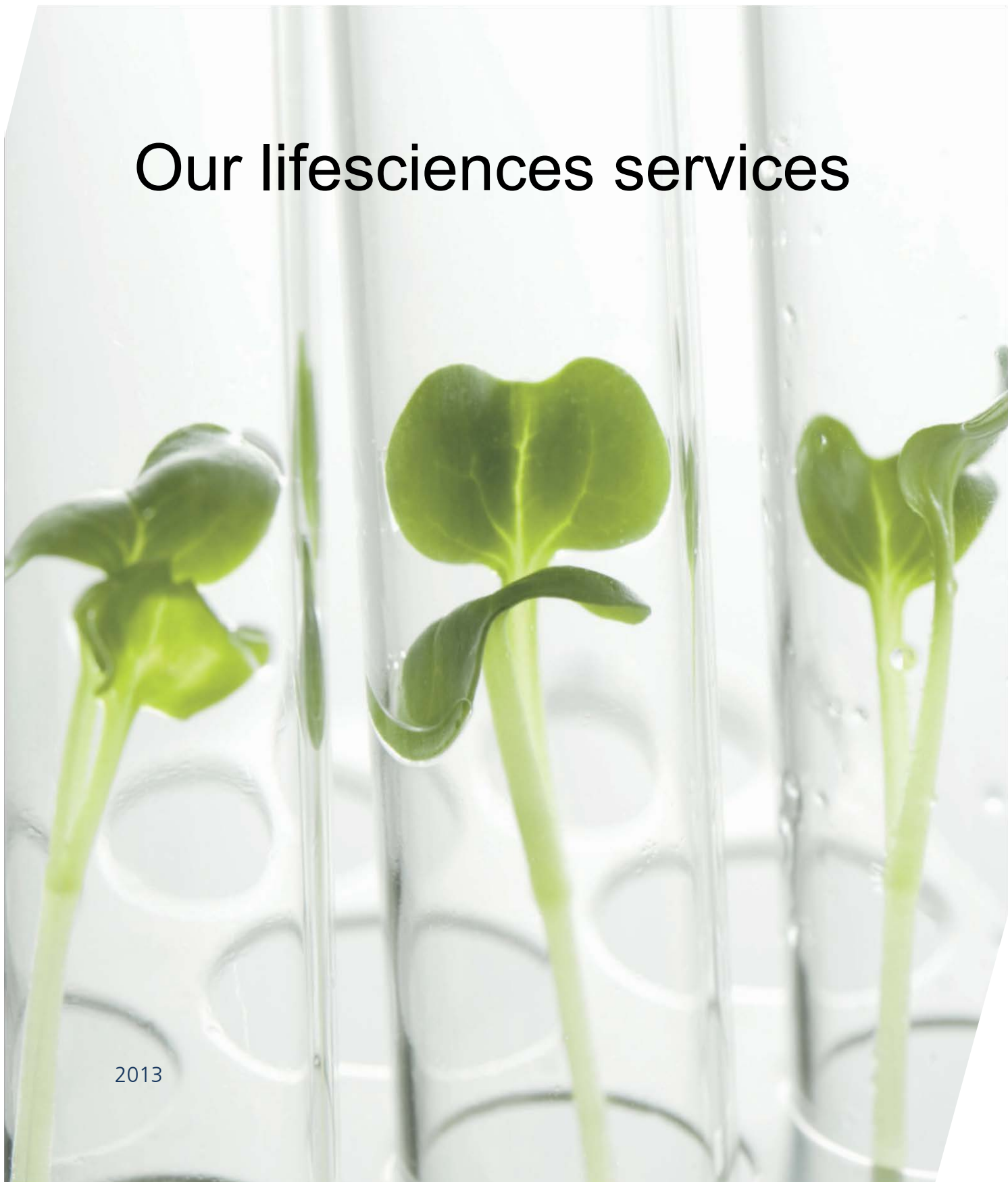


# Our lifesciences services

2013



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# Foreword

Our dedicated Lifesciences Group specialises in advising clients from the pharmaceutical, biotechnology and medical devices industries. The group acts for more than 100 European and worldwide lifesciences organisations including 8 of the top 10 medical device companies, 16 of the top 20 global pharmaceutical companies, the leading global biotech company, a variety of leading associations and other key market players.

We are a leading provider of legal and tax services in Europe. Our highly specialised lawyers operate across the majority of legal disciplines across the lifesciences sectors including intellectual property, regulatory, corporate, EU and competition, commercial, employment and pensions and real estate, which allows us to deliver to the wide business needs locally and internationally of our clients.

Acting for the top companies in the sector means that the Lifesciences Group understands the unique challenges and needs of the sector required to deliver sector specific service to our clients and partners. We are proud of our ability to translate knowledge of the sector into sound commercial advice and have worked on a number of high valued and profiled matters for our clients including Pfizer, Eli Lilly, Takeda, Johnson & Johnson, Bayer Healthcare, Otsuka, Boehringer Ingelheim, Medtronic, DuPont, Merck and more.

We focus on client relationships and believe it is essential to have a thorough understanding of our client's business and method of working if we are to provide truly client focused advice. We provide value for money and understand your requirements, and market players regularly confirm that we are highly competitive on fees. We believe this goes beyond the headline rates and clients praise us on our ability to deliver expert, commercially focused advice at a competitive rate. We work with you to determine exactly what you need. Our considerable expertise in the pharmaceutical, biotech and medicinal products arena allows us to deal with matters efficiently and cost effectively.

# CMS: An overview

CMS brings together leading legal and tax experts and comprises ten European headquartered law firms.

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 managed by a single contact; and
- advice in many complex and highly regulated areas of law across Europe, including emerging markets in Central and Eastern Europe, Brazil, China, Russia and United Arab Emirates.

Our comprehensive understanding of our clients' businesses and markets allows us to consistently deliver sound and commercially relevant advice.

## Facts & Figures

54 offices  
48 cities  
29 countries

### Europe:

Albania, Austria, Belgium, Bosnia and Herzegovina, Bulgaria, Croatia, Czech Republic, France, Germany, Hungary, Italy, Luxembourg, The Netherlands, Poland, Portugal, Romania, Russia, Serbia, Slovakia, Slovenia, Spain, Switzerland, Ukraine and United Kingdom

### Outside Europe:

Algeria, Brazil, China, Morocco and United Arab Emirates

> 750 partners  
> 2,800 fee earners  
> 5,000 total staff

Combined annual turnover:

EUR 808 million (2011)

# Austria: CMS Reich-Rohrwig Hainz

The Austrian Lifesciences and Healthcare Team comprises six partners and two associates, who provide comprehensive advice in all legal issues affecting the lifescience and healthcare sectors. Our Lifesciences Team focuses on IP, unfair competition and regulatory issues. Cases that are connected with other areas of law, such as labour, corporate or medical law are handled by, or together with, specialised teams in our firm. Clients in the lifesciences and healthcare sectors include pharmaceutical companies, producers of medical devices, manufacturers of biotechnological products, hospitals or hospital operators, institutions providing healthcare services, doctors' surgeries and social insurance bodies.

## Scope of services

- IP protection and enforcement
- Unfair competition
- Advertising
- Parallel imports
- Dispute resolution
- Regulatory issues
- Licensing
- Commercial contracts
- Public procurement
- Hospital law
- Medical malpractice law
- Anti-corruption

## Recent experience

### Lifesciences

- Representing the global leading manufacturer of reconstructive orthopaedic devices Corin in unfair competition and trade mark litigation procedures against a competitor.
- Advising Johnson & Johnson on commercial law and unfair competition matters in Austria.

- Advising Roche Diagnostics on various issues related to its trade mark portfolio.
- Advising Rottapharm Group in trade mark litigation against a competitor.
- Advising Sanofi-Aventis in relation to several of its promotional campaigns as well as in various commercial and intellectual property disputes.
- Advising Smith & Nephew, producer of medical devices and wound care products, on corporate law, unfair competition and labour law issues in Austria.

### **Healthcare**

- Representing the provider of medical imaging solutions Carestream in a procurement litigation matter regarding supply of X-ray equipment for a hospital in Southern Austria.
- Advising Medical University Vienna on labour law, medical malpractice law and medical device law.
- Advising the Social Insurance of Entrepreneurs on the privatisation process of several medical institutions and hospitals as well as advising the client on streamlining its back office activities.
- Representing SVD GmbH, a joint venture of the Social Insurance of Entrepreneurs and the Social Insurance of Farmers, in several procurement litigation matters regarding the supply of equipment and services for hospitals and rehab centres.

## The Team



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Egon heads up the IP team and has extensive experience in advising on all aspects of intellectual property. He deals in both contentious and non-contentious issues in relation to trade mark, patent, design, copyright, and unfair competition matters, and advises clients across a wide range of industry sectors, including pharmaceuticals, medical devices and biotechnology. Egon has substantial experience in coordinating complex multi-jurisdiction litigation, regularly working with IP colleagues throughout the CMS alliance and elsewhere.

Egon is the author of the leading Austrian commentary on trade mark law. He speaks at both internal and external conferences on intellectual property issues. He is frequently recommended by the Lifesciences Handbook for IP, regulatory and competition. Egon has a doctorate in law from the University of Vienna.

### **Relevant experience**

- Advising Takeda Pharmaceutical on IP related matters in its €9.6 billion (debt-free cash free) acquisition of Swiss drug company, Nycomed.
- Advising a US-based insurance company specialising in the pharmaceuticals and biotech industries regarding its entire clinical trial portfolio in several European countries.
- Representing the global leading manufacturer of reconstructive orthopaedic devices Corin in unfair competition and trade mark litigation procedures against a competitor.
- Advising Johnson & Johnson on the Austrian aspects of the worldwide sale of its professional woundcare business, Ethicon, to US-based One Equity Partners.
- Advising the Japanese pharmaceutical company Mitsubishi Tanabe Pharma on regulatory and unfair competition matters.
- Advising Roche Diagnostics on various issues related to its trade mark portfolio.
- Advising pharmaceuticals client Rottapharm Group in trade mark litigation against a competitor.

- Advising Sanofi-Aventis in relation to several of its promotional campaigns as well as in various commercial and intellectual property disputes.

**Bernt Elsner****Partner, Public Procurement, EU Competition, Public law****T +43 1 40443 1850****E [bernt.elsner@cms-rrh.com](mailto:bernt.elsner@cms-rrh.com)**

Bernt is head of the Public Procurement, EU Competition and Public Law Department at CMS Reich-Rohrwig Hainz. Bernt studied law and business administration, clerked at the Austrian Constitutional Court and has 14 years of experience as attorney in Austria and Brussels. Bernt has extensive experience in advising all areas of public procurement including PPP-Projects, EU-Competition with special focus on merger control, state aid, antitrust and public law. He is a leading expert and since 1999 author of six books on procurement law and co-editor of the leading Journal on Public Procurement and Building Contract Law. He has specific industry knowledge in a number of areas, including healthcare. Bernt speaks German and English.

**Relevant experience**

- Representing Assista Laborelectronics in several procurement litigation matters in proceedings with the Federal Procurement Tribunal.
- Advising the private equity house BC Partners in the merger control filing against the Austrian Competition Authority regarding the acquisition of FutureLab.
- Advising the private equity house BC Partners in the merger control filing against the Austrian Competition Authority regarding the acquisition of Synlab.
- Representing the provider of medical imaging solutions Carestream in a procurement litigation matter regarding supply of X-ray equipment for a hospital in Southern Austria.
- Representing Sanofi-Aventis in an arbitration proceeding.
- Advising Sanofi-Aventis on down stream distribution issues regarding drugs.
- Advising Sanofi-Aventis on regulatory issues regarding the introduction of drugs in Austria.
- Advising the Social Insurance of Farmers (SVB) on PPP projects regarding the Austrian rehab centres Bad Gleichenberg, Baden, Badgastein, Bad Hall and Bad Schallerbach.
- Advising the Social Insurance of Entrepreneurs (SVA) on a PPP project regarding the Austrian hospital Rosenhügel and the rehab centre Bad Ischl.

- Representing SVD GmbH, a joint venture of the Social Insurance of Entrepreneurs and the Social Insurance of Farmers in several procurement litigation matters regarding the supply of equipment and services for hospitals and rehab centres.



**Johannes Juranek**  
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Johannes heads up the Technology Law team and has extensive experience in advising on all aspects of technology law. He deals in both contentious and non-contentious issues in relation to technology law, copyright, corporate and commercial contracts. He advises clients across a wide range of industry sectors including information technology, medical devices, biotechnology and consumer products. He is regarded as being a leading expert on IT contractual law, and particularly on large-scale IT projects undertaken in the banking and insurance sectors. In addition, Johannes has authored a number of publications in copyright, technology and publishing law.

Johannes graduated from the University of Vienna and obtained a doctorate in law from the University of Vienna.

### **Relevant experience**

- Advising Takeda Pharmaceutical on labour related matters in its €9.6 billion (debt-free cash free) acquisition of Swiss drug company, Nycomed.
- Advising the Austrian based biotechnology company Apeiron on corporate matters; advice involved several capital increases as well as a licensing contract with GlaxoSmithKline worth EUR 236m. In addition, advising the client on several corporate and commercial matters in Austria on a regular basis.
- Advising Austria's market leader for DNA sequencing und oligonucleotide synthesis, on a wide variety of corporate and commercial matters as well as healthcare law in Austria.
- Advising the biotech company Haplogen GmbH on several matters of corporate law.
- Advising the client, producer of preventive genetic diagnostic products, on corporate and pharmaceutical law matters as well as in regard to unfair competition in Austria.
- Advising Johnson & Johnson on commercial law and unfair competition matters in Austria.
- Advising Smith & Nephew, producer of medical devices and wound care products, on corporate law, unfair competition and labour law issues in Austria.

- Advising Hermes Arzneimittel, leading manufacturer of OTC products, on IT law.
- Advising Innocoll, the US-based biopharmaceutical company specialising on biodegradable surgical implants, on labour law in Austria.



**Christoph Wolf**  
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Christoph specialises in the fields of medical, employment and pension law. In his role as head of the Medical Law Team, he advises on several matters of medical law and medical malpractice law including matters concerning anti-corruption, medical malpractice, clinical trials and professional regulations in the medical sector. As co-head of the Employment Team he advises mainly international clients on all aspects of individual and collective labour law, including pensions and regulatory provisions, labour contracts and social plans. In addition, Christoph is author of numerous commentaries and articles on labour law and lecturer at Vienna's Wirtschaftsuniversität. Christoph graduated from the University of Vienna and obtained a doctorate in law from the University of Vienna.

### **Relevant experience**

- Advising the Austrian association of medical device manufacturers on medical device law.
- Advising the Austrian stock listed bio-tech company Intercell in the course of a restructuring process including mass redundancy measures after the shutdown of a major research project.
- Advising the private equity house BC Partners on compliance matters and medical law in Austria.
- Advising biotech client Intercell on labour law in Austria.
- Advising Hospital Goldenes Kreuz on labour law, medical device law and medical malpractice law.
- Advising Hospital Friesach on labour law, medical device law and medical malpractice law.
- Advising Vienna Medical University on labour law, medical malpractice law and medical device law.
- Advising the Medical Association of Vienna on labour law, medical malpractice law and medical device law.
- Advising Merck Serono on clinical trial procedures in Austria.
- Advising the Union of Private Hospitals on labour law and medical device law.

- Advising Red Cross Austria on labour law and medical malpractice law.
- Advising Sanofi-Aventis on labour law in Austria.
- Advising pharmaceutical client Takeda on compliance matters in Austria.

**Armin Dollman****Partner, Banking and Finance, Insolvency, Medical Law****T +43 1 40443 1150****E armin.dallmann@cms-rrh.com**

Armin has many years of in-depth experience in handling cases involving banking and capital market law as well as M&A work. His counsel is provided to banks and other financial institutions operating on a national and international level. His expertise includes banking law, banking supervisory rules and banking regulatory work, but he is also recognised as an expert on advising social insurance institutions on corporate matters.

During his more than 20 years of serving as an attorney at law, Armin has also become a recognised expert in project finance as well as M&A. After completing his US-postgraduate studies at Georgetown University and at Harvard Law School, Armin worked for Shearman & Sterling in New York, amongst other positions.

**Relevant experience**

- Advising the Social Insurance of Entrepreneurs (SVG) on the privatisation process of several medical institutions and hospitals as well as advising the client on streamlining its back office activities through a joint venture with other social insurance institutions.
- Advising the Social Insurance of Farmers (SVB) on the privatisation process of several medical institutions and hospitals as well as advising the client on streamlining its back office activities together with other insurers.
- Advising several doctors and health professionals on the start up of group practices as well as on partnership arrangements in Austria. Legal assistance included comprehensive advice on corporate law and medical law.



**Hans Lederer**  
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Hans studied law at the University of Vienna and the University of Innsbruck and completed his education with stays in France and Belgium. Before joining CMS Reich-Rohrwig Hainz as an associate in 2009, he worked as a project coordinator and in the legal department of the Austrian Red Cross. Hans deals primarily with intellectual property, and, among other areas, lifesciences. He is fluent in German and English and has a good command of French.

#### **Relevant experience**

- Advising the Japanese pharmaceutical company Mitsubishi Tanabe Pharma on regulatory and unfair competition matters.
- Advising Sanofi-Aventis on competition matters in Austria.
- Advising GE Healthcare on compliance and unfair competition matters in Austria.
- Advising Bausch & Lomb on unfair competition matters in Austria.
- Advising the Japanese pharmaceutical company Takeda on IP related matters in the course of its EUR 9.6 billion acquisition of the European pharmaceuticals group Nycomed.
- Advising and representing Sanofi-Aventis in unfair competition proceedings in Austria.
- Advising and representing Syngenta in regard to a series of product piracy and parallel import issues (trademarks, patent) throughout Europe.
- Advising the Japanese pharmaceutical company Mitsubishi Tanabe Pharma on regulatory and unfair competition matters.



**Robert Keisler**  
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Robert is partner at CMS Reich-Rohrwig Hainz and a member of our team for public procurement law, competition law and public law. He is a sought-after specialist for public procurement law and advises procuring entities as well as suppliers from various industries on a national and international level. In addition, Robert has many years of experience in different areas of competition law including merger control, antitrust law and regulatory laws. He is author of numerous expert books and articles.

#### **Relevant experience**

- Advising the private equity house BC Partners in the merger control filing against the Austrian Competition Authority regarding the acquisition of FutureLab.
- Representing Carestream Austria in a procurement litigation matter regarding the supply of X-ray equipment for a hospital in Southern Austria as well as advising the client on regulatory matters.
- Advising the Social Insurance of Farmers (SVB) on PPP projects regarding the Austrian rehab centres Bad Gleichenberg, Baden, Badgastein, Bad Hall and Bad Schallerbach.
- Advising the Social Insurance of Entrepreneurs (SVA) on a PPP project regarding the Austrian rehab centre Bad Ischl and regulatory matters.
- Representing SVD GmbH, a joint venture of the Social Insurance of Entrepreneurs and the Social Insurance of Farmers in several procurement litigation matters regarding the supply of equipment and services for hospitals and rehab centres.
- Advising Merck Serono on clinical trial procedures in Austria.



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Monika is a senior attorney at CMS Reich-Rohrwig Hainz in Vienna and a renowned expert in labour law, medical law, medical malpractice law and pharmaceutical law; as well as unfair competition issues in labour and medical malpractice law. She is also the author of many publications on topics relevant to the lifesciences sector, and is a frequent speaker at lifesciences events.

Monika is the founding member and chairperson of FIRM, the Austrian research institute for medical law, and a member of the Austrian association for medical law (Österreichische Gesellschaft für Medizinrecht). Monika speaks German and English and has basic knowledge of French.

### **Relevant experience**

- Advising the Austrian association of medical device manufacturers on medical device law.
- Advising the private equity house BC Partners on compliance matters and medical law in Austria.
- Advising EmCools, a manufacturer of cooling products, on labour law in Austria.
- Advising biotech client Intercell on labour law in Austria.
- Advising Hospital Goldenes Kreuz on labour law, medical device law and medical malpractice law.
- Advising Hospital Friesach on labour law, medical device law and medical malpractice law.
- Advising Vienna Medical University on labour law, medical malpractice law and medical device law.
- Advising the Medical Association of Vienna on labour law, medical malpractice law and medical device law.
- Advising Merck Serono on clinical trial procedures in Austria.
- Advising the Union of Private Hospitals on labour law and medical device law.
- Advising Red Cross Austria on labour law and medical malpractice law.
- Advising Sanofi-Aventis on labour law in Austria.

