-in technology from universities, their spin-out companies and other organisations. We also advise on joint development and marketing agreements.

### Financing

We are continually involved in venture financing, equity financing, private placings, public offerings and other forms of finance required by companies. We have worked on a succession of IPOs for biotechnology companies. Our work includes liaison with overseas firms which specialise in raising finance in their markets, notably in the USA and Japan.



**“The firm’s biotech practice is exceptionally strong and it is difficult to see why the firm would not at least appear on any biotech company’s shortlist for strategic commercial advice or finance expertise.”**

*The insider’s guide to legal services, Pharmaceutical and Biotechnology*

## **Strategic alliances, mergers and acquisitions**

We have been involved in some of the major mergers, acquisitions and joint ventures of recent years, many of which have raised significant EU competition law issues.

A particular hallmark of our activities in this area has been advising biotechnology companies in connection with their strategic alliances, whether sponsored collaborations, strategic partnerships, co-promotion or co-marketing arrangements, with larger companies. Our experience in this particular area is second to none; we have been heavily involved in this type of work since 1980, advising on more than 150 such transactions.

## **Distribution and parallel import issues**

Entry into the European market, especially through co-promotion and co-marketing arrangements, can raise difficult legal issues particularly due to the impact of EU competition law. Furthermore, the differing markets existing within the Europe give rise to practical parallel import problems. We regularly advise on all these issues. We have significant expertise in relation to trade marks and have advised multi-national organisations in all aspects of their acquisition, transfer and enforcement.

## **Patent protection and enforcement**

As well as advising on the difficult legal issues arising in relation to patentable subject matters we are often called to consider the impact of competitive patent positions and disputed license and other agreements. Considerations of validity and infringement require an appreciation of the latest cases in the area in the UK, the US and elsewhere. Many disputes result in a commercial settlement, particularly involving cross-licensing, and we have recently completed a major arrangement of this sort.

## **Branding, trade dress, advertising and labelling**

We frequently advise on branding, trade dress and advertising issues and the application of all relevant regulations and codes of practice.

We also advise in respect of significant brand protection issues for the Lifesciences Sector including look-alike and counterfeit products.

## **Competition and tendering**

We help companies structure their commercial dealings, assess their commercial and competition risks and, where necessary, make submissions on their behalf to the anti-trust authorities.

We regularly advise clients on the legal implications of greater centralised procurement and on specific tendering processes.

## **Product liability litigation**

Product liability is an increasing concern for multi-national companies as society becomes more litigious and laws and legal procedures across Europe change, usually to the advantage of the consumer. The pharmaceutical and related industries are particularly exposed in this field and most of the major product liability suits in Europe have to date concerned pharmaceuticals and medical devices. The characteristics of such litigation often involve multi-claimants, massive documentation and discovery, are increasingly multi-jurisdictional and involve the application of law to complex scientific issues. We are one of the very few firms in Europe which has substantial experience in this area, having been involved over many years in defending product liability actions for major healthcare companies in the UK and co-ordinating the defence of such claims across Europe.



CMS Cameron McKenna is the only law firm described as a 'leading' law firm in the lifesciences sector for its advice relating to: regulatory, corporate partnering, product liability and corporate and commercial work.

*Life Sciences 2005/06 - Global Counsel Handbooks*

## Health and safety

We provide specialist advice on the impact of health and safety legislation on the biotechnology, pharmaceutical and healthcare product sector. In addition to providing advice on compliance with the increasingly complex health and safety legislation, we handle personal injury claims and conduct the defence of criminal prosecutions under the legislation.

## Environment

We monitor new developments in environmental law and policy in the UK, at European Union level and in other jurisdictions. We lobby on behalf of clients, advise on detailed regulatory compliance and carry out environmental due diligence. We also advise on environmental impact assessment and management systems and liaise with regulatory authorities in relation to permits and authorisations.

