

C/M/S/ Cameron McKenna

Passionate about Medical Devices

2008



“Central and Eastern Europe
Law Firm of the Year.”

PLC Which Lawyer 2007

Client-based 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.

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.

European coverage – The CMS network comprises 57 offices with almost 4000 employees and covers the majority of jurisdictions across Europe. In those jurisdictions not covered by CMS we have established relationships with other leading firms.

Value for money – independent research scores us highly on being competitive on fees. We are committed to staffing projects at the right level to deliver excellent service at a fair price and we have the depth of resources to allow us to do this.

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

A focus on medical devices – We understand that the medical devices sector, as an area of the wider lifesciences industry, presents its own unique challenges and needs. As such we have a medical devices team who are focused on building the links and expertise required to deliver sector specific service to our medical devices clients and partners. We are proud of our ability to translate knowledge of the devices industry into sound commercial advice. We have experience of working with many of the industry's major manufacturers as well as with smaller more specialist companies.

We offer a one stop shop approach – We are an international law firm ranked in the top 10 in Europe. We have developed a network of lawyers specialising in medical devices regulation, liability and enforcement issues. The lawyers in our network are accustomed to working together on these areas of law and risk management and we are consequently able to co-ordinate cost-efficient and effective advice across Europe and beyond on this basis.

Our track record of advising on a wide range of issues in the medical devices 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.



"CMS Cameron McKenna act for 9 of the top 10 global medical device companies."

Mergermarket

Our know-how, your benefit

Multi-disciplinary teamwork – We have a team of lawyers and our approach is based upon a multi-disciplinary team bringing together experience that spans across several practice areas.

Knowledge of the sector – We have a unique knowledge of the medical devices sector and all the team members devote time to maintaining this knowledge. We also chair the legal committees of the ABHI, EUCOMED and are involved with BIVDA.

Extensive network – We combine the strengths and reputations of our member firms in their national markets with a leading European cross-border capability and build an extensive network of useful relationships throughout the world.

Understanding your business – several of our team members are medically or scientifically qualified in addition to being lawyers and have also experienced working within lifesciences companies helping us to understand your business in greater detail.

Our range of services

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

Intellectual Property

We advise regularly on many issues relating to intellectual property including:

- acquisition, transfer and enforcement of trademarks
- patentability of inventions
- competitive patent positions
- disputed licenses
- patent validity and infringement
- UK registered and unregistered designs
- community registered and unregistered designs
- copyright
- confidential information, trade secrets and know-how.

We are also involved with many issues relating to entry into the European market, in particular:

- parallel importing
- co-promotion/co-marketing
- anti-counterfeiting
- competition law.

Collaboration and licensing

We have extensive experience advising companies on commercial arrangements associated with research and development including:

- collaborative R&D agreements
- agreements between clinical trial investigators and contract research houses
- Licensing-in and licensing-out technology
- strategic alliances and alliances
- co-promotion and co-marketing
- manufacturing and supply agreements
- terms and conditions
- distribution and agency agreements
- cross licensing

Regulatory

We have extensive experience on all matters concerned with the CE marking of medical devices and diagnostic products (including combination products) as well as the marketing of tissue-engineered products both at UK and EC level including advising on:

- CE marking
- application of regulations, MEDDEVs and codes of practice

- labelling
- advertising (pre-post-market)
- user information
- patient information
- legal status
- post market surveillance
- product liability
- adverse reaction reporting
- medical devices vigilance and parallel importing
- licensing appeals
- pricing and reimbursement issues.

We provide similar advice in relation to medicinal products, cosmetics, novel and other foods, pesticides, high-technology and biotechnology.

Pre-clinical and clinical research

We advise on both the regulatory aspects of research and development and on relevant commercial control. In particular we have extensive experience advising on:

- conduct of clinical investigations
- application and implementation of clinical research MEDDEVs
- research proposals (a number of our team have been members of ethics Committees)
- preparing and negotiating insurance policies for clinical research.

Competition and tendering

We help companies structure their commercial dealings including advising them on:

- commercial and competition risks
- submissions on behalf of anti-trust authorities
- greater centralised procurement
- specific tendering processes.