- Advising Takeda on compliance matters in Austria.

# Belgium: CMS DeBacker

The essence of CMS DeBacker's Lifesciences and Health Sector Group's approach is teamwork. The team has complementary expertise in pharmaceutical, biotechnology, medical device, diagnostic and related areas, and can offer pan-European and domestic advice in all practice areas of Belgian and European law.

With regard to commercial, intellectual property and regulatory matters, Veerle, Pierre and their associates work on a daily basis on lifesciences and health-related matters, representing the industry, hospitals and researchers, as well as healthcare insurers, and assisting them with specific questions for their daily business.

Other members of the firm also dedicate a significant part of their practices in corporate, tax and EU to the lifesciences and health sectors. Cedric, Didier and Annabelle have built extensive expertise in this industry and have a true understanding of clients' needs and challenges.

## Scope of services

- Regulatory
- Pre-clinical, clinical and post-clinical research
- Pricing and reimbursement
- Licensing, distribution agreements, co-marketing/co-promotion agreements, settlement agreements
- Financing/M&A stock option schemes
- Business restructuring, strategic alliances, M&A
- Distribution and parallel import issues
- IP (patents, SPC, trade marks, trade secrets, designs)
- Branding, trade dress, advertising and labelling
- Personal data
- Product liability and litigation
- Health and safety
- EU & Competition/Competition Enforcement
- Public sector tendering
- E-Health and telemedicine

## Recent experience

- Advising on clinical trials for pharmaceuticals, medical devices and methodologies.
- Representing a pharmaceutical company in trade mark litigation.
- Advising on legal classification, import and distribution of human-derived (engineered) tissue product.
- Assisting with contractual and corporate matters for a Dutch pharmaceutical group.
- Advising private investors on the sale of a Biotech Company to a German group in the sector of medical devices.
- Acting for a US listed company in R&D in Biotech in its establishment in Belgium and drafting various contracts and its stock option plan.
- Setting-up a telemedicine programme for imaging.
- Setting up a cross-border hospital.
- Acting in EU-litigation on free movement of medical devices.
- Acting in EU-litigation on public funding for hospitals.
- Acting in EU-litigation on insurance matters relating to life-insurance and healthcare insurance.
- Conducting acquisition due diligence for US, Japanese and French companies.

## The Team



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Veerle has been a partner with CMS DeBacker since 2002. She is head of CMS DeBacker's Lifesciences Team. She specialises in intellectual property law (trade marks, patents, copyrights, both contentious and non-contentious), advertising, media, privacy and commercial law, with a special focus on the lifesciences sector. Her expertise includes patent and trade mark litigation. With regard to pharmaceuticals, she is experienced in advising on regulatory aspects regarding pharmaceuticals, medical devices, cosmetics, biocides and plant protection products, classification, licensing, distribution and parallel import issues, as well as advertisement and promotion of the various aforementioned products. Veerle has published numerous articles in the field of IP Law, including an article on advertising of pharmaceuticals ("Geneesmiddelenreclame in België", BMM Bulletin 2004). Veerle is a native Dutch speaker and is fluent in English and French.

### Relevant experience

- Advising on customs seizure of counterfeit pharmaceuticals relating to a global pharmaceutical company.
- Acting in product liability litigation for a global medical devices company.
- Acting in patent infringement litigation for a global pharmaceutical company.
- Advising on transfer and pricing issues on the trade mark portfolio of a pharmaceutical company.
- Advising on 'borderline' status issues for a newly developed product of a global pharmaceutical company, i.e. cosmetic/medical device/pharmaceutical.
- Advising and assisting with regard to an incident during Clinical Trial Phase III in Belgium.
- Advising on privacy issues concerning clinical trials.
- Advising on the advertising and promotion of pharmaceuticals and medical devices, including comparative advertising.
- Drafting FTOs regarding pharma patents.

- Advising on and drafting of commercial contracts for pharmaceuticals and medical devices (distribution agreements, licence agreements, etc).



**Pierre Slegers**  
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Pierre joined the Brussels Bar after several years of experience in the chemical and pharmaceutical industry. Since joining the Brussels Bar, Pierre has provided lifesciences companies and public authorities with regulatory, financing, and pricing advice. Pierre is head of CMS DeBacker's Regulatory Team. Pierre's team specialises in: reimbursement; marketing authorisations; clinical trials; and other regulatory matters for biotech, pharmaceutical and medical device clients, including authorisations for blood-banks and transfusion centres; agreements relating to research and development, and manufacturing and supply; and organisation of hospitals. His practice includes constitutional and EU litigation on public funding of healthcare provision, free movement of medical devices and regulatory matters for healthcare products. He also advises lifesciences companies and hospitals on research agreements, sponsoring and inducement issues.

### **Relevant experience**

- Advising and acting in litigation on reimbursement of pharmaceuticals.
- Advising and acting in litigation on the so-called "pharmaceutical tax".
- Advising and assisting on the transfer of blood-banks between hospitals.
- Advising and assisting on the opening of a transfusion centre.
- Advising on clinical trials for drugs, medical devices, and methodologies.
- Advising on research agreements between the lifesciences industry and hospitals.
- Advising on free movement of medical devices.
- Advising on state aid issues in public financing of healthcare.



**Cedric Guyot**  
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Cedric has been a partner at CMS DeBacker since 1991. He is the Head of the Corporate and Finance Department. He specialises in Corporate law with a special focus on the lifesciences sector. In that sector among others, he has extensive experience in M&A and restructuring with an emphasis on shareholder agreements and corporate structures. He has a great deal of experience in negotiating and drafting agreements and has worked for various large international clients in the lifesciences industry on cross-border transactions. Cedric has also advised on numerous shareholder relations and disputes on behalf of clients. Cedric is a native French speaker and is fluent in English and Dutch.

### **Relevant experience**

- Assisting a French pharmaceutical company with the establishment of a holding company in Belgium and the transfers of assets.
- Assisting a Belgian services management company with the creation of an outsourcing company for sales representatives in the medical sector.
- Acting for an Indian lifesciences company in the acquisition of a key Belgian company in the pharmaceutical analysis sector.
- Acting for a Canadian listed company in the acquisition of the medical devices division of the Kodak group.
- Assisting a French group with the acquisition of a Belgian division of a large pharmaceutical company.
- Assisting a Japanese group with due diligence on the acquisition of a large division of a Belgian pharmaceutical company.
- Acting as general counsel for various medium-sized labo, biotech, pharma and medical related companies.
- Assisting a start-up company in the lifesciences sector with its initial private placement.



**Didier Gregoire**  
**Partner, Tax**  
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Didier is an expert in tax law and real estate. He joined CMS DeBacker in February 2002 and became partner in 2003. He advises domestic and foreign clients on a variety of tax issues, with a focus on indirect taxes (VAT, registration and succession duties). He has particular expertise in real-estate-related tax issues (sale and purchase of properties, restructuring and refinancing of real estate portfolios, leases, etc). Didier assists healthcare professionals and companies with investment and R&D issues as well as VAT-related product qualifications.

#### **Relevant experience**

- Advising a French REIT (SIIC) on the structure of its investment in a 32,000 sqm. commercial centre in the Brussels area.
- Acting for a Kuwaiti financial institution in connection with the sharia compliant financing of a large warehouse in Flanders.
- Advising an important publisher in connection with the acquisition of a Belgian publishing group and the setting up of a cash-pooling structure.
- Setting-up Belgian holdings for French clients.
- Advising an important French property developer listed in Paris on the acquisition structure of two large housing projects (470 units) in Brussels.



**Annabelle Lepièce**  
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Annabelle specialises in European law, in particular Competition law (state aid, mergers and anti-trust rules) and EU freedoms (services, establishment and capital). She provides legal advice and lodges notifications and complaints before the European Commission and the Belgian Competition Council, as well as procedures before the EC Court of Justice. She advises hospitals, healthcare insurers and pharma companies on state aid questions and free movement of goods, services and capital.

#### **Relevant experience**

- Assisting the Brussels Region in the enquiry of the European Commission on the financing of Brussels public hospitals following a complaint, and following its intervention in the annulment procedure launched before the General Court by the complainant against the positive decision of the Commission.
- Acting for a hospital in a complaint concerning PET scans before the European Commission for infringement of the freedom of goods.
- Representing 27 slaughterhouses in an enquiry of the Competition Council in an alleged cartel on the split of the market with laboratories concerning BSE tests.
- Advising on state aid questions regarding public funding of laboratories.
- Assisting a major pharmaceutical company in applying for subsidies to the Walloon Region.
- Assisting major pharmaceutical companies before the European Commission for interpretation of EU-law on marketing authorisations.



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Melanie joined the Brussels Bar after several years of experience as an in-house lawyer. Her particular expertise is in the field of intellectual property rights. Since she joined the Brussels Bar, Melanie has provided lifesciences companies with advice and litigation services in the field of intellectual property, as well as advice on market authorisations, and other regulatory matters.

### **Relevant experience**

- Advising with regard to complaints against the Federal Agency for the Safety of the Food Chain from food, nutrition, and drugs manufacturers.
- Advising and acting in litigation regarding market authorisations.
- Advising and assisting a major pharmaceutical industry-player with regard to the re-entry into the food chain of animals after drug testing.
- Providing due diligence examination and advice in the context of M&A by and between major players in the pharmaceutical industry, as well as in the medical devices industry.

# Bulgaria: CMS Cameron McKenna

The Commercial Team in Sofia is well-established and works on a day-to-day basis with a number of multinational companies. The lifesciences practice is particularly strong. David Butts, International Manager and Head of Lifesciences for CMS, holds a BSc. in Pharmacy and was previously in-house counsel at a multinational pharmaceutical company. The dedicated Sofia Lifesciences Team consists of two members; however many of the other 35 fee-earners in the office are capable of assisting in commercial matters at any time.

## Scope of services

- Legal due diligence of pharmaceutical and biotechnology companies and laboratories.
- Participation in negotiations and drafting relevant legal documentation and asset/share transfer documentation.
- Drafting licensing and distribution agreements, material transfer agreements, research collaboration agreements, manufacturing and supply agreements.
- Regulatory advice with respect to data protection and marketing exclusivity of medicinal products.
- Advice with respect to clinical trials and clinical trial insurance.

## Recent experience

- Acting for a multinational pharmaceutical company providing regulatory advice on data protection and marketing exclusivity of the client's priority medicinal product; providing litigation support for the withdrawal of generic marketing authorisations that infringed the data and marketing exclusivity of the client's product and initiated litigation against the generic drug manufacturer.
- Advising on a TV commercial and review of the website of a medical device company.
- Assisting a multinational pharmaceutical company in establishing their local subsidiary and the transfer of activity from their representative office, which included providing advice on public procurement, competition, employment and restructuring issues; as well as obtaining a wholesale trade licence and negotiation of outsourcing agreements.

- Advising a private equity fund in its proposed acquisition of one of the largest Bulgarian laboratories, including performing extensive due diligence and regulatory review.
- Advising a multi-national pharmaceutical company on the conduct of clinical trials in Bulgaria and on other clinical trial site agreements.

## The Team



**David Butts**  
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David is the International Manager at CMS Cameron McKenna Sofia and Head of the Lifesciences Sector Group for CMS. He has been an In-house Counsel to a multinational pharmaceutical company. His experience in the legal profession includes working at one of Canada's pre-eminent Corporate and Commercial law firms, acting as General Counsel for the Canadian subsidiary of a multinational pharmaceutical company, and being the founding partner of a commercial law firm located in Montreal, Canada, where he practised commercial law with an emphasis on M&A, intellectual property protection and technology licensing.

David is recognised as a "problem-solver who can find solutions in real time around the negotiation table" (Chambers and Partners Global). His wide experience in M&A and corporate matters across CEE is backed by significant experience in commercial matters relating to lifesciences, intellectual property and competition issues.

### Relevant experience

- Advising Takeda Pharmaceutical in 13 countries on its €9.6 billion (debt-free cash free) acquisition of Swiss drug company, Nycomed. This is one of the most significant M&A transactions to occur in the lifescience sector in 2011.
- Advising a major pharmaceutical company on establishing its operations in 10 countries across CEE, supervising a team responsible for incorporation of the legal entities, obtaining all necessary local registrations and licences and negotiating commercial agreements.
- Advising a US-controlled pharma/medical devices company on the sale of its European businesses to a strategic buyer, including coordinating CMS involvement in Switzerland, Germany and the UK.
- Advising Medtronic, together with CMS France, on the European aspects of its \$123 million acquisition of Osteotech.
- Advising an international pharmaceutical company with respect to the sale of its consumer healthcare (over-the-counter) business to a strategic buyer in nine jurisdictions across CEE.

- Advising Advent in its first deal in the Ukraine: a lifesciences acquisition involving the purchase of majority stake in a chain of female health (primarily IVF) clinics.
- Assisting a major pharmaceutical company in implementing a Global Compliance Program, including coordinating advice across 30 jurisdictions.



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Angelika is an associate at CMS Sofia. She acquired her LLM in business law in Lyon, France in 2007. Angelika has obtained a certificate in Corporate Law (Montpellier) and worked as an intern at Delsol et associés in 2007. She is a member of the core Lifesciences Team in Sofia and of our French desk. She has advised various clients on protection and market exclusivity of their products, regulatory issues under Bulgarian law, data protection and clinical trial agreements.

### **Relevant experience**

- Advising Johnson & Johnson during and after her six-month secondment to their Bulgarian office on establishing their local subsidiary and transfer of activity from their representative office. This included advice on public procurement issues, medical device distribution from a competition law perspective, employment and restructuring issues. Work also included obtaining a wholesale trade licence, negotiating outsourcing agreements and preparing the documentation for the conduct of clinical trials.
- Advising various multinational pharmaceutical companies on the setting up and conduct of clinical trials in Bulgaria.
- Advising an international research-based pharmaceutical corporation on the execution of a proposed licence, supply, manufacturing, promotion, and distribution agreement with a distributor in Bulgaria, as well as in respect of advertising matters and donation activities directed to hospitals and doctors in Bulgaria.
- Advising a research-based pharmaceutical company on a contemplated acquisition of a Bulgarian distributor, including in respect of corporate compliance matters.
- Advising a major international pharmaceutical company on data protection and marketing exclusivity of a client's priority medicinal product; providing support in initiated litigation against the Bulgarian Drug Agency to ensure withdrawal of generic marketing authorisations infringing the data and marketing exclusivity of the client's product.

- Assisting a major pharmaceutical company in implementing a standardised Global Compliance Program in Bulgaria, as well as coordinating advice across 30 jurisdictions.

# China: CMS China

CMS has been active in China on behalf of its clients for almost 30 years, and has had an office there since the mid-90s. We serve clients in China through our respective representative offices in Shanghai and Beijing, and also through several China Desks throughout Europe. We can advise you on Chinese issues face-to-face and in your own time-zone. As a leading European provider of legal and tax advice, we are well placed to advise both European companies doing business in the PRC, and Chinese companies doing business overseas.

## Scope of services

Clients and top industry publications recognise CMS as a leading legal advisor to the lifesciences sector in China, throughout Europe and in key emerging markets. Our legal experts in China come from a wide range of legal disciplines, catering to all your needs. Their lifesciences experience is extensive, and includes working at Chinese state government level.

## Recent experience

- Advising a top clinical development services provider on integration of its Chinese subsidiaries into the group cash pooling.
- Advising an international laboratory company on the acquisition of shares of a PRC company; legal due diligence and comprehensive legal and tax structuring, draft of entire transaction documents.
- Advising a world leading high-tech company focusing on production and medical technology on a land development contract, a land reservation contract and several lease contracts.
- Advising a global pharmaceutical company on product adverse events in China, including handling complaints, litigation, reconciliation and settlement.
- Advising a leading US pharmaceutical company on compliance matters, packaging and labelling.
- Advising a European research-based pharmaceutical company on patent litigation in Beijing, Hainan and Hong Kong.
- Advising a European multinational on its acquisition of a laboratory services company in Beijing.
- Advising a global pharmaceutical company on its acquisition of three manufacturing subsidiaries in China and operations in Hong Kong.

- Advising a leading European biomedical company on patent licensing and technology transfer relating to the acquisition and restructuring of a major Beijing based biochemistry and medicine manufacturer.
- Advising the International Federation of Pharmaceutical Manufacturers & Associations (IFPMA) on the protection of patent rights in China.
- Advising one of the world's largest manufacturers and distributors of dental anaesthetic on counterfeiting and smuggling strategy and enforcement before various authorities including local FDAs in Anhui Province, Guangzhou, Tianjin and Shanghai as well as on the distribution strategy between the manufacturer and the distributor in China.
- Advising a European research-based pharmaceutical company on invention patent litigation against a Hong Kong manufacturer and its Chinese distributors.

## The Team



**Nicolas Zhu**

**Partner, Head of Lifesciences, Corporate, IP, Tax, TP**

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Nicolas is head of the CMS China Lifesciences Sector Group. Nicolas has advised on numerous trade mark matters for pharmaceutical and medical device companies, including portfolio management, trade mark opposition, re-examination and trade mark counterfeiting. He has also advised on many patent protection enforcement and counterfeiting matters for drugs and medical devices, such as invention patent litigation. He also specialises in drafting and advising on intellectual property licence agreements and development agreements. He has extensive experience handling biopharmaceutical product liability cases with various local courts, hospitals and centres for disease control and prevention. Nicolas has also advised on transfer pricing matters for a number of lifesciences clients on cross border restructuring projects combining corporate, regulatory, intellectual property, tax and TP issues, together with CMS member firms in other jurisdictions. Nicolas speaks Chinese (Mandarin), English, French and Shanghai dialect.

### Relevant experience

- Advising an advanced medical device manufacturer on the restructuring of its subsidiaries as well as route to China market in China from the corporate, regulatory, tax, transfer pricing, foreign exchange and intellectual property perspectives, including: asset acquisition, liquidation etc; advising on the patent reward programme and patent reward agreement; and advising on the establishment of a regional headquarters in China.
- Advising a leading pharmaceutical company on biopharmaceutical product liability cases with various local courts, hospitals and centres for disease control and prevention, in an effort to coordinate the implementation of unified product liability policies in China.
- Advising a leading global pharmaceutical company on patent litigation against a Hong Kong pharmaceutical manufacturer as well as its distributors in Mainland China.
- Advising a leading pharmaceutical laboratory on a clinical agreement with the Chinese hospitals and advising on the establishment of a management company.

- Advising a leading pharmaceutical laboratory on allergic reactions and organising standard operation procedures and training for supervisors and managers in China handling allergic reactions disputes in China.



**Colin Liu**  
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Colin is a partner at CMS China, and head of the China Competition Practice Group. Based in CMS China's Shanghai office since 2000, where he has been a partner since 2008, Colin advises international industrial clients on a wide range of legal matters, with a particular emphasis on foreign direct investment, M&A, competition and intellectual property. Colin's recent work includes advising and representing international high-tech clients on engineering, procurement, construction and management of production plants and R&D facilities, merger control, establishment of compliance programs, antitrust compliance training and securing intellectual property rights in China.

He is author of several articles and books on Chinese law, including *The Effort Pays off - How to Protect and Enforce IP Rights in China* (Business Forum China 6/2004), *Legal Guide to Investment in Pudong* (Shanghai People's Publishing House, 1999 (co-author)), *E-Commerce Rules* (Fujian People's Publishing House 2001 (co-author)) and *New Comments on Science and Technology Laws* (Shanghai Jiao Tong University Publishing House 2001 (co-author)).

Colin studied law at Shanghai Jiao Tong University, and acquired an LL.M. from East China University of Politics and Law, Shanghai, People's Republic of China. Colin passed the Bar exam and qualified for admission to the Chinese Bar and as a trade mark attorney and company registration attorney in 1998. In 2007 Colin was seconded for six months to our Stuttgart Office, and thus has valuable insight in cross-border issues. He speaks Chinese (Mandarin) and English.