## Employment

Being aware of and complying with applicable employment legislation is vital for any business. Our employment team provides advice to employers on employment contracts, handling disciplinary issues and dismissals, managed terminations/compromise agreements and redundancies. The team also supports the firm's work on M&A, joint ventures and outsourcing.

## Pan-European presence

As the lifescience industries become increasingly pan-European and less national in operation and outlook, legal expertise is sought, which encompasses not only knowledge and familiarity with the regulatory and legislative requirements of the EU but also national legal requirements and local codes of practice.

In this complex and regulated environment, where EU regulations and legislation co-exist with national laws and custom, it is vital to have access to a Europe-wide network of legal experts who can provide advice and assistance. The Central and Eastern European States represent new markets of interest and new opportunities for the Lifescience industries. The CMS team can provide access to local lifescience legal expertise in Western Europe, the Czech Republic, Hungary, Poland, Romania and Russia, as well as a detailed knowledge of the EU regulatory and legislative environment.

We have frequently provided simultaneous national, legal advice from our other European colleagues on specific issues, such as local laws and national codes of practice in respect of pharmaceutical advertising, or pricing and reimbursement issues thereby providing clients with a Europe-wide view of the current legal and regulatory climate in which they may optimise and develop their business.



Peers are full praise for CMS Cameron McKenna pointing to its involvement 'in some of the key cases' in lifesciences landscape as evidence that it is "constantly investing in this area".

*Chambers and Partners, 2007*

## Our recent experience

- Representing a US corporation in relation to a European-wide licensing arrangement for a biotech product.
- Representing a UK listed plc in relation to collaboration arrangements with an Italian company for the development, manufacture and marketing of products.
- Advising a UK listed plc on the development of standard form agreements for R&D and collaboration arrangements for biotech products.
- Representing a Japanese corporation in relation to a range of R&D agreements in relation to medicinal products.
- Representing a UK listed biotech in relation to a wide range of commercial arrangements.
- Representing one of the major US biotech corporations in relation to a range of R&D and commercial contracts relating to the UK market.
- Representing a US corporation in relation to its proposed acquisition of needle-free injection technology.
- Representing a charitable foundation in relation to exploitation issues in respect of results of its funded research in the lifesciences field.
- Advising a leading pharmaceutical company in relation to its litigation with UK parallel importers regarding the constraints upon repackaging parallel imports in conjunction with other cases.
- Representing a leading pharmaceutical company in relation to its disposal of 60 European OTC and personal care brands.
- Advising a research-based healthcare company in a very significant ICC arbitration in relation to the withdrawal of an antibiotic product.
- Representing a veterinary health arm of a pharmaceutical company in the investigation of the UK veterinary medicines market by the Competition Commission.
- Advising a leading vaccine developer in relation to claims made under the Consumer Protection Act 1987.
- Advising a biopharmaceutical company on an acquisition of cancer drug company, which included advising on all UK aspects of the transaction and preparation of detailed listing particulars.
- Advising a biotech company on a highly complex, court-approved scheme of arrangement for returning cash to shareholders and subsequently taking the company private.
- Advising a global pharmaceutical company on its product liabilities in the devices field.
- Advising a leading US manufacturer in relation to device regulatory issues.
- Advising major clients on regulatory matters, including data protection, pharmaceutical pricing, internet pharmacy, clinical trials, advertising and promotions, data exclusivity and compliance.
- Advising one of the leading US manufacturers of medicated stents on its EU-wide clinical trials.
- Advising a leading pharmaceutical company on product liability litigation (a potential group action) relating to a hip implant.
- Advising a leading biotech company on the EU launch of an innovative medical device in Europe.
- Representing a major US medical device manufacturer in UK product liability litigation.
- Advising US lifesciences consultancies and manufacturers on EU and UK product classification analysing device/drug/biologic/cosmetic borderline products.
- Advising major EU manufacturers on EU commercialisation and regulatory status of human engineered tissue.

## Law-Now™

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Receive expert commentary and analysis on key legal issues affecting your business. Register for free email alerts and access the full Law-Now archive at [www.law-now.com](http://www.law-now.com)

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