Product liability litigation

Product liability is an increasing concern for multi-national companies, claims are often multi-claimant, involve massive documentation and discovery, multi-jurisdictional and involve complex scientific issues. We specialise in

- defending product liability actions
- co-ordinating multi-jurisdictional claims
- advising insurers on claims.

Mergers and acquisitions

We have been involved in some of the leading lifesciences mergers, acquisitions and joint ventures over recent years and have advised on:

- competition law issues
- strategic alliances
- sponsored collaborations
- strategic partnerships

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.

Financing

We are continually involved with:

- venture financing
- equity financing
- private placings
- public offerings.

We have also worked on a succession of IPOs for medical devices and biotechnology companies and often work with overseas firms specialising in raising finance notably in Japan and USA.

Health and safety

We provide specialised advice on

- impact of health and safety legislation
- compliance with legislation
- personal injury claims
- criminal prosecutions.

Environment

We have extensive experience in:

- advising on the impact and interpretation of current and proposed legislation including assisting with lobbying activities
- advising client on compliance and permitting issues and representing clients in connection with regulatory enforcement action
- carrying out due diligence and drafting and negotiating environment related contract wording
- advising clients in connection with contractual disputes and third party claims.

Employment

Being aware of and complying with applicable employment legislation is vital for any business. Our team provides advice to employers on a variety of issues including:

- employment contracts
- handling disciplinary issues
- dismissals
- managed terminations/compromise agreements and redundancies
- M&A, joint ventures and outsourcing.

“ABHI considers CMS Cameron McKenna to be the leading medical device law firm in Europe providing first class support to the industry across all legal specialities.”

Association of British Healthcare Industries (ABHI)

Our recent work

Medical device company

- Advising in relation to all intellectual property issues arising from licensing arrangements for a client involved in the manufacture of prosthetic limbs.

Major US based medical device company

- Advising on a potential third party claim for compensation in respect of an alleged failure to development and maintain a patent portfolio in respect of neuro-muscular blocking and monitoring technology.

Erbe Elektromedizin

- Acting in a multi-jurisdictional patent infringement dispute involving endoscopic probes.

A UK listed plc

- Advising in relation to collaboration arrangements with an Italian company for the manufacture and marketing of products.

A Japanese corporation

- Advising in relation to a range of R&D agreements in relation to medicinal products.

A US corporation

- Advising in relation to its proposed acquisition of needle-free injection technology.

A charitable foundation

- Advising in relation to exploitation issues in respect of results of its funded research in the lifesciences field.

A medical device company

- Advising on appeal against NICE preliminary guidance in a device technology appraisal.

A research-based healthcare company

- Advising in a very significant ICC arbitration in relation to a product withdrawal.

Medtronic Inc

- We acted for Medtronic Inc on its strategic collaboration with Lombard Medical Technologies plc in relation to the distribution and licence of Lombard's Relix™ endostapler.

A pharmaceutical company

- Representing the veterinary health arm in the investigation of the UK veterinary medicines market by the Competition Commission.

A leading vaccine developer

- Advising in relation to claims made under the Consumer Protection Act 1987.

A global lifesciences company

- Advising on its product liabilities in the devices field.

A leading US manufacturer

- Advising in relation to device regulatory issues.

A leading US manufacturer of medicated stents

- Advising on its EU-wide clinical trials.

A leading lifesciences company

- Advising on product liability litigation (a potential group action) relating to a hip implant.

A leading biotech company

- Advising on the EU launch of an innovative medical device in Europe.

A major US medical device manufacturer

- Advising on UK product liability litigation.

US lifesciences consultancies and manufacturers

- Advising on EU and UK product classification analysing device/drug/biologic/cosmetic borderline products.

Major EU manufacturers

- Advising on EU commercialisation and regulatory status of human engineered tissue.

Baxter Healthcare

- We advised on the disposal of its UK rental therapy services division to B Braun Avitum.