### **Relevant experience**

- Advising a major German manufacturer of operation room facilities on obtaining a medical device distribution permit in Jiangsu Province.
- Advising a major Swiss healthcare company on actions against parallel imported products and legal compliance issues.
- Advising a major German dental equipment supplier on actions against counterfeiters in China.
- Advising a major Italian dental equipment supplier on actions against counterfeiters in China.

Advising a major German medical device manufacturer on medical device registration in China.

**Hugh Zhou****Senior Associate, Real Estate & Construction, Corporate****T +86 21 6289 6363****E [hugh.zhou@cmslegal.cn](mailto:hugh.zhou@cmslegal.cn)**

Hugh is a senior associate who joined the CMS Shanghai office in 2005. Before joining CMS, he worked with a reputable PRC law firm. Hugh was previously seconded to a leading German pharmaceutical company's Shanghai office to take on the role of internal counsel. Hugh was involved in an acquisition project by a foreign invested healthcare company of a Wuhan pharmaceutical company. Hugh speaks Chinese (Mandarin), English and Shanghai Dialect.

**Relevant experience**

- Advising a leading German pharmaceutical company's Shanghai office on various legal matters.
- Advising a foreign-invested healthcare company on the due diligence related to the acquisition of a local pharmaceutical company.
- Advising an advanced medical devices manufacturer on the extension of business scope of one of its subsidiaries to research and development. This involved advising on liquidation issues following the restructuring of the company's subsidiaries in China, and advising on the various licence agreements for the route to China market project.
- Advising a global bio-pharma on a labour dispute and other general corporate issues.
- Advising a leading pharmaceutical company on the establishment of a veterinary trading company in China.

# Czech Republic: CMS Cameron McKenna

## Scope of services

The Prague-based Lifesciences Group advises on a wide range of legal issues such as price regulation and registration of reimbursed drugs, anti-corruption issues, the unfair competition, agreements and structures of medicinal product distribution, parallel trade and the prohibition of exports. The group also drafts agreements for clinical trials, clinical and non-interventional studies and drafts and reviews internal procedures for pharmaceutical companies.

Our legal advisors never underestimate the differences between local markets, whilst taking into account EU and EEA standards.

The Prague-based Lifesciences Group has a significant track-record of advising companies in the pharmaceutical sector as well as working with regulatory agencies and government departments and understands how they work. We have the legal and commercial expertise to deliver focused and practical advice and have a track record of advising on a wide range of transactions, coupled with insight developed through long-term relationships with some of the key players.

## Recent experience

- Advising a world-leading supplier of healthcare technical products with respect to protecting its assets from being the subject of the proceeds of insolvency of a business partner.
- Advising a major biotechnology company on: the launch of a new medicament on the market; relations with the doctors; advertising issues; and data protection advice in relation to patients' confidential information.
- Advising a major clinical research organisation on review of agreements entered into with hospitals regarding performance of clinical trials for three leading lifesciences companies.
- Advising Georgia-Pacific Sarl, a producer of hygienic products, on: proceedings before the Czech State Institute for Drug Control; clinical trials and tests; registration of products; and launch of products in the Czech Republic.
- Advising the supporting club of banks during the tender process for potential financing of the Prague Military Hospital project on construction, financing, maintenance and operation of a hotel-type lodging house, car park and other related facilities, as the first PPP Project in the Czech Republic.

- Advising a leading manufacturer of cosmetic and healthcare products on a new distributor model and distribution agreements.
- Advising BC Partners, a private equity fund, on the acquisition of Synlab and Futurelab, companies operating medical laboratories in Germany and in the Czech Republic. The advice included detailed due diligence, transactional advice, a complicated merger clearance procedure and advice on restructuring post completion.
- Advising a lifesciences company on due diligence of agreements entered into by a dominant producer of medical devices and their compliance with competition and other regulation.
- Assisting a French biopharmaceutical company specialising in the treatment of allergy related respiratory conditions with general corporate work, commercial and regulatory issues.
- Advising a private equity fund on its potential acquisition of a medium size Czech pharmaceutical company.
- Advising Aventis Pasteur in respect of a liability claim concerning an allegedly defective medicinal product.
- Advising a major medical device company in respect of its liability in the course of clinical trials of pharmaceuticals.
- Advising a biopharmaceutical company specialising in the treatment of allergy related respiratory conditions on intellectual property rights with regards to trade marks and copyright of their pharmaceutical products and their distribution in the Czech Republic.
- Advising a leading world biotechnology company on their entry into the Czech market, including advice on intellectual property rights with regards to trade marks and copyright of their pharmaceutical products and on their distribution and clinical testing and trials on the territory of the Czech Republic, as well as processing the application for licence.

## The Team



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Tomáš is a Czech lawyer who graduated from Charles University Law School and studied at Ecole National d'Administration and Universite de Perpignan. He focuses on commercial law and has extensive experience in domestic litigation and international arbitrations, contract negotiations and regulatory matters. Prior to joining CMS Cameron McKenna in 2008, Tomáš worked for a Czech law firm and before that for the Ministry of Foreign Affairs. Tomáš works for international clients and leads teams of lawyers in disputes, transactions, as well as day-to-day business matters. He has represented clients in various types of litigation and proceedings at all levels, such as commercial, unfair competition and damage claim disputes at regional courts, Superior Courts, the Supreme Court, and the Constitutional Court. He has also handled administrative proceedings and disputes before the Constitutional Court and the European Court of Human Rights. He has advised many pharmaceutical companies on various issues in the Czech Republic including sector specific regulatory matters, clinical trials problems and anti-corruption issues, as well as providing general commercial advice regarding company start-ups, distribution agreements and general day-to-day advice. Tomáš speaks Czech, English and French.

### Relevant experience

- Advising a French biopharmaceutical company specialising in the treatment of allergy-related respiratory conditions on its entry into the Czech market, including on the establishment of distribution businesses in the Czech Republic and Slovakia and advising how to structure the most efficient distribution models for both countries.
- Advising on specific regulatory matters as well as marketing; authorisations relating to their pharmaceutical products; intellectual property rights with regards to trade marks; modalities of co-operation with medical specialists and on treatment of patients' personal data including their transfers out of the Czech Republic.

- Advising a client on sector specific regulatory issues in various due diligence processes, e.g. regulatory issues in respect of acquisition of pharmaceutical companies operating in the Czech Republic.
- Advising three large pharmaceutical companies on clinical trials, studies and issues related to prohibited substances and pharmacogenomics.



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Vladěna is a Czech junior associate and a graduate of Masaryk University, Faculty of Law in Brno, the Czech Republic. She joined CMS Cameron McKenna in 2010 and her primary area of expertise is litigation and commercial law, with a focus on the lifesciences sector.

Vladěna has experience of arbitration, litigation, due diligence, Commercial Register agenda, corporate law, and security documents' preparation. She has advised clients on several trade mark registration proceedings, as well as on intellectual property related matters such as patents, designs and copyrights, including reorganisation and data transfers. Vladěna has recently advised a leading manufacturer of cosmetic and healthcare products on trade mark registration in the Czech Republic as well as within the EU rules, including the legal issues related to possible trade mark disputes.

Vladěna speaks Czech, English and has a working knowledge of German.

### **Relevant experience**

- Advising STALLERGENES CZ, s.r.o. on Pharmaceuticals Advertisements issues.
- Advising Amgen on lifescience matters such as clinical trials agreements, non interventional studies issues, and pharmaceutical samples distribution.
- Advising Novartis Europharm Ltd., on the Marketing Authorisation Process.
- Advising Exelgyn on the registration procedure of new pharmaceuticals under the Directive 2001/83/EC, on the Community code relating to medicinal products for human use.
- Assisting Axellus s.r.o on administrative disputes regarding health claims on food supplements labels.
- Advising CooperVision on questions relating to contact lenses that were about to be put on the market.
- Assisting Outcome on revision of clinical trials agreements.

# France: CMS Bureau Francis Lefebvre

## Scope of services

With over 20 lawyers specialising in various legal and tax practices, the French Lifesciences Team covers the entire health sector and advises major industrial health companies and medical professionals on issues such as regulation, liability, and advertising. It attracts clients such as pharmaceutical laboratories, manufacturers of medical devices, health companies and health professional bodies.

- Competition – The team excels in matters relating to the drug lifecycle, government investigations, civil complaints, consumer cases, joint ventures, strategic alliances, and mergers.
- Commercial & Regulatory – The team negotiates and structures agreements across the global supply chain to optimise financing, development, manufacturing, and distribution.
- M&A, Restructuring - The team negotiates and structures strategic mergers, acquisitions, divestitures, spin-offs, and joint ventures to enhance the development and commercialisation of new technologies and scientific breakthroughs.
- Tax - With a highly recognised tax practice, clients can rely on a team specifically dedicated to the lifesciences sector, advising on corporate taxation, transfer pricing, or specific pharmaceutical taxes.
- Product Liability – The team defends pharmaceutical and lifesciences companies against allegations of defective products.
- Industrial Property – The team gives advice and assists clients from the lifesciences sector involved in litigation for all IP related issues, with a particularly focus on patents and trade marks.

## Recent experience

- Acting in litigation on behalf of a pharmaceutical company against a ministerial order.
- Advising Merck KGaA (Germany) on various M&A and restructuring transactions.
- Advising Axcan Pharma on the tax aspects of its sale to TPG Capital and affiliates.

- Handling product liability matters for a major medical device manufacturer and other clients, notably in relation to contentious and non-contentious expert proceedings (including US class actions and proceedings in France), potential recall or withdrawal situation, and settlement negotiations.

## The Team



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Catherine joined CMS Bureau Francis Lefebvre Lyon in 2008. She previously worked as a lawyer at Ernst & Young (1999-2000) and was the group legal department manager of BIOMNIS Group, formerly known as Laboratoires Marcel Mérieux (Laboratory medicine and hospitalisation) from 2002 to 2007.

She specialises in Health and Corporate Law, and in particular, clinical laboratories.

She acts for a large number of clients in health areas, particularly for health-related businesses such as private healthcare institutions, healthcare professionals and clinical laboratories.

### **Relevant experience**

- Advising on the sale of the French leader in reference biology.
- Advising on the management, restructuring and sale of regional Group of Clinics.
- Advising regional/national companies working in the medical testing services field within the frame of restructuring and development operations.
- Assisting with restructuring functions within companies taking regulatory aspects into account.



**Jean-Philippe Clement**

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Jean-Philippe joined the Corporate Department of CMS Bureau Francis Lefebvre Lyon in 1993. He holds a postgraduate degree in Business and Tax Law from the University of Lyon and worked in a solicitors' office (Manchester). He acts for a large number of French and international clients, particularly in relation to joint ventures, mergers, acquisitions, restructuring, private equity, shareholders' relationships and pre-litigation, general corporate work.

He is a lecturer at the Bar School of Lyon. He is a native French speaker and is fluent in English.

**Relevant experience**

- Advising a UK listed company on the acquisition of a French medical devices distribution company.
- Advising Praxim SA (France) on funds raising issues, acquisition, shareholders' agreements and restructuring.
- Advising a company operating in the development of products for the surgical management of obesity on M&A activities and private equity issues.
- Advising medchem-orientated research and service companies on general corporate issues including the organisation of relationships between shareholders, and M&A activities.
- Advising a company operating in the development of innovative robotics solutions for surgeries on private equity issues.
- Advising a business angel in the investment in the share capital of a company operating in the development of innovative medical imaging software.



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Jean joined the Contracts & Commercial Department of CMS Bureau Francis Lefebvre in 1984. He specialises in international contracts, product liability, pharmaceutical law and more specifically in contractual and commercial relationships, including the setting up of distribution schemes on an international scale, especially in the pharmaceutical sector. Jean advises on product liability issues for major pharmaceutical laboratories such as French subsidiaries of major US, European and Japanese laboratories, medical device manufacturers, electronic devices producers etc. Jean also undertakes contractual due diligence in the context of acquisitions in the pharmaceutical sector and has experience with international contracts including those involving international private law issues and arbitration. He graduated from King's College London, and holds a postgraduate degree (DEA) in French commercial and civil law from the University of Paris II (Panthéon-Assas). He is a member of the ACE (French association of corporate legal advisors), the ELA (European lawyer Association) and DRI (Defense Research Institute). Jean has written several articles in his areas of expertise in various publications, notably the M.O.C.I. A. He is a native French speaker, and is fluent in English.

### **Relevant experience**

- Advising on product liability matters for major medical device manufacturers, in particular implementation and coordination of judicial proceeding strategy involving US class actions and proceedings in France.
- Participating in worldwide acquisitions in the pharmaceutical field.
- Drafting international contracts including agency, distributorship, licensing, manufacturing relationship, lease, and supply agreements between pharmaceutical firms and other players in the lifesciences sector.



**Pierre-Jean Douvier**  
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Pierre-Jean joined CMS Bureau Francis Lefebvre's international taxation team in 1986. He specialises in international law, particularly transfer pricing, M&A, cross border transactions, financing, refinancing, hybrid financing and restructuring, financial leasing, international taxation, energy law, and trusts. He graduated from Paris II Assas and Business School. Pierre-Jean is a member of the institute for Tax Advisors (IACF), the International Fiscal Association (IFA), the International Bar Association and is the honorary vice-president of the Trusts Committee (IBA). He has written several articles including: *International Taxation: 20 Case Studies* (LITEC); *Tax Law in International Relationships* (PEDONE); *The Regime of Permanent Establishment* (IBFD Amsterdam 2005); *Treasury Management* (Ed. F. Lefebvre); and *The Regime of Partnerships* (IBFD Amsterdam 2006). He specialises in pharmaceutical companies (Pharma, OTC, R&D, brand reengineering). He is a lecturer in international taxation at the University of Paris II Assas and also speaks at conferences on topics such as: transfer pricing; cross border mergers and demergers; trusts; and assets reorganisation. A native French speaker, he is fluent in English and speaks Italian and German.

### **Relevant experience**

- Acting in the acquisition of a worldwide OTC department.
- Advising on the restructuring of pharmaceutical activity contracts within Europe.
- Assisting in restructuring functions within companies taking regulatory aspects into account.
- Advising on establishment in CEE.



**Bernard Geneste**  
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Bernard joined CMS Bureau Francis Lefebvre's Competition & Regulatory department in October 2002. He used to be the leader of Landwell's European department (1996-2002). A partner since July 2000, he specialises in the pharmaceutical sector and his practice area covers regulatory, public and economic affairs, competition (mainly in the hospital sector), and pharmaceutical taxes. His clients include French subsidiaries of major international groups and professional representation bodies. After being Adviser of the Tribunal Administratif (the French court dealing with Public law matters), he held office as: Committee Chairman at the French Competition Council; Legal Secretary at the Court of First Instance of the European Communities; and Legal Director of the Conseil Régional d'Ile-de-France (French Council of the Ile-de-France region). After completing his MA, Bernard graduated from I.A.E. (MBA). He has written several books and articles in his areas of expertise and teaches at the Universities of Paris II - Assas and Paris IX - Dauphine. A native French speaker, he is fluent in English. Bernard's litigation cases for pharmaceuticals in the ECJ include: 19 September 2000, Sanofi/DSF du Val-de-Marne, C-181/99; and 22 November 2001, Ferring/ACOSS, C-53/00.

### **Relevant experience**

- Advising Ferring in the Ferring/ACOSS case.
- Advising the Belgian government in the "goldenshares" case.
- Acting in various disputes in comparative advertising cases before the Paris and Versailles Courts.
- Acting in merger notifications before the French DGCCRF and the EC.
- Providing regulatory support on pharmaceutical deals, advice on clinical research, advertising, data protection, specific regulations on communication via the Internet.
- Assisting pharmaceutical firms in designing their promotional practices, and writing their internal codes.
- Conducting due diligence on regulatory matters and good promotional practices.



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Anne is a tax partner in CMS Bureau Francis Lefebvre. She joined the VAT department of CMS Bureau Francis Lefebvre in 1983 and became a partner in 1998. She specialises in VAT, planning and consultancy, intra-EU trade, exports, location of offices and operations, and special VAT regimes. She holds a masters degree in corporate law from the University of Paris V. Anne is an active member of the International Fiscal Association (IFA), the Institute for Tax Advisors (IACF) and the Association for Corporate Legal Advisors (ACE). Anne is the co-author of *Gestion de la T.V.A.: la T.V.A. expliquée par les praticiens*, (Dossiers pratiques, Editions Francis Lefebvre, 2002) and *T.V.A* (Editions Francis Lefebvre, 1993). She is the author of several publications on VAT matters. A native French speaker, she is fluent in English.

#### **Relevant experience**

- Assisting major pharmaceutical companies in the audit of their electronic invoicing systems.
- Advising major lifesciences groups in an analysis of their computerised audit systems.



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Jacques started his career as a lawyer in a US law firm in Paris. In 1983, he joined the legal department of the Californian based construction and engineering group Bechtel, where he acted mainly in the areas of pipeline and hotels construction. In 1986, he joined the legal department of a major paper manufacturing company listed on the Paris stock exchange market (Arjomari-Prioux), and, after the merger between this group and Wiggins Teape Appelton (UK paper manufacturer), he became the General Counsel of the new group called Arjo Wiggins Appelton plc. listed on the London Stock Exchange. In 1993, he joined CMS Bureau Francis Lefebvre as head of the M&A corporate department. He acts for a large number of French and international clients, particularly in relation to joint ventures, M&A, restructuring, private equity, IPO and general corporate and stock exchange regulatory work. He is an active member of the French Association for Corporate Legal Advisors (ACE). He graduated from the Sorbonne University with a masters in law and he also holds a masters in economics from INSEAD. A native French speaker, he is fluent in English and he speaks Spanish.

### **Relevant experience**

- Advising Merck KGaA (Germany) on various M&A and restructuring transactions.
- Advising Otsuka Pharmaceutical (Japan) on the acquisition of 49% of Alma (mineral waters Cristaline, Vichy Saint-Yorre, Vichy Célestins, Vals, Chateldon).
- Advising Johnson & Johnson on the acquisition of Pfizer's worldwide consumer healthcare and products division.
- Advising Vetoquinol in its IPO.



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Edouard is a partner of CMS Bureau Francis Lefebvre, practising in the international tax group. From 1994 to 2000, Edouard practised in the New York office of CMS Bureau Francis Lefebvre. Edouard advises on M&A and cross-border restructuring and corporate finance projects. He acts for multinationals including lifesciences corporations.

He is a member of the International Fiscal Association (IFA), the International Bar Association (IBA), the American Bar Association (ABA), the French Association for Corporate Legal Advisers (ACE) and the Institut des Avocats Conseils Fiscaux (IACF).

He speaks French and English.

### **Relevant experience**

- Advising Johnson & Johnson Consumer France ("J&JCF") on the termination of the joint venture (50/50) (tax aspects) between J&JCF and Georgia Pacific France. J&JCF acquired 50% of the companies Vania SNC and Polivé SNC.
- Advising Johnson & Johnson on general tax matters including on the disposal of McNeil Property (holding company) and McNeil Manufacturing to Famar Group.
- Advising Otsuka Pharmaceutical Ltd on the acquisition of 100% of Nutrition & Santé (No. 1 in France, range of functional & diet foods) held by the funds Abenex and L Capital by Otsuka.
- Advising Ethicon on the divestiture (tax aspects) of Ethicon's Professional Wound Care business and on the transfer of the R&D and manufacturing facility in Gargrave (England) to One Equity Partners.

**Jean-Guillaume Monin****Partner, IP / IT – Distribution and Competition Law****T + 33 4 78 95 47 99****E [jean-guillaume.monin@lyon.cms-bfl.com](mailto:jean-guillaume.monin@lyon.cms-bfl.com)**

Jean-Guillaume was admitted to the Bar in 1992 and he joined CMS Bureau Francis Lefebvre's Lyon office with his team in 2006, after being partner in the IP department of a famous regional French law firm. As a CMS partner, he is particularly devoted to litigation in all fields of IP and IT law, with a particular focus on patents and trade marks, and in the domain of product liability.

Regarding the lifesciences sector, Jean-Guillaume has expertise in due diligence and litigation, with a particular focus on patent litigation (nullity and infringement).

Jean-Guillaume passed the specialisation in IP and he is a certified INPI pre-assessor. He is a lecturer at the University of Lyon and at the Bar School of Lyon. He also lectures at the Chamber of Commerce and at professional organisations. He belongs to the GRAPI association (regional group of the AIPPI), where he is the secretary.

**Relevant experience**

- Carrying out IP due diligence in the process of the acquisition of a medical devices manufacturing company.
- Advising and representing clients in the lifesciences sector (medical devices, cosmetics) in patent litigation before all French Courts.
- Advising on trade mark strategy.
- Assisting in trade marks opposition proceedings (French, US, Mauritius).
- Advising and representing companies, particularly in the pharmaceutical area, in trade mark litigation before the French and Community Courts.
- Assisting clients in product liability litigation.

**Jean-Christophe Sauzey****Partner, Tax****T + 33 1 47 38 40 02****E [jean-christophe.sauzey@cms-bfl.com](mailto:jean-christophe.sauzey@cms-bfl.com)**

Jean-Christophe joined the tax department of CMS Bureau Francis Lefebvre in 1987 where he became an equity partner in 1999. He was appointed Head of the Tax Practice Area Group of the CMS alliance in January 2006. He holds a postgraduate degree (DEA) in Business Law and Taxation from the University of Paris II. He specialises in direct taxation, and his clients include multinationals, pharmaceutical groups, private investors and real estate and financial advisors. He is a lecturer and pedagogical advisor in tax law at the University of Paris II (Panthéon-Assas). He is the author of several articles, amongst others *Le crédit d'impôt recherche: un régime toujours plus performant* (Option Finance, Jan 2008). He has spoken at numerous conferences, notably the CMS Annual Tax Conference, on topics such as tax audits relating to transfer pricing – the approach in Europe, and optimising intangible asset taxation. He is a permanent member of the MEDEF Committee on Research and Innovation as well as a member of the International Fiscal Association (IFA), the International Bar Association (IBA), the Institute for Tax Advisors (IACF) and the French Association for Corporate Legal Advisors (ACE). A native French speaker, he is fluent in English.

**Relevant experience**

- Advising the Canadian group Axcan Pharma, a leading pharmaceutical company focused on the treatment of gastrointestinal disorders, on the tax aspects of a sale to TPG Capital and Affiliates.
- Advising major French, Canadian and Swiss pharmaceutical companies on tax matters such as assistance during tax audits, tax aspects of business restructuring, transfer pricing policies, or R&D tax credit schemes.



**Pierre-Jean Sinibaldi**  
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Pierre-Jean joined the employment law department of CMS Bureau Francis Lefebvre in 1986 and became an equity partner in 1998. He co-manages a team of lawyers providing advice and handling disputes in collective and individual labour relations and on the employment implications of strategic decisions. He specialises in labour law, social security law and social care. His clients include many pharmaceutical companies. In the lifesciences industry, he has handled several litigation cases on the promotion of pharmaceutical products and/or social security audits. He has advised laboratories especially the French subsidiaries of foreign-based pharmaceutical companies, on restructuring their operations, employee benefits and stock option schemes and continues to provide them with employment law advice on a day-to-day basis. He holds a postgraduate degree (DEA) in employment law from the University of Paris I - Panthéon- Sorbonne. Pierre-Jean is a member of the French Association for Corporate Legal Advisors (ACE), and is a lecturer at the Cergy-Pontoise University (DJCE). A native French speaker, he is fluent in English and Italian.

### **Relevant experience**

- Representing several pharmaceutical companies before various courts in the fields of pharmaceutical products, advertising, taxes, and social security contribution adjustment.
- Advising on the restructuring of several pharmaceutical companies and pharmaceutical sales forces.
- Advising on the establishment of employee share scheme policies and other employee benefits.
- Assisting several pharmaceutical companies on a day-to-day basis in various areas of employment law and social security law.



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Vincent joined CMS Bureau Francis Lefebvre's employment team in 1999 and became an equity partner in 2010. He co-manages a team of lawyers providing advice and handling disputes in collective and individual labour relations and on the employment implications of strategic decisions. He specialises in consulting and litigation in the areas of employment law, pensions and benefits, profit sharing schemes, secondment schemes, working time, social security law and social security coverage. He used to practise within PriceWaterhouseCoopers. He holds a postgraduate degree (DESS) in employment law and social security law from the University of Paris II (Panthéon-Assas, 1996). He has been published in several law magazines. He is a lecturer on employment law at the Universities of Paris II – Pantheon Assas and Montpellier (DJCE). A native French speaker, he is fluent in English and speaks German.

### **Relevant experience**

- Representing several pharmaceutical companies before various courts in the fields of pharmaceutical products, advertising, taxes, and social security contribution adjustment.
- Advising on the restructuring of several pharmaceutical companies and pharmaceutical sales forces.
- Advising on the establishment of employee share scheme policies and other employee benefits.
- Assisting several pharmaceutical companies on a day-to-day basis in various areas of employment law and social security law.
- Assisting several pharmaceutical companies in spin-off operations.



**Virginie Coursière**  
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Virginie joined CMS Bureau Francis Lefebvre's competition team in January 2005. She specialises in all aspects of French and European competition law, industry and commerce regulations, as well as product regulation. She is heavily involved in the CMS Competition Practice Area Group and the CMS Lifesciences Sector Group. She holds a masters degree in English Law from the University of Paris II and the University of Oxford (Maîtrise 2001) as well as post-graduate degrees in Public Business Law (DEA 2002) and European Business Law (DESS 2003). A native French speaker, she is also fluent in English.

#### **Relevant experience**

- Preparing a competition assessment as part of a bid by a French veterinary company for products divested at EU-level pursuant to a merger authorisation by the European Commission.
- Acting in litigation on behalf of a pharmaceutical company against a ministerial order approving a medical convention containing anticompetitive provisions.
- Advising on non-compete clauses to be inserted by the veterinary branch of a major pharmaceutical company in its contracts with manufacturers and distributors.
- Conducting a regulatory audit in the context of the acquisition by a pharmaceutical company of the main assets of a competitor.



**Mathieu Daudé**  
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Mathieu joined CMS Bureau Francis Lefebvre's international taxation team in January 2004. He specialises in the taxation of national and international M&A and restructuring, taxation in the financial sector, taxation of investment funds and other investment companies, transfer pricing, non-salary benefits (stock options, incentive schemes, etc), patrimonial taxation, and assistance during tax audits. He graduated from HEC in 2000, the Institute of Political Science in 2002, the DEA of Taxation in 2000, and the Paris Bar in 2003. He participated in the drafting of the *Guide fiscal du patrimoine 2007* (Gestion de Fortune - April 2007) as well as the article *Patrimonial taxation in Europe* (Challenge - July 2006). Mathieu is a native French speaker. He is also fluent in English and speaks Italian, German, and Polish.

### **Relevant experience**

- Assisting French and international key-pharmaceuticals groups with international reorganisations, re-engineering of services, and transfer of functions.
- Assisting international distribution and manufacturing groups with transfer pricing.
- Acting in the review of transfer pricing methodologies to reduce risks in the event of future tax audits.
- Assisting in M&A transactions especially thin cap rules and transfer pricing methodologies.
- Providing tax advice with respect to permanent establishment and the corresponding tax risks.
- Advising on the withholding tax aspects of various cross border flows (fees, software content, licensing of intangibles).
- Advising on transfer pricing/allocation of taxable income and expenses.
- Advising on issues with respect to the effective seat of management of companies.
- Advising on localisation of companies and assets depending on the activities involved.



**Stéphanie de Giovanni**  
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Stéphanie is both a French attorney and Member of the New York bar. She joined the Contracts and Commercial Department of CMS Bureau Francis Lefebvre in 2000. She specialises in international contracts, product liability and pharmaceutical law. More specifically, her practice is focused on international contractual relationships, including the setting up of international distribution schemes in the lifesciences sector (relating to products such as OTC drugs or medical devices). She advises on international contract issues including conflict of laws and arbitration, contractual due diligence and negotiation of sale of business ("cession de fonds de commerce") in the context of acquisitions of target companies for the pharmaceutical industry and aeronautics fields. She handles ICC arbitration and assists clients with product liability issues (including recall or withdrawal actions and follow-up of amicable or judicial expertise) especially for pharmaceutical laboratories, medical device manufacturers and their insurance companies.

She studied both French law and Anglo-American law for four years within the DEJA program of the Paris X University where she obtained her LLB ("Maîtrise") in 1997. She holds a LLM - Master in international law from the American University of Washington DC (1998) and a postgraduate degree (DESS) in French business law from the University of Paris XI in partnership with HEC (1999), the year in which she also passed the New York Bar. A native French speaker, she is fluent in English and has knowledge of Spanish.

### **Relevant experience**

- Advising foreign clients (especially American, English and Japanese pharmaceutical companies) in connection with contractual negotiations, anti-corruption and FCPA issues and due diligence exercises, limitation of liability, comparative law and appraisal of Anglo-American agreements so as to ensure full conformity with French law.
- Negotiating and drafting international contracts including agreements for sale of a business ("cession de fonds de commerce"), general sale or purchase conditions, agency, distribution, commissionaire, licensing, supply and toll manufacturing for foreign clients and/or French entities belonging to a foreign group.

- Handling product liability matters for major medical device manufacturers, seed producers and other clients, notably in relation to judicial or amicable expertise proceedings, potential recall or withdrawal situations and settlement negotiations.



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Damien joined CMS Bureau Francis Lefebvre's employment team in 2002. He specialises in advice and litigation in employment law, pensions and benefits, profit sharing schemes, secondment schemes, working time, social security law, and social security coverage. He holds a postgraduate degree (DESS) in business law as well as a DJCE from the University of Paris II (Panthéon-Assas, 2001). He has written various articles in several specialised publications. A native French speaker, he is fluent in English and speaks German.

#### **Relevant experience**

- Representing several pharmaceutical companies before various courts in the fields of pharmaceutical products, advertising, taxes, and social security contribution adjustment.
- Advising on the restructuring of several pharmaceutical companies and pharmaceutical sales forces.
- Advising on the establishment of employee share scheme policies and other employee benefits.
- Assisting several pharmaceutical companies on a day-to-day basis in various areas of employment law and social security law.



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Arnaud joined CMS Bureau Francis Lefebvre in September 2003. He heads the Strasbourg office. Specialising in tax, he holds a postgraduate degree in business and tax law from the University of Strasbourg and previously headed up Landwell & Associés' tax department in Strasbourg. A native French speaker, he is fluent in English and also speaks German.

#### **Relevant experience**

- Advising the Aventis group on tax matters.



**Maia Spy**  
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Maia joined CMS Bureau Francis Lefebvre's competition & customs team in 2004. She specialises in all aspects of French and European competition law, industry and commercial regulations, as well as products regulation. Her activities also encompass consumer law, sales promotion and advertising law. She holds a post-graduate degree (DESS) in Litigation, arbitration and alternative dispute resolution from the University of Paris II (Panthéon -Assas) and a postgraduate degree (DEA) in Business and Economy law from the University of Paris I (Panthéon-Sorbonne). She is the co-author of the chapter on French law in the *PLC Crossborder Competition Handbook 2006*. She is a lecturer in European competition law at the Catholic University of Paris. A native French speaker, she is fluent in English.

#### **Relevant experience**

- Advising on regulations applying to different products (drugs, medical devices, blood products, crop protection products), such as classification of new products, clinical trials, marketing authorisation, advertising, and prohibition of reimbursement rules.
- Advising on litigation for pharmaceutical companies before administrative courts and actions for annulment of decisions adopted by administrative authorities, such as, decisions prohibiting advertising medicinal products and the subsequent financial penalties, and decisions regarding the reimbursement of health products.



**Francine Van Doorne-Isnel**  
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Francine joined the Contracts and Commercial Department of CMS Bureau Francis Lefebvre in 1989. She specialises in commercial, product liability, and pharmaceutical law. She holds a postgraduate degree from the University of Rennes (1988). She has written several publications on liability for defective products including an article on liability for defective products under a law enacted in 1998. A native French speaker, she is fluent in English.

#### **Relevant experience**

- Participating in a worldwide sale and purchase of assets deal in the pharmaceutical field.
- Advising on international commercial contracts and non contractual law including agency, distributorship, licensing, manufacturing relationship, lease agreements, supply agreements.
- Acting in contractual due diligence in the context of acquisition or sale of target companies in the pharmaceutical field.
- Advising a pharmaceutical laboratory in relation to the termination of its foreign distributor contracts.
- Advising and assisting a pharmaceutical company regarding their distribution network.
- Advising a private clinic in relation to the termination of contracts with its practitioners.



**Claire Vannini**  
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Claire joined CMS Bureau Francis Lefebvre's Regulatory and Competition department in 2001. She specialises in EU/competition law, pharmaceutical law and public law. She graduated from the Institute for Political Sciences Paris (IEP Paris) and holds a Masters degree in public law from the University of Paris I (Panthéon-Sorbonne). A Member of the AFEC (Association Française d'Etudes de la Concurrence) and the AJSP (Association des Juristes de Sciences Po), she is a lecturer in EU law at the Paris Bar School. A native French speaker, she is fluent in English.

#### **Relevant experience**

- Advising pharmaceutical companies in the field of competition law especially on the risks of predatory pricing in the hospital market, promotional practices, supply chain management and parallel trade.
- Advising negotiation and litigation on pricing and reimbursement issues with regard to pharmaceutical and medical devices.
- Acting in obtaining marketing authorisations (French and European), the regulatory aspects of advertising, and regulation of orphan drugs.



**Laurent Romano**  
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Laurent was admitted to the Bar of Lyon in 1995. He then worked in Canadian law firms and for a major pharmaceutical company, before joining CMS Bureau Francis Lefebvre's Lyon office, where he is now a partner. Today, he primarily assists clients from the lifesciences industries and more specifically pharmaceuticals, biotech, medtech (medical devices) and fine chemicals companies. He advises them on drafting and negotiating IP agreements, including patent licensing, research and development agreements, collaborations, clinical trials agreements, manufacturing and distribution agreements. He also has extensive experience with issues relating to the protection and exploitation of IP assets, and he carries out specialised due diligence notably in the lifesciences sector. He also assists with competition law matters (notification of concentration, antitrust and competition practices).

Laurent is an active member of the International Association for the Protection of IP (AIPPI). He contributed to the Question 202 ("the impact of public health issues on exclusive patent rights").

### **Relevant experience**

- Negotiating and drafting of consortium agreements, patent licenses for biotech and pharmaceutical companies regarding molecules, biotechnologies (biotech tools, monoclonal antibodies, insertion of genes) notably in the framework of the "Lyon Biopôle" cluster (a world competitive cluster focused on infectious diseases).
- Negotiating and drafting of manufacturing agreements related to active pharmaceutical ingredients and cGMP batches.
- Conducting due diligence relating to pharmaceutical product portfolios, medical devices (regarding orthopaedic, urology, bariatric devices), review of R&D, industrial and distribution contracts, and Intellectual property assets.
- Negotiating and drafting of engineering contracts for designing and building of pharmaceutical production units.



**Valéry Brisson**  
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Valéry joined the tax department of CMS Bureau Francis Lefebvre Lyon in 2008. He graduated from the Lyon III University, and holds a tax and corporate law masters. He worked for three years as a tax lawyer at Deloitte & Touche Lyon, three years at Ernst & Young Lyon and, before creating his own law office Brisson Avocats in 2006, he was the Group Tax Director of BIOMNIS Group, formerly known as Laboratoires Marcel Mérieux (Laboratory medicine and hospitalisation).

He regularly assists clients with respect to tax matters in M&A, restructuring and private equity. He has a large number of clients in health areas such as public or private healthcare institutions, medico-social institutions, healthcare professionals and clinical laboratories.

He has extensive experience in advising and planning the most tax-efficient structure for entrepreneurs.

He is experienced in achieving negotiated settlements with the French tax authorities and, where necessary, he deals with tax investigations, appeals and litigation.

### **Relevant experience**

- Advising on the sale of the French leader in reference biology.
- Advising on management, restructuring and sale of regional Group of Clinics.
- Advising on all aspects of corporate taxation.
- Advising on litigation between shareholders and healthcare professionals.



**Yannick Francia**  
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Yannick joined CMS Bureau Francis Lefebvre Lyon in October 2009. He specialises in public and private law in the health and biotechnology sectors. He started his career as a lawyer in health law for a company in Paris which specialised in PMSI coding, health and economic decision counselling and quality certification for health related businesses. He was involved, with other health professionals, in the writing of a self-rating manual for healthcare institutions in order to assist them with the first accreditation procedure of April 2001. In 2004, he joined the Lyon Bar and worked in a specialist private healthcare law firm. In 2008, he joined Bismuth Associates as head of the Health and Biotechnologies Laws Department.

He acts for a large number of clients in health areas, particularly for health-related businesses (public/private healthcare institutions, medico-social institutions, healthcare professionals, laboratories, pharmacies, pharmaceutical industries) in their relationships with government institutions, guardianship authorities, social services, public or private investors, hospital doctors or private practices and patients. His experience allows him to assist his clients when setting up health administrations, hospital cooperation and/or networks, writing and negotiating private practice contracts, analysing and implementing service and care rates (T2A/CCAM), setting up and regulating hospital and medical information systems, protecting pharmaceutical products and pleading before administrative, civil, penal or ordinal courts.

Yannick supervised the legal and fiscal writing section of the *Territorial Cooperation Guide* co-published in March 2011 by the National Support Agency for the Performance of Health Facilities and by the Care Services Head Office.

### **Relevant experience**

- Creating cooperative structures, such as GIE (conventional radiology, scanner and IRM), GCS in different healthcare and specialised fields
- Assisting clients before guardianship authorities, paying systems or decision-making bodies (through SROS, CPOM, sanitary authorisations, external control and litigation T2A/CCAM).
- Negotiating and writing liberal practice contracts with doctors, setting up a liberal activity for hospital doctors, evaluating medical issues.



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Charles-Yves joined CMS Bureau Francis Lefebvre Lyon in 2008. He graduated a DJCE from the Lyon III University, and holds a tax and corporate Law Master degree. He previously worked ten years as a lawyer at Ernst & Young. He then established his own law firm Rivière Avocats.

He usually advises on M&A, restructuring and private equity. He assists a large number of clients in the health sector, in particular health-related businesses such as public/private healthcare institutions, medico-social institutions and laboratories, as well as healthcare professionals.

#### **Relevant experience**

- Advising on the sale of the French leader in reference biology.
- Advising on the management, restructuring and sale of a regional group of clinics.
- Advising regional or national companies working in the medical testing services field within the frame of restructuring and development operations.



**Solène Vilfeu**

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Solène has been an associate in the CMS Francis Lefebvre's team since 2006. She specialises in all fields of IP with a particular focus on patents, trade marks, domain names, advertising law and unfair competition. In these fields, she conducts litigation, advises and assists clients in the negotiation of settlement and in drafting contracts.

She holds a postgraduate degree in Biotechnology Law (University of Versailles, France) as well as an LLM with a specialisation in IP Law (University of Queensland, Australia). She was admitted to the Bar in 2004 and, prior to joining CMS, worked in another law firm specialising in IP and IT law.

Solène is an active member of the GRAPI association and a certified INPI pre-assessor.

**Relevant experience**

- Acting in patent litigation regarding validity, infringement and patent ownership in the cosmetics and health sectors.
- Handling counterfeiting proceedings, advising clients regarding related trade mark issues, assisting in trade mark opposition proceedings (France, US, Mauritius) in pharmaceutical, cosmetics and medical devices sectors.
- Handling domain names disputes (alternative resolution cases and litigation before the French courts regarding parasitism acts).
- Assisting clients in the protection and acquisition of IP rights.
- Handling of advertising litigation cases.