About us

CMS Cameron McKenna is ranked in 65 practice areas in the UK Legal 500 and Chambers & Partners. The firm advises across a range of business sectors and provides services to companies, financial institutions and governments. Full details of all the services we offer may be found on our website (www.law-now.com). In brief these include:

- Banking & International finance
- Capital Markets & Asset-Backed Securities
- Competition
- Corporate
- Dispute Resolution
- Employment
- Financial Services
- Health & Safety
- Immigration
- Intellectual Property
- Insurance
- IT
- Pensions
- Projects
- Project Finance
- Real Estate
- Tax

As the lifesciences industries become increasingly pan-European and less national in operation and outlook, legal expertise is required 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 either via CMS firms or Cameron McKenna's own offices in most CEE states.

We have frequently provided simultaneous legal advice from our other European colleagues on specific issues, such as local laws and national codes of practice in respect of medical devices regulatory liability, compliance and enforcement and risk management.

CMS is the European legal and tax services provider which is the natural choice for businesses based in, or seeking to move into, Europe. CMS combines a deep understanding of the legal, tax and commercial issues in its home jurisdictions with the broader perspective and expertise

which comes from an extensive European coverage, a common strategy and shared client service standards. CMS has 57 offices in 26 jurisdictions in Europe and beyond and is managed by a dedicated team based in Frankfurt. The organisation currently employs in excess of 2,000 lawyers, and operates in 45 business centres around the world. Working with us, you would benefit from our network of offices and extensive international connections.

All CMS member firms are major players in their local markets. The current firms are:

- CMS Adonnino Ascoli & Cavasola Scamoni (Italy)
- CMS Bureau Francis Lefèbvre (France)
- CMS Cameron McKenna (UK and Central and Eastern Europe)
- CMS Derks Star Busmann (The Netherlands)
- CMS von Erlach Henrici (Switzerland)
- CMS Hasche Sigle (Germany)
- CMS Debacker (Belgium)
- CMS Reich-Rohrwig Hainz (Austria)
- CMS Albiñana & Suárez de Lezo (Spain)

In those jurisdictions not covered by CMS we have established relationships with other leading firms.

“The CMS network is definitely something that is a feather in the cap and makes for a more seamless service.”

Client feedback

Support when and where you need it

CMS brings together leading legal and tax experts across Europe and beyond. CMS comprises nine European headquartered law firms, which include CMS Cameron McKenna LLP a founding member. CMS stands for exceptional client service and through its member firms delivers:

- Integrated, high quality services across all offices and jurisdictions
- Lawyers who regularly work closely together on cross-jurisdictional cases
- Coordinated advice and instructions are managed by a single contact

- Advice in many complex and highly regulated areas of law across Europe, including emerging markets in Central and Eastern Europe and China
- Access to market leading advice in the Middle East through our association with The Levant Lawyers www.tll.cc

CMS key facts

- 9 member firms
- 575 partners and over 2,000 lawyers
- 57 offices in 26 jurisdictions
- CMS covers the major EU markets and offers local advice with international coordination
- 8 Sector Groups bringing together sector specialists across Europe

CMS and associated offices



The Medical Devices team



Nick Beckett
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Nick's practice covers all areas of intellectual property (contentious and non-contentious), with particular expertise in patent litigation, patent counselling and parallel trade matters in the pharmaceutical, biotechnology, medical device and agrochemical sectors.

Nick has for many years advised numerous life-sciences clients on a variety of intellectual property issues relating to pharmaceutical products including fluoroquinolone antibiotics, non-sedating antihistamines, antidepressants, acellular pertussis vaccines, high affinity monoclonal antibodies, enzyme replacement therapy and Photodynamic therapy. Nick has also advised in relation to needleless injection devices, blood transfusion leucodepletion devices, argon plasmacoagulation probes, neuromuscular blocking monitor devices, prosthetics and contact lenses.



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Niall advises on a wide range of corporate matters, including private equity, M&A and corporate finance transactions with a particular focus on the lifescience sector. He has over 15 years' experience of advising on private equity and venture capital investments, advising both investors and investee companies. During 2006, he advised on six biotech funding rounds, three for investors and three for the companies.