# Germany: CMS Hasche Sigle

## Scope of services

CMS Hasche Sigle has broad legal experience in the lifesciences sector. We are familiar with the specific requirements of the lifesciences industry and advising our clients on the following legal issues:

- Regulatory law (medical devices and medicinal products)
- EU and German competition law and merger notification issues
- Trade mark, patent and parallel import litigation
- Marketing and advertising of medicinal products and medical devices
- Research and development agreements/in and out licensing
- Integrated care agreements with health insurance schemes
- Marketing and supply agreements/contract manufacturing
- Product protection/anti-counterfeit
- Reimbursement issues
- Corporate restructuring/transformation and M&A
- Labour law

## Recent experience

- Acting on the acquisition of medicinal products from 3M and Wyeth.
- Instructed by the German Association of homeopathic doctors regarding integrated care agreements under sections 140a SGB V with Techniker Krankenkasse, Innungskrankenkasse, Betriebskrankenkassen etc.
- Acting for a leading European drug store retailer (including medicinal product regulatory law).
- Advising on a multinational patent litigation for a leading lifesciences company (worldwide) with regard to medicinal product (top 3 product in Germany).
- Acting on behalf of a leading research based pharmaceutical company (worldwide) with regard to patent litigation under the special mechanism.
- Acting in the largest German case on the sale of fake pharmaceuticals (the Adler case).

- Acting in the Zytostatica case regarding reimbursement fraud (Staatsanwaltschaft Mannheim).
- Acting on the Bayer Healthcare AG sale obtaining a carve-out of the anti-infectives business.
- Obtaining a carve-out of biotech business (Fresenius).

## The Team



**Heino Büsching**  
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Heino has over 10 years of experience providing lifesciences companies with corporate and tax advice. He specialises in M&A and tax structuring. He has provided advice in negotiating and drafting M&A agreements for biotech and pharmaceutical clients.

### **Relevant experience**

- Advising Pfizer on the sale of its German consumer healthcare business to Johnson & Johnson.
- Advising DocMorris with regard to various financing rounds and restructuring of the DocMorris group.
- Advising in relation to the sale of the DocMorris group to Celesio AG.
- Advising Vita 34 with regard to the acquisition of CorCell Inc. in the US, the structuring of business activities in Europe and several financing rounds including the IPO of Vita 34.
- Advising Merck & Co. in relation to the sale of the Pakistan business.
- Advising pharmaceutical companies in tax compliance issues.



**Markus Deck**  
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Markus is a Partner in the IP team. He is also a member of the lifesciences and TMT industry focus groups. He has over 20 years of experience in all aspects of IP and has a strong track record in contentious and non-contentious matters, with a focus on patents, licensing, combating product piracy, plagiarism and embezzlement of trade secrets. Markus had advised on several multi-jurisdiction litigations involving patents, trade marks and unfair competition, relating to, amongst other things, choice of forum issues, gathering of evidence and the coordination of proceedings in Europe and the US.

On the non-contentious side, Markus takes advantage of his experience gathered as an associate in corporate M&A work. He regularly advises on technology-driven transactions, including technology-driven joint ventures, international licensing structures and employee invention schemes.

Markus is a member of Licensing Executive Society, the European Patent Lawyers Association, AIPPI, the German Association for IP and Copyrights and the American IP Law Association. He regularly presents on the enforcement of IP rights for the Forum Institute for Management and is co-author of the Munich Attorneys Handbook on IP. In addition to German, Markus speaks English, French and basic Spanish.

### **Relevant experience**

- Acting in several multi-jurisdictional patent litigations for major pharmaceutical companies.
- Developing employee invention remuneration schemes under German law for multi-national corporations, mainly in the pharmaceutical and automotive industry.
- Acting for Otis in multi-jurisdictional patent litigation; coordinating with counsel in several European countries and the US.
- Acting for a major British-US pharmaceutical company defending patent suits.
- Coordinating patent litigation defence and antitrust proceedings for a major herbicide and crop protection company.
- Coordination of German and Austrian patent litigation for a major German pharmaceutical company.



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Regine joined CMS Hasche Sigle in 1993 and is an equity partner in the firm's M&A and corporate department. She is located in Stuttgart. She has been in the Lifesciences Team since its foundation and has been in charge of a large number of transactions in the lifesciences sector (biotechnology and pharmaceutical). Her practice covers venture capital and private equity deals as well as trade sales. She has been involved in transactions with a reconstruction background as well as transformation and merger of companies with an international background.

Regine has been a qualified lawyer in Germany ("Rechtsanwalt") since 1992. She received her doctorate in European corporate law at the University of Tübingen. She is a member of various supervisory boards of companies and foundations.

### **Relevant experience**

- Acting for biotechnology and pharmaceutical companies as regards their financing.
- Acting for financial investors acquiring interests in biotechnology and pharmaceutical companies.
- Restructuring of biotechnology and pharmaceutical companies.
- Advising companies regarding medical devices (regulatory).
- Advising companies in different corporate matters.



**Dr Philipp Koehler**  
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Philipp is a partner in the firm's IP and Lifesciences Team and he has extensive experience in advising on trade mark and unfair competition law as well as food labelling and pharmaceutical law. His practice spans both contentious and non-contentious issues including licensing, R&D, contract manufacturing and clinical trial agreements. He advises national and international clients with a focus on medical devices, pharmaceuticals and food. He has substantial experience in coordinating multi-jurisdictional litigation and working with IP colleagues from other jurisdictions.

Philipp has published numerous professional articles on IP law. His latest publications concern licensing agreements in insolvency proceedings of licensor or licensee, the exhaustion of copyrights, and agreements via the internet. He is co-author of a book on German unfair competition law for comparative advertising and trade secrets and of a compendium for attorneys on licensing agreements and insolvency.

Philipp has been a qualified lawyer in Germany (rechtsanwalt) since 1999 and in England and Wales (solicitor) since 2000. In 1998 he received his doctorate in copyright law from the University of Muenster. In 1999 he obtained a diploma (with distinction) in English Commercial Law at the College of Law, London.

### **Relevant experience**

- Acting for pharmaceutical manufacturers in numerous trade mark litigation matters in relation to their well-known trade marks and on distribution agreements with US distribution partners.
- Acting for a US bioscience company in respect of regulatory issues for licensing and distribution of tissue repair cells.
- Acting for a manufacturer of medical devices in contentious and non-contentious matters regarding various advertising campaigns for the distribution of medical devices.
- Advising manufacturers of medical devices in relation to various regulatory issues, e.g. classification and clinical studies, and contract manufacturing agreements.



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Ralf is a partner and head of the Corporate Practice in our Berlin office. He is an expert in corporate law, cross border M&A transactions and joint ventures. He advises international clients and has an industry focus on lifesciences. Ralf regularly represents foreign clients in acquisitions in Germany.

**Relevant experience**

- Advising Bayer Healthcare on sale of anti-infectives business.
- Advising UK based Astex Therapeutics on merger with German MetaGen.
- Advising UK based LGC Group on the acquisition of Germany based AGOWA.
- Advising Ribopharma on merger with US based Alnylam.
- Advising on German/US reverse triangular merger of two lifescience companies.



**Dr Kolja Petrovicki, LL.M. (UPenn)**  
**Counsel, Corporate, Lifesciences**  
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Kolja joined CMS Hasche Sigle in 2006 and is a Counsel in the firm's corporate department. He is located in Frankfurt. Kolja is specializing in corporate law, cross border M&A transactions and joint ventures and advises European and Non-European companies from the biotech, pharmaceutical, medical devices and chemical industries on all aspects of corporate law. Kolja spent secondments with the corporate M&A department of a leading German pharmaceutical company, the legal department of a leading US chemicals company, and the corporate lifesciences team of a New York law firm.

### **Relevant experience**

- Advising seller on its sale of E. Begerow GmbH & Co. to Eaton.
- Advising Boehringer Ingelheim on various corporate law matters.
- Acting for a strategic investor at its purchase of a minority interest in a German medical devices company.
- Advising a medical devices company on the set up and structuring of its German group business.
- Acting for purchaser at the cross-border acquisition of a CRO company.
- Advising a medical devices company on its acquisition of a German and foreign medical devices group.
- Advising a pharmaceutical company on its cross-border acquisition of an interest in a biotech company.
- Advising a major US chemicals company at the restructuring of its German business.
- Advising a major US chemicals company on the sale of an industrial park in Germany.
- Advising one of the largest privately held US chemicals companies on various corporate law and commercial law matters.
- Advising a leading German specialty chemicals company on supply agreements.
- Advising strategic investors acquiring interest in biotech and lifesciences companies.
- Restructuring of pharmaceutical companies.
- Advising a leading German DAX-listed company on its asset sale in the lifesciences industry.
- Acting for a financial investor in the financing round of a red biotech company.



**Dr Oliver Simon**  
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Oliver is an acknowledged specialist in employment law. He advises national and international companies, including lifesciences companies, on all aspects of employment law. He focuses on restructuring, outsourcing business divisions and changes in collective bargaining agreements as well as the related negotiations with trade unions and employee representatives on reconciliations of interest, social plans and transitional agreements. He also provides ongoing legal advice to large companies and SMEs on all aspects of employment law. He has been published widely and is a frequent contributor to publications on employment law topics. He lectures on employment law at the Steinbeis Hochschule Berlin.

#### **Relevant experience**

- Advising Procter & Gamble on labour and employment law issues, including outsourcing measures and restructuring.
- Advising Yves Rocher on hive-out and the sale of a business division, including information to employee representatives and staff; negotiation with employee representatives.
- Advising Schwarz Group (Lidl) on a Europe-wide compliance audit regarding employment contracts.
- Advising a local authority owned hospital on a privatisation project, in particular on issues of pensions for public service employees, including negotiations with the pension provider (ZVK and VBL) on maintaining or terminating membership, and on special forms of membership in pension schemes for the public service.
- Advising ACCO brands on several restructuring projects including cross-border restructuring, such as the outsourcing of production from Germany to the Czech Republic and the outsourcing and centralisation of the distribution centre in Germany to the Netherlands.



**Dr Jens Wagner**  
**Partner, IP**  
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Jens joined CMS Hasche Sigle in 1994 and is a partner in the firm's IP and Lifesciences Team. He is a member of the CMS Lifesciences Sector Group.

Jens' practice covers both contentious and non-contentious issues in relation to intellectual property (including R&D agreements, in and out licensing agreements, trade mark and patent litigation), unfair competition (including health related advertising claims) and manufacturing and distribution (including contract manufacturing and co-promotion and co-marketing agreements). He also advises clients in regulatory and healthcare compliance matters (in particular anti-corruption).

Jens is recommended by the JUVE handbook on German law firms in the areas of trade mark law and unfair competition law, patent litigation and pharma and medical devices law. Jens is co-author of the lawyer handbook on intellectual property law (customs seizure) and co-author of the lawyer handbook on sales and supply law (pharmaceutical sales and supply law).

### **Relevant experience**

- Advising Hutchinson Technology & Eli Lilly on regulatory law (medical devices and medicinal products).
- Advising Boehringer Ingelheim, Eli Lilly and Pfizer on trade mark and parallel import litigation.
- Advising Boehringer Ingelheim, GE Healthcare, Eli Lilly, Pfizer and Johnson & Johnson regarding marketing and advertising of medicinal products and medical devices.
- Acting for Johnson & Johnson on compliance matters.
- Advising on research and development agreements/in and out licensing for Berlin Heart, Bioserv AG & Oncoscience.
- Advertising on co-promotion and co-marketing agreements and on M&A agreements for MSD.



**Volkmar Wagner**  
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Volkmar specialises in all public procurement matters in a number of sectors including the lifesciences and healthcare sectors. He advises pharmaceutical and medical device clients in the public procurement procedures of the public health insurance companies in Germany (gesetzliche Krankenkassen). He also advises hospitals on procurement law issues.

### **Relevant experience**

- Advising Erbe Elektromedizin GmbH and associated companies on public procurement issues, including the foundation of various bidder partnerships in public procurement procedures.
- Advising DAP Deutsches Arzneimittelportal on various public procurement procedures.
- Advising medical device companies (mostly mid-sized) on public procedures.
- Advising numerous hospitals as purchasers of pharmaceuticals and medical devices on public procurement issues.
- Advising Deutsches Krebsforschungszentrum Heidelberg on public procurement issues.



**Dr Heidi Wrage-Molkenthin**  
**Partner, Competition, IP**  
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Heidi is a partner at CMS Hasche Sigle. She advises clients on all aspects of unfair competition law and anti-trust law, both on contentious and non-contentious issues.

From 1994 until 1998 she was a lecturer at the University of Leipzig teaching unfair competition law and anti-trust law. She has published numerous articles and made contributions to books on competition and anti-trust law.

Heidi is a graduate of the University of Hamburg. She was a research associate at the Institute of Trade and Company Law from 1981 until 1983, and obtained her doctorate degree with her work *Sanctions of Unfair Competition Law in the case of Anti-Trust Law Offences*. Heidi is an associated member of the BVMed (German Medical Technology Association) legal issues group. She is named as recommended counsel in the field of unfair competition law in the *JUVE Handbook on German Commercial Law Firms 2010*.

### **Relevant experience**

- Advising major international producers of medical devices on advertising campaigns and product launches, as well as product liability, including product recall issues.
- Advising medical devices companies in unfair competition issues.
- Advising a service provider in the healthcare sector.
- Advising a pharmaceutical wholesaler in anti-trust issues.
- Advising medical devices companies in contractual issues including aspects of interaction with healthcare professionals.



**Dr Jörg Zättsch, LL.M.**  
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Jörg is a partner in the Corporate Practice in Berlin. He specialises in M&A transactions, venture capital and corporations with a focus on the biotechnology sector. Jörg regularly advises biotech companies on venture capital financing as well as on cross border M&A transactions.

He is chairman of the Corporate and Capital Markets Group of the biotechnology association BioDeutschland and he teaches commercial and corporate law as part of the MBA-course BioMed-Tech at the University of Potsdam.

#### **Relevant experience**

- Advising Keyneurotek Pharmaceuticals AG on a financing round.
- Advising Novosom AG on a financing round.
- Advising investors in Revotar Pharmaceuticals AG on a financing round.
- Advising investors in Signature Diagnostics AG on a financing round.
- Advising Bayer Healthcare on the sale of its anti-infectives business.
- Advising Ribopharma in its merger with Alnylam.
- Advising Astex Therapeutics in its merger with a German biotech company.
- Advising on several cross border transactions in the lifesciences industry.



**Dr Ulrich Külper**  
**Of Counsel, IP**  
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Ulrich has extensive experience in advising on all aspects of intellectual property. His practice spans both contentious and non-contentious issues in relation to trade mark, patent, design, copyright, and passing off. He advises clients across a wide range of industry sectors including consumer products, unfair competition and pharmaceutical law, high technology, engineering and pharmaceuticals.

Ulrich is a member of the GRUR-Patentrechtsausschuss.

#### **Relevant experience**

- Providing permanent legal representation to two pharmaceutical manufacturers (both among the five leading companies worldwide).
- Advising and representing exclusively one of Germany's biggest cigarette manufacturers for more than 30 years, especially in the IP field.



**Dr Heike Blank**  
**Senior Associate, IP**  
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Heike has been a senior associate in the IP team in the Cologne office since 2001. She has expertise in both contentious and non-contentious issues in relation to unfair competition and trade mark law with a special focus on pharmaceuticals. Her forensic work concentrates on representing major German and international corporations particularly with regard to interim injunctions. Her considerable experience includes advising on all aspects ahead of new product launches and new marketing methods and plans, including comparative advertising, consumer promotions and lotteries.

Heike studied law at the University of Cologne. She has a doctorate in unfair competition law in relation to new distribution channels on the topic of *Permissibility of Legal Advice via Telephone Value-Added Service Providers*. She is a member of German Association for IP and Copyright Law (GRUR) and has been admitted to the Higher Regional Court of Cologne. Heike regularly lectures on unfair competition law and on the mandatory training for specialist attorneys.

### **Relevant experience**

- Acting for Bayer Healthcare AG and its subsidiaries in a broad number of court procedures with a focus on advertising both OTC and POM products.
- Acting for an international corporation in various interim injunction procedures to protect all relevant business secrets (in particular all customer data) of the company.
- Advising a large pharmaceutical manufacturer on an international launch of a new medical device.



**Dr Jan Dombrowski, LL.M.**  
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Jan is an associate in the IP Team in the Stuttgart Office. He has been with CMS Hasche Sigle since 2005. He advises on national and cross-border patent infringement proceedings such as compensation proceedings and opposition and nullity proceedings in a variety of sectors including the medical and pharmaceutical industries. He provides legal advice on matters concerning employee inventions, licensing agreements and technical property rights.

Jan studied at Frankfurt and Düsseldorf and obtained a doctorate in law at the University of Frankfurt in 2004. In addition he obtained an LLM in IP law at the University of Düsseldorf. He is a member of the German Association for IP and Copyright Law (GRUR), the International Association for the Protection of IP (AIPPI), the European Patent Lawyers Association (EPLAW), the American IP Law Association (AIPLA) and the German-Chinese Business Association (DCW). He has been a lecturer at the Duale Hochschule Baden-Württemberg in Stuttgart since 2010. Jan speaks regularly at both internal and external conferences and workshops on IP issues. In the past he has also worked in the Shanghai office of CMS Hasche Sigle. Jan is a native German speaker and he is fluent in English.

### **Relevant experience**

- Acting for TRUMPF in various patent infringement cases. TRUMPF is one of the largest European manufacturers of machine tools and a specialist in medical devices.
- Acting for ERBE Elektromedizin, an important manufacturer for medical devices, in patent infringement proceedings.
- Acting for one of the largest research-focused healthcare companies in patent infringement proceedings.



**Jill Nina Theuring, LL.M.**  
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Jill joined CMS Hasche Sigle in 2006. She focuses her practice on the lifesciences industry where she advises clients from Europe, the US as well as Asia on corporate and commercial law.

She works on venture capital and private equity transactions and counsels clients from the biotech, pharmaceutical, medical devices and CRO industry in all aspects of corporate law. She is also involved in structuring and implementing joint ventures in this industry sector.

She has extensive experience in advising clients in commercial matters such as R&D collaborations, intellectual property, licensing and supply and distribution.

Prior to working with CMS Hasche Sigle, Jill interned with Kirkland & Ellis in Chicago, New York and London as well as Rigel, Inc., a small molecule discovery company in South San Francisco. She also worked for the Munich office of Jones Day, where she was a member of the Lifesciences Practice Group.

### **Relevant experience**

- Advising 3i in numerous private equity transactions in the lifesciences sector, in particular in several secondary transactions. She also worked in many cross-border M&A transactions.
- Acting as general legal counsel of the publicly listed company Epigenomics AG in Berlin.
- Acting as the long-term corporate counsel of an Indian CRO company with regard to its German subsidiary and as well as its business matters in Germany;
- Advising numerous clients of the German biotech sector in corporate and commercial matters;
- Advising the German Biotechnology Industry Organisation (BIO Deutschland).



**Dr Roland Wiring**  
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Roland is an associate in the Hamburg IP Team. He advises clients in all fields of IP law and competition law, both in contentious and non-contentious matters. His focus is on antitrust law, media law, unfair competition law and trade mark law. He also has particular expertise in the field of European chemicals law, in particular under the REACH Regulation, and extensive experience in dealing with issues relating to the media, consumer products, pharma, energy and chemistry sectors.

Roland teaches competition law with a focus on media at the University of Hamburg. He has published various legal articles, mainly in the fields of antitrust and unfair competition law, and regularly gives lectures on current issues in these areas. Roland is a member of the German Association for IP and Copyright (GRUR), the German-American Lawyers' Association (DAJV) and the German-French Lawyers' Association (DFJ).

#### **Relevant experience**

- Advising a major international producer of medical devices on advertising and competition law issues.
- Advising a major international pharmaceutical company on distribution and pricing strategies.
- Advising producers and downstream users of chemicals on civil law issues related to the REACH Regulation, particularly in relation to the cooperation within SIEFs and access to relevant data.
- Advising a major international tobacco company on all aspects of competition law.



**Dr Jörn Witt**  
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Jörn joined CMS Hasche Sigle in 2006 and is a senior associate in the firm's IP and Lifesciences Team located in Hamburg. Jörn is also part of the Competition Law group.

Jörn regularly works both on contentious and non-contentious issues in relation to IP, unfair competition and competition law. His practice in lifesciences in particular focuses on regulatory matters, product piracy protection and competition law issues in the sector. Jörn also has expertise in drafting business contracts in the lifesciences sector (including Co-Marketing, Co-Promotion, Contract Manufacturing agreements).

#### **Relevant experience**

- Advising Eli Lilly, Du Pont and Bayer Healthcare on product piracy matters.
- Advising and acting in litigation for Lilly Deutschland on health advertising, regulatory issues and parallel import cases.
- Advising pharmaceutical companies on M&A deals with a focus on regulatory implications.
- Advising pharmaceutical companies on licensing and other business development contracts.
- Advising a major German doctors' association on health insurance and contractual issues.
- Advising and acting in litigation for a major international crop company on release trials for genetically modified crops.

# Hungary: CMS Cameron McKenna

## Scope of services

The Lifesciences Team in Hungary is composed of three associates headed by partner Dóra Petrányi. The team has expertise in all aspects of pharmaceutical regulatory and commercial law. Clients receive quality support on negotiating with authorities or contracting parties. The Budapest office also has considerable experience in advising on clinical trial agreements and applying the special environmental requirements relating to clients' operations and products. Our lifesciences experience coupled with the insight we have developed through long term relationships with some of the lifesciences industry's key players means that our clients benefit from working with a team that really understands the sector and its issues.

The Budapest team can offer:

- experience in advising leading organisations in the pharmaceutical sector;
- experience in negotiating with the National Institute of Pharmacy and the National Health Insurance Fund;
- specialist lawyers that can assist with competition, intellectual property, data protection and other issues related to commercial law; and
- a team geared to meeting the standards that international organisations expect as a result of a client base that includes many foreign investors.

## Recent experience

- Advising a US-based global pharmaceuticals company on promotional activities and the sales representative tax. Advising on distribution of products, review of distributorship agreements as well as competition law.
- Advising a US-based multinational medical instruments and supplies company on all aspects of their operations, including ethical issues, general employment works, a dawn raid response program and a domain name dispute.
- Advising a US-based medical technology company on its Hungarian green-field investments, including company set up, project support during the construction phase and day-to-day legal support once the production started, including employment matters of the Hungarian operations.
- Advising a German-based chemical and pharmaceutical company on data exclusivity, reimbursement and litigation matters.
- Advising a private biopharmaceutical company on clinical trial agreements.

- Advising a biotechnology company in connection with the establishment and operation of research and development capabilities in Hungary.
- Advising a leading American based biotech Company on a wide range of corporate, commercial and regulatory issues (advertising products, data protection issues, competition law advice).
- Advising a Swiss global healthcare company on general commercial contracts, employment issues.
- Advising a Japanese pharmaceuticals company on the preparation of sponsorship policy with regard to advertising their products, organizing and participating in congresses.
- Advising a major pharmaceutical company in relation to a distribution agreement with a major competitor for distributing certain products.
- Advising a major German chemical company on carrying out the Hungarian part of the global competition audit, reviewing local distribution and other agreements for smoking guns.
- Advising a major American producer and distributor of household, healthcare and personal products on corporate and commercial restructuring of the Hungarian operation.
- Advising one of the world's leading pharmaceutical companies on the sale of its consumer healthcare business.
- Advising a world leading British vaccine manufacturer on the development of its business in Hungary.
- Advising the German subsidiary of a major Italian pharmaceutical company in relation to trade mark infringement issue and representing them against a competitor.
- Advising a major American chemical company on trade mark infringement matter; representing the client before the customs authority.
- Advising a HR service provider, providing services solely to the lifesciences sector, regarding trade mark registration.
- Advising a company dealing with international and national management of clinical trials on the establishment of its Hungarian subsidiary and advice on transferring the sponsor's trial-related duties and functions of a clinical trial.
- Advising a pharmaceutical company on importing medical devices.
- Representing a medical devices company in a number of proceedings, including proceedings for labelling/marketing medical devices.
- Advising a pharmaceutical company on the registration of medical devices.
- Advising a pharmaceutical company on requirements concerning medical devices, including in particular certificates of quality, labelling/marketing, and CE marking.

## The Team



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Dóra is a partner at the Budapest office of CMS Cameron McKenna LLP. She has 17 years of legal experience. Her major clients are lifesciences companies, telecommunications companies foreign-owned commercial banks, and major joint ventures. Her areas of specialisation include: the lifesciences and tech-media telecom sectors; IP law matters; competition law; general commercial contracts; corporate restructuring; and M&A. She advises major pharmaceutical, biotechnological and medical device manufacturing companies at a national and European level on a wide variety of issues, from general pharma law to representation before the competent authorities. Dóra is also a specialist in eHealth. Dóra is fluent in English and German and she has conversational level French and Russian.

### Relevant experience

- Representing a major American Medical technology company before relevant authorities in connection with the establishment of a plant in Hungary. Providing regulatory advice on promotional activities and sponsoring agreements and advice on general commercial law and compliance matters.
- Advising a US-based global pharmaceuticals company on promotional activities and the sales representative tax. Reviewing distributorship agreements from a competition law perspective.
- Representing a major pharmaceutical company on a biological tender; providing overall tax advice and representation in the marketing authorisation procedure before the National institute of pharmacy and in the reimbursement procedure before the Health Insurance Fund.
- Advising a major US chemical company on a trade mark infringement matter; representing the client before the customs authority.
- Advising a major US lifesciences company on a trade mark infringement matter; representing the client before the customs authority.
- Advising a major US pharmaceuticals company on speaker and sponsorship agreements.
- Advising major international lifesciences companies in relation to competition procedures (misleading of customers, alleged abuse of dominant position).



**Dr Ágnes Sólyom**  
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Ágnes is an associate at our Budapest office who specialises in intellectual property and litigation matters. Ágnes has experience in dealing with a wide range of IP and litigation matters, including representing clients before the Hungarian Patent Office, WIPO, OHIM and in court procedures, and advising and assisting clients in day-to-day IP and litigation matters. Ágnes has significant experience in advising clients from the lifesciences sector. Ágnes is fluent in English, Italian and French.

### **Relevant experience**

- Advising a US-based multinational medical instruments and supplies company in connection with a domain name dispute.
- Advising a global manufacturer and marketer of differentiated chemicals on the preparation of their invention policy.
- Advising one of the world's leading pharmaceutical companies on the sale of its consumer healthcare business.
- Advising a Swiss global healthcare company on trade mark registration issues and on various employment matters.
- Advising a France-based multinational pharmaceutical company on various employment matters.
- Advising a HR service provider, providing services solely to the lifesciences sector, on trade mark registration.
- Advising a major US lifesciences company on a trade mark infringement matter; representing the client before the customs authority.
- Advising a major US chemical company on a trade mark infringement matter; representing the client before the customs authority.
- Advising a major international lifesciences/consumer products company on corporate and commercial restructuring of their Hungarian operation.
- Advising a US-based medical technology company on debt collection matters.
- Advising a major US lifesciences company on a patent infringement matter; representing the client before the customs authority.



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Veronika is a pharma-law specialist, with over 5 years of experience working on a range of issues for the biggest Lifesciences companies in the country. She has been involved in various regulatory matters including medical devices and medical aids, as well as matters on the distribution, marketing and advertisement of medicinal products. She also has in-depth experience in drafting wholesale distribution agreements, assisting pharmaceutical (Lifesciences) clients with their promotional activities on a daily basis, supporting them in sensitive cases such as liability and product recall procedures. She has spent 6 months secondment at one of our biggest Lifesciences clients, and gained an in-depth understanding of the business of an international pharmaceutical client, as well as advising various divisions of the company on a wide-range of matters. Veronika speaks fluent English and German.

### **Relevant experience**

- Advising an Italian pharmaceutical company on distribution, registration, labelling and packaging of medicinal products and medical devices and advising on the distribution of food supplements. Representing the client before the national authorities.
- Providing legal advice to a US-based pharmaceutical company on the promotion of medicinal products, the registration of sales representatives, the promotional activities of sales representatives and pharmaceutical companies' obligation to pay the sales representative tax.
- Advising a UK pharmaceutical company on clinical trials and drafting various clinical trial agreements. Advising the client on the authorisation of clinical trials in Hungary, representing the client in the authorisation procedure before the National Institute of Pharmacy. Drafting the Patient Information Sheet and the Informed Consent Forms. Advising the client in relation to the investigator's duties and responsibilities, and providing legal advice on the recruitment of patients in clinical trials. Assisting the client in several patient claims in relation to alleged damages caused by taking the medicinal product.
- Advising a major UK pharmaceutical company in all aspects of its operations, including ethical issues, pharma-regulatory and general commercial matters. Representing the company before the National Consumer Protection Authority in relation to an advertisement of the company's medicinal product in pharmacies.
- Advising a company dealing with international and national management of clinical trials on transferring the sponsor's trial-related duties and clinical trial functions.



**Dr Miriam Fuchs**  
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Miriam is a trainee lawyer in the Budapest office's general commercial team. She joined the firm in 2011. She graduated from the Eötvös Lorand University in 2011. She assists in reviewing and drafting general commercial agreements and in preparing various memoranda relating to commercial regulatory issues. Besides Hungarian, Miriam speaks fluent English.

### **Relevant experience**

- Providing day-to-day legal advice to a pharmaceutical company, including drafting contracts, reviewing promotional campaigns.
- Updating the internal policy of a pharmaceutical company regarding the promotion of medicinal products and medical aids.
- Providing legal advice to a US based pharmaceutical company in connection with its health care awareness campaign including legal research on the handling of medical devices, and the public procurement of medical devices.
- Reviewing a US based pharmaceutical company's promotional campaigns.
- Drafting and reviewing commercial contracts for a Swiss pharma company.
- Legal review of the promotional website of a US based pharmaceutical company's, carrying out regulatory type assignments regarding the donation of medicinal products.
- Providing legal advice to a UK based and a US based pharma company in connection with the legal regulations on clinical trials in Hungary.

# Italy: CMS Adonnino Ascoli & Cavasola Scamoni

## Scope of services

The firm's lifesciences practice assists clients operating in the fields of pharmaceuticals, biotechnology, medical devices and more generally, healthcare services.

We regularly advise lifesciences companies on corporate governance matters, licensing and contracts, as well as day-to-day corporate issues.

CMS AACCS has provided assistance over the years to over 20 national and international clients operating in the lifesciences sector.

Our areas of expertise in this sector include:

- Manufacturing agreements
- Distribution agreements
- Service agreements with parent companies
- R&D agreements
- Regulatory issues
- Acquisition and disposal of production plants
- Joint ventures
- Spin-offs
- IP protection and enforcement
- Antitrust
- Cost sharing agreements
- Transfer pricing
- Compliance issues (Law 231/2001)
- Employment related issues including collective dismissals.

## Recent experience

- Advising a leading international dental care company and a major international pharmaceutical company in relation to privacy and on the drafting of compliance programmes under Law 231/2001.

- Advising an international medical company (engaged in medical diagnostic testing and health management) in relation to the Italian 32 legal framework for the classification of a cholesterol test as an IVD self-diagnostic device.
- Advising a multinational medical devices company on the Italian legal framework for the sale to consumers of HIV testing kits and services.
- Advising an international company producing medical devices for healthcare professionals on the Italian legal minimum requirements for post-sale product support requirements in relation to capital equipment supplied for professional medical use in Italy.
- Advising in the acquisition of Nutrition & Santé (a company within the food and beverage sector) by the Japanese group Otsuka Pharmaceutical Co.
- Advising a leading international dental care company (controlled by the ONEX Fund) on the Italian law aspects of the acquisition in various jurisdictions of several branches of Eastman Kodak Company for a total value of \$2.5m and \$168m in Italy.
- Advising a multi-specialty healthcare company focused on pharmaceuticals on the de-merger of its Italian production plant in Pomezia, Rome.
- Advising a major international pharmaceutical producer on the sale (authorisations) and licensing of several pharmaceutical products in Italy.
- Advising a major international pharmaceutical company in relation to the transfer of OTC products (including cosmetics) to a fund. We have also assisted the company in complying with privacy regulations in Italy.
- Advising a major international pharmaceutical producer on the licensing of homeopathic products to an Italian company.
- Advising a veterinary pharmaceutical company on likely violation of patent rights related to an active ingredient of the company's main product.
- Advising a major pharmaceutical company operating in the advanced refractive technologies on an ongoing basis for all legal assistance both in contractual and in contentious matters.
- Advising a major international vaccine producer in the management of claims related to adverse effects of its products.

## The Team



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Laura joined the Firm in 1989 and was appointed partner in 1994. Her areas of interest include trade mark and protection related issues including commercial contracts (distributorship, franchising and agency).

She has also assisted various pharmaceutical companies and has worked more generally in the lifesciences area. She has experience in relation to the drafting of compliance models for companies and has reviewed various compliance policies according to Italian Law n.231/2001 (Anti Bribery Law).

She has attended various training courses in ADR, International commercial Mediation and Advocacy in Mediation provided by CEDR (Centre for Effective Dispute Resolution, London) and provided by ADR Centre of Rome.

She writes for the Ipsos Francis Lefebvre Publisher (Memento) and her contributions include: *Italian Company Law* and *Trade Contracts* (relating to distributorship, franchising and merchandising agreements).

In addition to Italian, Laura is fluent in English and French.

### **Relevant experience**

- Advising a multi-specialty healthcare company focused on pharmaceuticals on the de-merger of its Italian production plant in Pomezia, Rome.
- Advising a major international pharmaceutical producer on the drafting of sale and purchase agreements in Italy and abroad.
- Assisting a major pharmaceutical company operating in advanced refractive technologies in Italy on an ongoing basis with all its legal assistance, both in contractual and in contentious matters.



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Emilio joined CMS with his team and he heads the Italian Fraud & Corporate Criminal Defence Team. His practice focuses on corporate, automotive, energy (multi-utilities), litigation (including civil and criminal proceedings), internal investigations and compliance matters.

Prior to joining CMS Adonnino Ascoli & Cavasola Scamoni, Emilio worked for several years as a partner in other prestigious Italian law firms (Tonucci & Partners and the law firm operating mainly on Law 231/2001 managed by Prof. Astolfo Di Amato).

Emilio has also written various articles relating to compliance matters and has recently completed the section on sanctions (Le Sanzioni) included in the new volume *Il Trattato di Diritto Penale dell'impresa* published by CEDAM.

In addition he is chair of commercial law at the Università di Camerino.

Emilio is fluent in Italian and English.

### **Relevant experience**

- Advising a leading international dental care company and a major international pharmaceutical company in relation to privacy issues and on the drafting of the model of organisation, management and control (i.e. compliance programmes) under Law 231/2001.
- Advising a multi-specialty healthcare company focused on pharmaceuticals on the drafting of the model of organisation, management and control (i.e. compliance programmes) under Law 231/2001.



**Pietro Cavasola**  
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Pietro is a partner in the corporate department of CMS Italy. He is a member of the board of directors of various companies. He has extensive international experience. His clients include several important national and multinational companies, operating in industries ranging from pharmaceuticals to publishing and printing.

He has assisted various clients operating in the lifesciences sector on a wide variety of issues. Major clients in this area include: Pfizer, Allergan, Madimo S.r.l. and BioPharm Italia S.r.l. (BioProgress Plc group), Lisapharma, AMO Italy and Carestream.

Pietro sits in the boards of directors/auditors of several major Italian and international companies. His areas of specialisation include corporate law, M&A, joint ventures, international contracts, and antitrust issues.

He has written several publications on joint ventures and the European company. In addition to Italian, Pietro speaks English, French and has a basic knowledge of German.

### **Relevant experience**

- Advising a major international pharmaceutical company in relation to the transfer of OTC products (including cosmetics) to a fund.
- Advising a major international pharmaceutical company on privacy regulation compliance.
- Advising a major neuroscience-based biotechnology company on its ongoing activity in Italy (including the servicing agreements for the management of the plant based in Pomezia). Assisting in the separation of the commercial and manufacturing activities and the disposal of the latter.
- Advising a manager of medical services on add-on acquisitions of two Italian lab service providers.
- Advising in the acquisition of Nutrition & Santé (a company in the food and beverage sector) by the Japanese group Otsuka Pharmaceutical Co.



**Paola Nunziata**  
**Senior Associate, IP**  
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Paola joined the firm in 2004 and works in the Italian IP department. She was admitted to the Italian Bar in 1998. As a senior associate her areas of specialisation include intellectual property issues, commercial contracts, and general litigation. She was seconded to CMS Hasche Sigle in 2006. She is a member of the IP Practice Group and she is currently based in Rome. Paola has also written various articles in relation to different legal issues.

In addition to Italian, Paola speaks fluent English and French and has a basic knowledge of German.

### **Relevant experience**

- Advising a major international pharmaceutical producer on the sale and licensing of several pharmaceutical products in Italy.
- Advising a major international pharmaceutical company in relation to the transfer of OTC products (including cosmetics) to a fund.
- Advising a major international pharmaceutical company on privacy regulation compliance.
- Advising a major pharmaceutical company on the licensing of homeopathic products to an Italian company.
- Advising a veterinary pharmaceutical company on likely violation of patent rights related to an active ingredient of the company's main product.



**Maria Letizia Patania**  
**Senior Associate, Litigation & Commercial**  
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Maria is an associate in the Rome office. After completing her studies, she joined the firm in the Rome office and was admitted to the Bar in 2006. As a senior associate, her main areas of specialisation include civil and commercial litigation and commercial contracts. She has assisted clients operating in the lifesciences and pharmaceutical sectors in commercial litigation.

In addition to Italian, Maria is fluent in English.

### **Relevant experience**

- Advising a major international pharmaceutical producer on the sale and licensing of several pharmaceutical products in Italy.
- Advising a major international pharmaceutical company in relation to the transfer of OTC products (including cosmetics) to a fund.
- Advising a major international pharmaceutical company on privacy regulation compliance.
- Advising a major pharmaceutical company on the licensing of homeopathic products to an Italian company.
- Advising a veterinary pharmaceutical company on likely violation of patent rights related to an active ingredient of the company's main product.

# The Netherlands: CMS Derks Star Busmann

## Scope of services

CMS Derks Star Busmann's Lifesciences Group specialises in advising clients from the pharmaceutical, biotechnology, medical devices and cosmetics industries. Our highly specialised lawyers operate across the majority of legal disciplines in the lifesciences sector, including: intellectual property; regulatory; corporate; EU and competition; commercial; employment and pensions; and real estate. This allows us to meet the wide business needs of our clients locally and internationally.

Our considerable expertise in the pharmaceutical, biotech and medical products areas allows us to deal with matters efficiently and cost effectively. We advise and represent clients in all matters which are important in the lifesciences sector today, including on:

- European and national procedures for marketing authorisations
- Regulatory issues
- Prices and fees
- Patents, SPCs, trade marks and other intellectual property rights
- Know how protection and data exclusivity
- Advertising and promotion for medicines
- Competition law
- M&A
- Parallel import
- Product liability
- Joint ventures
- R&D agreements
- Commercial contracts
- Contract research
- Agreements for clinical trials
- Distribution and licence agreements
- EC regulations on GMP, GCP and GLP
- Funding of pharmaceutical and biotechnology projects

- Regulations in the area of medical aid, food and cosmetics

## Recent experience

- Acting for a Danish pharmaceutical company in a patent case. This matter led to many proceedings before the district and appeal patent court in the Hague and the Dutch Patent Council.
- Representing a Dutch company and supplier of medical devices in a dispute with another pharmaceutical company regarding an allegation that the client was producing medical devices that were non-compliant with the European medical device directive.
- Acting for a pharmaceutical company in a case where a third company was in possession of and using confidential and commercial information and in taking action against the competitor to prevent the competitor using this confidential information.
- Advising and assisting a global pharmaceutical company in cross border patent matters (FTO) concerning the introduction of a new pharmaceutical product on the European market.
- Advising one of the largest pharmaceutical companies worldwide on the proposed acquisition of the pharmaceutical division of another large pharmaceutical company through the acquisition of the entire issued capital of one of the holding companies in the top of the target group structure. This involved elaborate pharma, commercial and IP due diligence.
- Advising two major hospitals on their merger.
- Advising the shareholders of Diagnos Biochemical Cattle Management in the sale of technology for progesterone detection to CEVA Sante Animale.
- Acting on matters of Dutch law for NASDAQ listed Digene Corp. in its US\$1.6 billion merger with the Frankfurt and NASDAQ listed Dutch company QIAGEN N.V.
- Acting for PamGene, a developer of multi-protein interaction technology for cancer biomarker discovery, drug development and disease diagnoses, in its second and third financing rounds.
- Acting for a global biopharmaceutical company supporting them on a large number of agreements, including all commercial agreements and general terms and conditions.
- Advising on legal classification, import and distribution of human-derived (engineered) tissue products.
- Advising on the set up of a cross-border internet/post order pharmacy.
- Acting for a global cardiovascular company with its global marketing and sales headquarters in the Netherlands. Drafting all commercial agreements such as distribution agreements, agency agreements as well as the general terms and conditions and sales agreements.