Shuna Mason
Head of Regulatory
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Shuna is one of the few lawyers specialising in the law and regulation of medical devices and in vitro diagnostic devices. Shuna also has extensive experience in handling English product liability and other litigation and co-ordinating and managing product liability litigation and recalls across Europe and beyond for manufacturers, including numerous medical device manufacturers.

Shuna advises and represents medical device and IVD manufacturers in relation to vigilance and other compliance issues (including recall and field safety corrective action, labelling/IFU, promotion and product development compliance). She also frequently represents device companies when dealing with UK and EU regulatory authorities, particularly in connection with defence of regulatory prosecutions and administrative challenges to regulatory decisions. She is a member of the ABHI human tissue working group and is also a fluent German speaker.



David Marks
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David has specialised for over 20 years in EU and competition law, David advises on a broad range of areas from mergers and compliance issues to state aid and procurement. His work spans a cross section of industry sectors particularly in relation to lifesciences, as well as telecoms and infrastructure projects. David has practised in Brussels, as well as in London, and is a member of the legal committee of the Association of British Pharmaceutical Industries.



Sarah Hanson
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Sarah has over 10 years' experience of providing lifescience companies with corporate and commercial advice. She specialises in negotiating and drafting commercial agreements for biotech, pharmaceutical and medical device clients, including agreements relating to in and out licensing, sales and distributor arrangements, research and development, manufacturing and supply, strategic alliances and co-promotion and co-marketing arrangements. During her time with the firm she has been on secondment with Warner Lambert (now part of Pfizer).



Nicholas Stretch
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Nicholas specialises in employee share incentives and heads this area having previously been a partner at another city firm for several years. He acts for a number of lifesciences clients, ranging from small spin-outs to large, quoted companies.



Michael Draper
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Michael specialises in lifesciences-related transactions, including the financing of companies at all stages of their development, biopharma IPOs on major stock exchanges and secondary offerings. Michael also has extensive M&A experience in the sector and recently acted for Pfizer on its \$16.6 bn disposal of Pfizer Consumer Healthcare to Johnson & Johnson.



Jonathan Selvadoray
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Jonathan is the Chief Representative of CMS Bureau Francis Lefebvre Shanghai office. He advises on a wide range of corporate matters, with a particular focus on M&A and lifesciences related issues such as product liability. He specialises in drafting and advising on intellectual property licence agreements, collaboration arrangements (including research and development agreements, joint ventures, and partnerships), sales and distributor arrangements, research and development, manufacturing and supply. Jonathan also has experience advising in relation to patent, design, copyright, trademark, and confidential information issues. Before moving to China in 2002, he acted for more than two years as legal adviser at the Swiss Institute of Intellectual Property (department international trade relations) and member of the Swiss delegation to the WTO and was part of the negotiation team on the accession procedure of China. He has closely cooperated during that time with the Association of pharmaceutical research firms in Switzerland. Jonathan speaks English, French, German, Spanish and Chinese (Mandarin).

“The firm has cemented its position as a credible alternative to the magic circle firms, attracting attention with its resources and ability to manage multi-jurisdictional matters.”

Chambers and Partners, 2007

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The associated international offices of CMS Cameron McKenna LLP are separate and distinct from it.

CMS Cameron McKenna LLP and its associated offices are members of CMS, the alliance of independent European law firms. Alliance firms are legal entities which are separate and distinct from CMS Cameron McKenna LLP and its associated international offices.

CMS offices and associated offices worldwide: Amsterdam, Berlin, Brussels, London, Madrid, Paris, Rome, Vienna, Zurich, Aberdeen, Algiers, Antwerp, Arnhem, Beijing, Belgrade, Bratislava, Bristol, Bucharest, Budapest, Buenos Aires, Casablanca, Cologne, Dresden, Dusseldorf, Edinburgh, Frankfurt, Hamburg, Kyiv, Leipzig, Ljubljana, Lyon, Marbella, Milan, Montevideo, Moscow, Munich, New York, Prague, Sao Paulo, Sarajevo, Seville, Shanghai, Sofia, Strasbourg, Stuttgart, Utrecht, Warsaw and Zagreb.

www.cmslegal.com

The members of CMS are in association with The Levant Lawyers with offices in Beirut, Abu Dhabi, Dubai and Kuwait.