## The Team



**Willem Hoorneman**  
Partner, IP  
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Willem is the head of the IP Practice Group and has been practising as a lawyer since 1987. He specialises in all areas of intellectual property law, with a particular emphasis on patent and trade mark law.

Willem has a broad advisory and litigation practice. He has also earned an excellent reputation as a legal advisor on the marketing of inventions, and has experience in the area of intellectual property licences.

In the Netherlands, Willem is one of the best-known patent and trade mark lawyers. He frequently publishes articles on intellectual property issues and is a regular speaker at congresses and seminars on the same theme. He is the editor-in-chief of the BMM Bulletin, the only legal magazine in the Benelux countries on the subject of trade mark and design rights. In 1999 Willem won the prestigious Wim Mak Award for his article *Is design law worthwhile in addition to copyright?* Willem is an active member of various national and international specialist associations on intellectual property law.

### Relevant experience

- Advising Takeda Pharmaceutical on its €9.6 billion (debt-free cash free) acquisition of Swiss drug company, Nycomed.
- Acting for a Danish pharmaceutical company in a patent case regarding a pharmaceutical product. This matter led to many proceedings before the district and appeal patent court in the Hague and the Dutch Patent Council.
- Representing a Dutch company and supplier of medical devices in a dispute with another pharmaceutical company regarding an allegation that our client was producing medical devices that were non-compliant with the European medical device directive.
- Acting for a pharmaceutical company in a case where a third company was in possession of and using confidential and commercial information and in taking action against the competitor to prevent use of this confidential information.



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Martijn is a partner with CMS Derks Star Busmann and a civil law notary in the Corporate/Corporate Finance Practice Group. His experience includes national and international M&A, divisions of enterprises, reorganisations, private equity, joint ventures, business succession, management buy-outs and management buy-ins, employee participation schemes, investment funds and corporate governance, including healthcare governance. In addition, Martijn advises on setting up joint ventures as well as major mergers within the care and welfare sector.

**Relevant experience**

- Advising two major hospitals on their merger.
- Advising a major health insurance company on a merger.
- Advising a major biopharmaceutical company on a private equity investment.
- Advising hospitals and medical specialists on setting up joint ventures.
- Advising hospitals and medical specialists on setting up institutions for specialist medical care.



**Marcoline van der Dussen**  
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Marcoline is an excellent and highly knowledgeable IP litigator. She is renowned in the field of product protection and design protection. In her 20 years of experience Marcoline has built longstanding relationships with high profile clients who commend her for her dedication and pragmatic approach.

Apart from her focus on trade mark, copyright and design law, Marcoline is also well versed in advertising law. She regularly advises international advertising agencies on promotional campaigns and assists companies in proceedings before the Dutch Advertising Committee.

Marcoline has written over 75 hands-on articles on legal subjects of particular interest to businesses and advertising agencies, and has a regular column in the Dutch trade journal *Product*.

#### **Relevant experience**

- Advising on IP issues (particularly advertising issues) for the pharmaceutical industry.



**Anita Canta**  
**Commercial**  
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Anita is an attorney at law and an associate with CMS Derks Star Busmann's Corporate and Lifesciences team and has been practising as a lawyer since 2002.

Anita is engaged in advising companies and organisations in the Netherlands and internationally that are active in the field of pharmaceuticals, medical devices, food products, industrial products and related industries (such as manufacturers, wholesalers and importers).

She regularly advises clients on a large number of agreements (including distribution agreements, agency agreements, manufacturing agreements, franchise agreements and clinical trial agreements). Anita also has experience in licensing affairs and acquisitions and auditing in the pharmaceutical industry.

Anita frequently lectures and publishes on topics that relate to contracting (e.g. franchising, general terms and conditions). She is a member of the Supervision Commission of a forensic hospital.

### **Relevant experience**

- Acting for a medical device company. Drawing up their commercial agreements and supporting them on regulatory matters.
- Acting for a pharmaceutical company, supporting them on a large number of agreements, including all their commercial agreements and general terms.
- Carrying out legal due diligence of pharmacies.
- Representing a pharmaceutical company in conflicts about potential acquisitions.
- Advising a pharmaceutical company regarding the termination of a clinical trial agreement.



**Bart Essink**  
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Bart has been a member of the Lifesciences Group since 1 January 2009, specialising in commercial and company law. Bart has gained wide ranging experience in the lifesciences industry and has worked in London for GE Healthcare as a legal counsel secondee. Bart has assisted national and international companies on regulatory matters, commercial contracts, advertising, clinical trials and recall procedures, not only with respect to contentious matters but also providing practical advice on day-to-day business operations. Bart has published a number of articles and is a regular contributor to our corporate law magazine.

#### **Relevant experience**

- Advising and assisting a global leading pharmaceutical company on clinical trials.
- Advising and assisting a company specialised in the sale of medicines on advertising law.
- Advising and assisting a company specialised in the food industry on general conditions.
- Advising and assisting a global leading company specialised in the food industry on advertising law.
- Advising and assisting a global leading pharmaceutical company on commercial contracts.
- Advising and assisting a company specialised in the manufacturing of medicines on recall procedures.
- Advising and assisting several healthcare institutions on the rules and regulations regarding the sale of medicines.



**Ellen Gielen**  
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Ellen is engaged in advising companies and organisations both in the Netherlands and internationally that are active in the field of pharmaceuticals, medical devices, food products and related industries (such as manufacturers, wholesalers and importers). She regularly advises clients on a large number of agreements (including distribution agreements, agency agreements, manufacturing agreements and clinical trial agreements). She also has experience in regulatory affairs, pricing and reimbursement, and compliance and acquisitions in the pharmaceutical industry. Ellen has experience in many areas of healthcare law, particularly relating to contracts, market regulation, partnerships and privatisation, acquisitions, licences, admissions, fees, reimbursements and budgeting and health insurance.

#### **Relevant experience**

- Advising a US-based medical device company on regulatory issues for a medical devices clinical trial.
- Advising on legal classification, import and distribution of human-derived (engineered) tissue products.
- Advising on the set-up of health management services in the Netherlands, including drafting all the necessary agreements.
- Advising on the set-up of a subsidiary of a global pharmaceutical company in the Netherlands, assisting them with obtaining the necessary licences and drafting agreements.
- Acting for a global cardiovascular company with global marketing and sales headquarters in the Netherlands. Drawing up all their commercial agreements such as distribution agreements and agency agreements, as well as their general terms and conditions and sales agreements, and supporting them in discussions regarding the termination of such agreements.
- Acting for a global biopharmaceutical company. Supporting them on a large number of agreements, including all their commercial agreements, general terms, and on regulatory matters.



**Steffen Hagen**  
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Steffen is an attorney at law and an associate with CMS Derks Star Busmann's IP/IT team and has been practising as a lawyer since 2001. Steffen joined CMS Derks Star Busmann in early 2007. Prior to joining CMS he worked for a major international law firm in Amsterdam and in New York. He holds a postgraduate masters degree (LLM) in economic public and business law from the University of Utrecht (2001) as well as a postgraduate masters degree (LLM) in private law from the University of Utrecht (2001). He was admitted to the Amsterdam Bar in January 2002, and subsequently to the Utrecht Bar in March 2007.

His main practice areas are intellectual property, including trade mark law, trade name law, design law, patent law, copyright law, neighbouring rights, database rights, data protection, domain names, advertising law, counterfeiting, unfair competition, and, more generally, contractual or tortious liability in these areas. Steffen advises, assists and represents clients both in transactions and in litigation. His clients include corporations, organisations and individuals.

### **Relevant experience**

- Advising one of the largest pharmaceutical companies worldwide on the proposed acquisition of the pharmaceutical division of another large pharmaceutical company through the acquisition of the entire issued capital of one of the holding companies in the top of the target group structure, involving elaborate pharma, commercial and IP due diligence.
- Advising on the set-up of health management services in the Netherlands.
- Assisting a pharmaceutical company in litigation concerning the interpretation/alleged infringement of the advertising rules in the Dutch Medicines Act.
- Advising and assisting on the proposed acquisition of a European group of companies in the business of medical devices, involving IP/IT legal due diligence on the Dutch subsidiary.



**Reinout Slot**  
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Reinout was admitted to the bar in 1992. His expertise includes the acquisition and sale of quoted and private companies in the Netherlands and abroad, joint ventures, venture capital and later stage financing transactions, the establishment of funds, stock exchange listings and other capital markets transactions.

### **Relevant experience**

- Advising Takeda Pharmaceutical on its €9.6 billion (debt-free cash free) acquisition of Swiss drug company, Nycomed.
- Advising the shareholders of Diagnos Biochemical Cattle Management in the sale of the technology for progesterone detection to Ceva Sante Animale.
- Acting on matters of Dutch law for NASDAQ listed Digene Corp. in its US\$1.6 billion merger with the Frankfurt and NASDAQ listed Dutch company QIAGEN N.V.
- Advising on the sale of the entire issued share capital of Innosource Holding B.V. to Frankfurt stock exchange listed Centrotec Sustainable A.G.
- Acting for PamGene, a developer of multi-protein-protein interaction technology for cancer biomarker discovery, drug development and disease diagnosis, in its second and third financing rounds.
- Acting for PamGene in its merger with Vitromics Healthcare.
- Acting for Medco Health Solutions in the establishment of its joint venture with Celesio AG.
- Acting on various corporate matters for Cardinal Health, Thermo Fisher, CareFusion and Catalent Pharma Solutions.



**Rogier de Vrey**  
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After 6 years of experience in the academic field, as lecturer and researcher at the University of Utrecht, Rogier put his passion into practice in 2005 when he became an IP lawyer with a large Amsterdam law firm.

During his PhD, Rogier conducted research at several renowned institutions, including the European Commission, the Queen Mary IP Research Institute in London and the Max Planck Institute in Munich. His thesis, titled *Towards a European unfair competition law*, was published by Brill Academic Publishers (2005).

Joining CMS in 2008, Rogier is known by his clients for combining the assertiveness and agility of a practical attorney with the steadiness and overview of an academic. In his practice, Rogier has a particular focus on international patent matters, both transactions and litigation. His clients include global pharmaceutical companies, a global manufacturer of audio and video systems, a successful European footwear manufacturer and a leading wireless handset company.

Rogier still lectures regularly, in particular on the enforcement of IP rights. He is co-author of the upcoming Dutch handbook on IP enforcement and is also a contributor to the IP loose-leaf handbook.

### **Relevant experience**

- Advising and assisting a global leading company in the textile and graphics printing market and precision metal products on protecting (via patent law) their newly developed medical technology.
- Advising and assisting a global biopharmaceutical company with regard to various IP issues in commercial agreements and technology transfer documentation.
- Advising and assisting a global pharmaceutical company in cross-border patent matters (FTO), concerning the introduction of a new pharmaceutical product to the European market.
- Advising and assisting a company specialised in the field of artificial turf in patent litigation.
- Advising one of the largest worldwide producers of tobacco products on tobacco law and advertising law.
- Advising and assisting one of the largest worldwide biofuel producers in various IP contractual matters.



**Luurt Wildeboer**  
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Luurt specialises in general administrative law and the law of administrative procedure, particularly in relation to environmental law and spatial planning law. In these areas his main interest is the relationship between the environment and spatial planning, and the consequences of environmental standards on spatial development, especially with regard to noise nuisance. Luurt's activities consist mainly of providing advice and litigating for animal feed companies.

Luurt has also advised many clients on administrative law and other issues to do with regulated markets such as health care, pharmaceutical industry, post, telecom, energy, and aviation, and has represented clients in proceedings against the OPTA, NMa and various other regulatory bodies.

He has wide-ranging experience of government regulation in many sectors, in which he represents both businesses and government authorities. In particular he assists them in obtaining and granting licences and in all kinds of disputes.

Luurt joined CMS Derks Star Busman at the start of July 2008. Since 2000 he has worked as a lawyer for Allen & Overy LLP in the Competition and Regulated Markets practice group. Before that he worked at the registry of the Administrative Jurisdiction Division of the Council of State and the Legal Affairs Department of the Ministry of Housing, Spatial Planning and the Environment. He regularly publishes articles on matters of administrative law relating to these areas. He is also a lecturer at the VU Law Academy.

### **Selected experience**

- Assisted Novum an Bronovo with regard to market entry of healthcare clinics
- Assisted the Bios-Groep and Witte Kruis with regard of the new regulations of ambulance transport
- Assisted AGIS with regard to procedures regarding the personal health care budget of different insured persons
- Assisted different pharmaceutical companies with regard to the public access of information (Wob)
- Assisted De Heus B.V. during legal (court) proceedings regarding environment permitting and compliance of industrial production plant in Utrecht.
- Advised and assisted ForFarmers on spatial planning representing ForFarmers in court proceedings regarding zoning and environmental issues of their production plant in Lochem.

- Advised and assisted the municipality of Voorst with respect to the development of the residential zone in Wilp on spatial planning and environmental zoning matters.
- Assisted VolkerWessels with the purchase (from estate agent Fortress) and sale (to Green Real Estate) of the yet to be constructed Anna van Bueren building in the Hague. The Anna van Bueren building is approx. 24,000 m<sup>2</sup> GFA in size and consists of retail, educational provisions and 396 student accommodations.
- Advised AM and Rochdale on the sale of the Banne Binnen shopping centre. CMS provided counsel on the preparation of these contracts, and provided advice on subsidies, tax issues, state aid, the partitioning into apartment rights and the issue of warranties.
- Advised Holcim on land sale to Havenbedrijf Rotterdam. Advised in relation to environmental law aspects.
- Advising ConocoPhilips i Norge on implementation in the Netherlands of European Environmental legislation on IPPC and LCP.
- Advising De Heus Diervoeders and Rijnvallei on environmental issues and permits.
- Advised Koppers on environmental law aspects in connection with the acquisition of Cindu Chemicals BV. Koppers International BV has acquired Cindu Chemicals BV from joint owners Cindu BV and Corus Staal BV.
- Advised Pioneer Hi-Bred Northern Europe on European environmental law issues relating to testing fields of genetically modified organisms (GMO's) (including litigation).
- Advising Smink (part of Shanks group) on environmental permitting, advised and litigated on environmental procedures and spatial planning.
- Advising V.O.F. Nieuwe Gracht Stad Milieu Landschap on noise matters with respect to the project 'Stadshavens' (construction and expansion in the (old) docks area in Rotterdam)



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Edmon (born 1975) works as a lawyer in the competition law practice. He is based at the CMS EU Law Office in Brussels, Belgium.

Edmon has broad expertise in EU law and specializes in competition law. He advises clients on antitrust law, state aid and merger control and conducts proceedings before competition authorities, national courts and the Court of Justice of the European Union in Luxembourg. He works in four languages – Dutch, English, German and French.

Edmon acts for a wide variety of clients, but in particular for companies and governments in the fields of life sciences, real estate and land development. He also represents companies operating in the petrochemical industry and automotive industry.

Edmon joined CMS Derks Star Busmann in 2011. He previously worked as a référendaire (law clerk) at the Court of Justice of the European Union in Luxembourg, and as a lawyer with Houthoff Buruma in Brussels and Pels Rijcken & Droogleever Fortuijn in The Hague.

#### **Selected experience**

- Advising and assisting Siemens, a multinational active on the market for technological services and products.
- Advising DZ-Bank, a German financial institution.
- Advising and assisting Dyckerhoff, a multinational active on the market for cement and concrete mortar.
- Advising and assisting Coöperatie MegaMix, a Dutch company active on the market for dry mortar.
- Advising Delta, a Dutch energy and telecom company.
- Advising Nationale Nederlanden, a Dutch insurance company.
- Advising Pioneer, a multinational active in the field of home theatre entertainment and audio products.
- Advising Koninklijke Nederlandse Munt (Royal Dutch Mint).
- Advising Diageo, a multinational active on the market for alcoholic beverages.
- Advising and assisting Qbuzz, a public transport company partly owned by Nederlandse Spoorwegen (Dutch Railways).

- Advising and assisting NOC\*NSF, the Dutch Olympic Committee.
- Advising and representing Ballast Nedam, a Dutch construction company



**Wouter Seinen**  
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Wouter heads the CMS Derks Star Busmann data privacy team, which regularly assists national and international clients with respect to Personal Data Protection regulations and issues concerning ownership and protection of electronic data.

In 2008, Wouter was elected the “Gouden Stoofpeer” award for the most promising under 35 IT lawyer of the Dutch Bar and is regarded among his peers as one of the leading young IT & IP lawyers in the Netherlands.

Wouter graduated in law in 1998 and has worked as a specialised IT & IP attorney ever since. He has been working for the IP & TMT Practice Group of CMS Derks Star Busmann since 2007. Wouter has a particular interest in all internet related issues with respect to privacy, (copyright-) infringements and database rights, and is a keen negotiator and litigator, not only when commercial interests are at stake, but also when principle is involved.

In 2004 he successfully completed, with distinction, the Grotius/VIRA post-degree specialist programme in Computer Law.

Wouter Seinen was vice-president and president, respectively, of the Intellectual Property, Media & New Technologies Commission of the AIJA (Association Internationale des Jeunes Avocats) from 2007 to 2011 and is member of a number of other (inter)national professional associations. He was one of the chief editors of the report on Open Source Software published by the NvVIR (the Netherlands Association for IT and Law), is regularly invited as (guest-) speaker and teaches in post-degree programmes on various subjects in the area of Intellectual Property and Information Technology.

Wouter is also one of the chief editors of the IT-Law news site [www.itenrecht.nl](http://www.itenrecht.nl) and the Kluwer model IT contracts series.

## **Relevant experience**

### **Pharma**

- Advising and representing Dutch Hospital Data in respect of regulatory data protection and IT security requirements and contractual terms of in respect of DHD's services;

- Drafting and negotiation data exchange agreement between the Dutch Association of Hospitals and the appointed authority for the maintenance of Diagnosis Treatment Combination (DBC) –data.
- Assisting a global service provider for the healthcare sector in the outsourcing of IT services for hospitals and clinics in the Netherlands.
- Advising Intel Digital Health on data protection compliance issues in respect of various digital healthcare devices and associated research projects.
- Advising GE Intel Care Innovations its Dutch affiliated research companies in respect of regulatory (medical ethical commission and data protection) requirements applicable to current research projects.
- Assisting and representing a Dutch leading IT Healthcare service provider in respect of interfacing-, software license-, partnership- and other commercial contracts

#### **Data protection**

- Assisting Ageviewers, the provider of a cutting edge electronic age verification solution in all data protection matters, including representation of the client in a compliance investigation of the Dutch Data Protection Authority



**Tjeerd Hoekstra**  
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Tjeerd is an attorney in the labour law practice group. He specialises in individual and collective labour law, the dismissal of directors appointed under articles of association, employee representation and reorganisations and in that respect he has also experience with large corporate transactions.

He advises large and mid-size companies operating in a wide range of industries, mainly covering financial institutions, industrials and consumer goods. In addition to his advisory practice Tjeerd is also an excellent litigator in a wide range of procedures.

Prior to joining CMS Derks Star Busmann in 2011, Tjeerd practised law in both the labour law and corporate litigation divisions in the Amsterdam office of a large global law firm.

### **Relevant experience**

- Advising various Dutch companies – including pharmaceutical companies – on different aspects of reorganisations;
- Advising and litigating in respect of corporate dismissals of directors;
- Conducting legal proceedings for a large Dutch financial institution relating to a collective claim regarding performance of employment conditions;
- Advising a US company on employee participation in respect of corporate acquisition in Europe.



**Petra Heemskerk**  
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Petra is a lawyer in our Real Estate practice group. She concentrates her entire practice on tender law.

Petra acts as counsel to companies inviting tenders, as well as those submitting them. She focuses on preventative testing of tender processes, assists with editing tender documents and represents clients in tender-law disputes. In addition, she also advises on the tender-law aspects of regional development projects and public-private partnerships. Her particular speciality is in the area of public transport, in which context she represents both principals and contractors.

Petra has worked for the Netherlands Association for Purchasing Management *Nederlandse Vereniging voor Inkoopmanagement* as a lecturer on tender law. She is a member of the editorial staff for Construction Law *Bouwrecht* magazine and a lecturer for the Grotius Academy. She worked for Pels Rijcken & Droogleever Fortuijn from 1997 to 2006, prior to joining CMS Derks Star Busmann in 2006.

## **Relevant experience**

### **Hospitals**

- Preferred supplier of Antonius Hospital Nieuwegein in cases involving public procurement and state aid.
- Several court proceedings concerning the legitimacy of tender processes organised by hospitals (purchase of works, supplies and services).

### **Real Estate**

- Advising hospitals in tendering of developments.
- Assisting procuring entities (hospitals) in assessing and managing procured contracts.
- Assisted several construction companies in participating in tender proceedings and submitting tenders.

### **Government**

- Advising the Centraal Orgaan OPvang Asielzoekers on several tenders.

### **Concessions**

- Advised Gemeentelijke Vervoersbedrijf Amsterdam on the negotiation proceedings that the Municipality of Amsterdam will hold with regard to the purchasing procedures they have organised, as well as advising on the participation in the tender procedures



**Jurjen Groot**  
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Jurjen is a member of our Corporate practice group and specialises in corporate law and China related matters. Jurjen has ample experience in advising on a wide range of corporate law transactions and in corporate litigation.

From the end of 2008 until the beginning of 2012, Jurjen has worked in the CMS Shanghai office. He is the direct contact person for our Dutch clients in China and our Chinese clients in The Netherlands.

In China, Jurjen has been assisting a fair amount of Dutch companies with corporate, commercial and intellectual property matters relating to their China business. He furthermore advises an increasing number of Chinese companies on setting up and expanding their business in The Netherlands, and through The Netherlands in the rest of Europe.

Jurjen publishes regularly on corporate law related matters. In 2011 he appeared as a China expert in Dutch TV-discussion program "Buitenhof".

### **Relevant experience**

- Advising several Dutch companies on lifescience, corporate, commercial and intellectual property matters in China.
- Advising a Chinese inventor of an anti-HIV medicine on regulatory matters and market-entry strategies in Europe
- Advising a Dutch medical device company in relation to production of blatter scanners in China
- Advising a Dutch university on a multi-level partnership with the largest Chinese dental institution in China
- Assisting several Dutch companies on litigation strategies against defaulting companies in China.
- Assisting a Chinese company with challenging anti-dumping duties imposed by the European Commission.



**Ayşegül Avci**  
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Ayşegül is an attorney at law in our Employment Law practice group. She advises (international) companies about outsourcing, reorganisations, dismissals, participation, employment conditions, compensation forms and transfer of undertaking.

She also litigates on various labour disputes. Within corporate labour law, she advises on employment law issues in (international) transactions, including employee participation in an (inter)national context.

Ayşegül is also an active member of CMS Derks Star Busmann's Turkish Business Desk which is the point of contact for businesses in the Netherlands that wish to do business in Turkey, but also for Turkish companies that are considering similar in the Netherlands, including pharmaceutical and life sciences companies in Turkey and the Netherlands.



**Roderick Nieuwmeyer**  
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Roderick works as a lawyer in our competition law practice. He is based at the CMS EU Law Office in Brussels, Belgium.

Roderick has broad expertise in EU law and specialises in competition law. He advises clients amongst others on merger control, distribution practices and cartel proceedings.

Roderick joined CMS Derks Star Busmann in 2012. He previously worked as a lawyer with a major national law firm in Amsterdam.

### **Relevant experience**

- Advising a private equity firm on the corporate matters of the acquisition of a company worldwide active in the pharmaceutical industry and coordinating the due diligence process.
- Advising a private equity firm, specialized in healthcare, on the merger control filing and other competition law matters regarding the acquisition of a hospital.
- Advising a private equity firm, specialized in healthcare, on the merger control filing regarding the acquisition of a specialised health clinic.

# Poland: CMS Cameron McKenna

## Scope of services

CMS Cameron McKenna is the largest and one of the most experienced international law firms operating in Poland, having provided legal services on this market for over 20 years. The 150 lawyers that are based in the Warsaw office provide legal support and advice to clients operating in various industry sectors.

The team has a wealth of experience providing clients with a variety of sector-specific advice on issues such as: pharmaceuticals, medical devices, dietary supplements, clinical trials, health insurance, transactions in the healthcare sector, trade marks and patents, pricing and reimbursement, parallel import, data protection, product liability, intellectual property and more.

Pharmaceutical, medical devices and dietary supplements businesses face numerous challenges in Poland, including the increasing burden of regulation, increased sector competition, consumer activism, growing retailer power and supply chain management issues. Our track record in advising on a wide range of matters, coupled with the expertise that we have acquired as a result of the long-term relationships that we have developed with some of the key players from the industry, allows our clients the benefit of working with a team that understands this sector and the challenges that it currently faces. We act for a significant number of companies operating on the pharmaceutical and healthcare markets and have a second to none understanding of the legal issues facing the industry. We are highly experienced in advising multinational clients on cross-border matters both in respect of specific projects and day-to-day issues.

## Recent experience

- Advising a major American pharmaceutical company with respect to submitting a reimbursement dossier, including risk sharing schemes, according to the new Reimbursement Law.
- Advising a leading British medical company with respect to risk sharing instruments.
- Advising a major international baby food producer on the new Reimbursement Law with respect to P&R, regulatory and commercial issues.
- Advising a major international food company on the establishment of a new distribution model, redrafting supply and distribution agreements with business partners.
- Advising a major American company on a number of tender procedures for the supply of medical equipment including analysis of the tender documentation, assisting the company in drafting letters to clients and conducting protest, appeal and judicial proceedings related to tenders.
- Advising a major Polish food company with respect to proceedings regarding numerous registrations of borderline products in Poland.

- Advising a leading biotech company on the establishment of its operations in CEE. Our advice focused on various corporate issues, social security, employment, tax and customs, real estate lease agreements, competition issues, EU regulations as well as on the marketing and distribution of their products.
- Advising a major British company on medicinal product advertising standards, marketing programmes and promotional materials.
- Advising a major American company on anti-corruption practices and compliance with these practices, including co-operation between pharmaceutical sector companies and doctors.
- Advising a German client on notification of medical devices and dietary supplements, as well as representing clients before supervisory authorities during audits and investigations, and advising on labelling and advertising dietary supplements.
- Preparing guidelines and reviewing standards of performance with regard to public-awareness campaigns for a major American company.
- Advising a global medical devices manufacturer on compliance issues, establishing of marketing and advertising policies, providing advice on issues relating to co-operation with healthcare professionals.
- Advising an international baby food producer on a competition law compliance audit of the client's Polish operations (with a focus on the anti-trust dimension of the activities of sales representatives), interviewing key personnel, reviewing agreements, e-mail correspondence and the trade policies of the company, the preparation of a report setting out various compliance recommendations.
- Advising a major British eye care company with respect to a launch of new products in Poland.

# The Team



**Monika Duszyńska**  
**Partner, Head of Lifesciences Group in Poland**  
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Monika is a Polish-qualified advocate and a Partner in CMS Cameron McKenna in Warsaw, with 14 years' experience in providing legal services to the pharmaceutical and healthcare sector. Her experience in Lifesciences includes regulatory issues, data protection (data exclusivity), advertising and marketing of medicinal products and medical devices, manufacturing and distribution. Monika also advises clients in reimbursement matters, and represents them in proceedings before the Minister of Health in relation to pricing and reimbursement of medicinal products, medical devices and food for special nutritional purposes, including drafting and negotiating risk-sharing instruments. As an attorney, she represented clients before courts, and in particular before the administrative court in reimbursement matters. Monika also specialises in providing legal assistance to clients from the healthcare sector, with a particular focus on models of cooperation between public and private operators of healthcare institutions, including public-private partnership. Monika is a graduate of the Faculty of Law and Administration and of the Faculty of Italian Language and Culture at the Warsaw University. She speaks fluent English and also provides legal services in French, Italian and Spanish.

## **Relevant experience:**

- Advising major global pharmaceutical and medical devices companies in reimbursement proceedings, including: risk-sharing proposals; attending negotiations with the Economic Commission; drafting successful appeals from the Minister of Health's decisions on reimbursement matters; advising on strategy during negotiations in reimbursement proceedings, assistance in proceedings before the administrative courts.
- Reviewing all the marketing and distribution activities of a leading medical devices company in the light of the new Reimbursement Law.
- Advising a leading Polish insurer on a new insurance product involving reimbursed medicines.
- Advising a French pharmaceutical company on changing a product's status from a medical device to a medicinal product.
- Advising a number of global pharma companies on marketing and promotion, including international campaigns.
- Advising major pharma and medical devices companies on product recalls and product liability

issues.



**Bartosz Michalski**  
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Bartosz is a legal advisor and an associate in the Lifesciences Group of CMS Cameron McKenna in Warsaw. Bartosz has seven years' experience in advising pharmaceutical companies. His practice includes providing reimbursement advice, regulatory advice on medicinal products, medical devices and biocides, preparing opinions on various aspects of marketing activities and distribution strategies, drafting and negotiating clinical trial agreements, and representing clients before the Minister of Health and in court disputes. He was also involved in legal projects for private hospitals and healthcare operators. Bartosz lectures at many conferences and professional training sessions for the lifesciences sector. He also is the author of numerous articles on law and regulations relating to medicinal products and healthcare insurance. Before joining CMS Cameron McKenna, Bartosz was a legal advisor at an international law firm and an in-house lawyer in an international pharmaceutical company. Bartosz is a graduate of Adam Mickiewicz University in Poznań. He has completed a course in British and European law co-organised by the University of Cambridge. Bartosz speaks fluent English.

#### **Relevant experience**

- Advising an Italian pharmaceutical client in an acquisition of a Polish pharmaceutical company
- Advising an international pharmaceutical company on a regulatory strategy concerning one of their key medicinal products.
- Representing a Polish medicinal products and medical devices manufacturer in a dispute with regulatory authorities.
- Advising a Spanish pharmaceutical company on legal issues connected with biocides registration.
- Advising a Danish pharmaceutical company on conducting clinical trials in CEE countries (drafting and negotiating clinical trial agreements, and advising on legal issues connected with conducting clinical trials).
- Advising major pharmaceutical companies on various marketing activities concerning medicinal products and medical devices.
- Advising an international pharmaceutical company in relation to a breach of obligation under exclusive distribution agreement.
- Advising a major Swiss pharmaceutical company on product liability issues concerning veterinary medicinal product.



**Łukasz Sławatyniec**  
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Łukasz is a trainee advocate and an Associate in the Lifesciences Group of CMS Cameron McKenna in Warsaw. Since 2006, he has developed considerable expertise within the lifesciences sector at CMS Cameron McKenna. He advises on a broad scope of activities undertaken by pharmaceutical companies including: registration procedures, marketing and the reimbursement of medicinal products and medical devices. He drafts and negotiates clinical trials and distribution and service agreements. Łukasz has participated in many administrative and court proceedings. He prepares and reviews licence agreements for entities from different sectors and takes part in IP rights proceedings regarding domain name enforcement, trademark and copyright infringement, and image protection. Łukasz also advises on matters regarding PR, media contacts and other press-related law issues. He has delivered presentations at sector conferences. He graduated from the faculties of law and journalism at the Warsaw University, where he currently teaches. Łukasz is co-author of a book on medicinal product advertising and European law and regularly publishes articles in daily newspapers and magazines. Łukasz speaks English and German.

#### **Relevant Experience**

- Advising a German client in a successful court dispute with the Minister of Health regarding medicinal product registration.
- Drafting and reviewing SOPs for various global pharmaceutical players.
- Reviewing various promotional materials of medicinal products, medical devices and dietary supplements for numerous lifesciences companies.
- Advising a major Swiss pharmaceutical company in dispute regarding parallel trade of medicinal products.
- Advising international clients on distribution schemes and commercial conditions for the sale of medical products.
- Advising a major Belgian company on the assignment of medical product dossier rights.
- Secondment to a leading American pharmaceutical company.
- Advising a major American pharmaceutical company on trademark infringement and unfair competition issues.
- Advising international clients on numerous issues regarding application for reimbursement in Poland under new regulation.



**Katarzyna Kęska**  
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Katarzyna is a Lawyer in the Lifesciences Group of CMS Cameron McKenna in Warsaw. Katarzyna has been co-operating with the lifesciences sector group at CMS Cameron McKenna since 2010. She advises on the registration and notification procedures for medical devices and medicinal products. She has experience dealing with matters relating to labeling and advertising of both medicinal products and dietary supplements. In her current practice, Katarzyna also advises on the marketing of dietary supplements, including so-called novel food. Furthermore, her experience includes advising on intellectual property law, particularly on copyright, patent and personal data protection issues. Katarzyna graduated from the Faculty of Law at the Warsaw University and the Faculty of Law and Social Sciences at the University of Poitiers where she studied business law, obtaining the title of Master professionnel de Droit des Affaires, Spécialité français et Droit Européen des affaires. Katarzyna speaks English and French.

#### **Relevant experience**

- Advising a major American pharmaceutical company and a major international baby food producer with respect to submitting reimbursement dossier, including risk sharing schemes, according to new Reimbursement Law.
- Advising a German client on notification of dietary supplements to the Polish Authority.
- Advising a major British eye care company with respect to a launch of new products in Poland.
- Advising a leading American pharmaceutical company on a broad scope of activities including reviewing promotional materials.
- Advising several Polish clients on notification and registration of medicinal devices.
- Hotline secondment to a leading American pharmaceutical company.



**Mikołaj Piaskowski**  
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Mikołaj is a Polish-qualified legal advisor and a Senior Associate in the Competition Group of CMS Cameron McKenna in Warsaw. Mikołaj specialises in competition law. He advises clients from various sectors, in particular from the pharmaceutical industry drawing on his in-depth knowledge of this sector and the regulatory environment. Mikołaj's experience includes advising clients on issues related to anti-competitive practices, abusing dominant position, acts of unfair competition or consumer protection issues including verification of tariffs, internal regulations, distribution, franchising and agency agreements and models. He has been a lecturer at a number of seminars organised for the pharmaceutical sector. Mikołaj graduated from the Faculty of Law and Administration at the Jagiellonian University in Krakow. He has also completed postgraduate studies in EC Competition Law at King's College of Law in London and postgraduate Studies in EC Law at the Warsaw University. Mikołaj speaks fluent English.

#### **Relevant experience**

- Advising a major pharmaceutical company on competition aspects of its distribution systems in CEE, including parallel imports.
- Representing an international pharmaceutical company in merger control proceedings in front of the European Commission related to the concentration of competitors.
- Advising an international pharmaceutical company on competition law issues related to refusal to supply a dominant product.
- Advising a leading pharmaceutical company on promotional actions and rebate schemes.
- Advising an international pharmaceutical company on competition law issues related to cooperation with a competitor.
- Advising a pharmaceutical company on issues related to an exclusive distribution agreement.
- Assisting a leading medical products firm in an unfair competition dispute with a competitor.
- Running training for pharmaceutical companies on topics including dawn raids, competition and public procurement issues.



**Hubert Tański**  
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Hubert is a Polish-qualified legal advisor and a Senior Associate in the Competition Group of CMS Cameron McKenna in Warsaw. Hubert specialises in public procurement issues and infrastructure projects realised within a PPP framework. Hubert has broad experience in providing advisory services to Polish and foreign entities, in the field of public procurement law, concerning, among other things, tender procedures conducted on the basis of Public Procurement Law, acting both for contracting authorities and contractors. Additionally, he has provided legal advice on tender procedures concerning procurement of healthcare services (as provided for the Health Care Institutions Act), weaponry (on the basis of Decision No. 291/MON of the Ministry of Defence), frequency booking (under the Telecommunications Law), proceedings concerning the construction and operation of motorways (on the basis of the Act on Toll Motorways and the National Road Fund). Hubert Tański has an industrial security certificate entitling him to access classified information marked “SECRET”, “NATO SECRET” and “EU SECRET”. He is a graduate from the Faculty of Law and Administration at the Warsaw University and the University of Bonn. Hubert also completed a course at the Center for American Law Studies organised by Florida University and the Warsaw University, the British and European Law Studies Centre organised by Cambridge University and the Warsaw University and the German Law School organised by the University of Bonn and the Warsaw University. Hubert speaks fluent English and German.

#### **Relevant experience**

- Advising healthcare institutions on regulatory aspects relating to the transfer of agreements concerning healthcare services.
- Advising a pharmaceutical laboratory in various proceedings relating to purchase of laboratory services and application of legal remedies.
- Advising a leading American biopharmaceutical company on public procurement proceedings.
- Advising a leading global medical device manufacturer on public procurement proceedings, including filing appeals, responding to the appeals and representing the manufacturer in the National Appeal Chamber and in the court.



**Andrzej Pośniak**  
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Andrzej, a Polish-qualified tax advisor, is a senior associate in CMS Cameron McKenna's Warsaw Tax Department.

He specializes in tax and corporate law, focusing on transfer pricing, value added tax and corporate income tax matters. He also advises on tax aspects of JV/consortium structures, international tax and corporate planning and restructuring of multinational companies, as well as M&A transactions.

Andrzej is the author of a large number of publications focusing on legal-tax issues and regularly appears as a tax expert on nationwide TV. He is also conducting tax seminars, workshops and professional trainings. Andrzej graduated with an MA in Law from Stefan Wyszyński University in Warsaw, and MA in Economics from the Faculty of Economics, Management and Finance at Graduate School of Business Economics in Warsaw. He is fluent in English.

#### **Relevant experience**

- Providing daily tax advice to a global pharmaceutical company.
- Providing tax advice connected with entry into the Polish market to a biopharmaceutical company.
- Providing tax and corporate advice to a global American pharmaceutical company on structuring a supply chain involving a number of different jurisdictions and international trade aspects.
- Providing tax and corporate advice to a global pharmaceutical company regarding establishing a branch in Poland and doing business in Poland.
- Providing tax advice to a number of global pharmaceutical companies in connection with marketing activities in Poland.
- Providing international clients with advice on distribution schemes and commercial conditions for the sale of medicinal products.

# Portugal: CMS Rui Pena & Arnaut

CMS Rui Pena & Arnaut provides legal advice in the lifesciences sector; namely in health, medical devices, pharmaceuticals and biotechnology. Our team is multi-disciplinary with a deep knowledge of the sector.

## Scope of services

- Licensing
- Patent protection and enforcement
- Regulation
- Competition
- Finance
- Mergers and acquisitions
- Business recovery
- Litigation
- Labelling
- Public tenders
- Marketing and supply agreements
- Labour law
- Commercial contracts

## Recent experience

- Advising pharmaceutical companies in several civil and administrative proceedings connected with marketing authorisations of pharmaceutical products;
- Advising one of the biggest Portuguese pharmaceutical companies on proceedings related to the manufacturing and marketing of pharmaceutical products;
- Advising pharmaceutical companies in administrative proceedings concerning price approval as well as reimbursement;
- Advising pharmaceutical companies concerning marketing strategies, labelling and advertisement;
- Acting as legal counsel to a pharmaceutical company undergoing a commercial restructuring following legally imposed lower prices of pharmaceutical products. The process involved employee restructuring;

- Advising a pan-European medical service provider specialising in diagnostics investigations, renal care services, clinical laboratories, cancer treatment and teleradiology services in the restructuring and reorganisation of its laboratory and diagnostic businesses which includes several mergers and de-mergers as well as internal sales of companies and share capital increases;
- Advising a pan-European medical service provider specialising in diagnostics investigations in the due diligence and Q&A process regarding the sale of its dialysis business in Portugal (which was included in a broader international transaction involving the sale of the Group's entire dialysis business);
- Advising a psychology public body on a wide range of issues, particularly on the elaboration of regulations, such as Electoral Rules, Stages Rules or Code of Ethics.
- Patent litigation on pharmaceutical products;
- Advising on the advertising and promotion of pharmaceuticals, including comparative advertising.
- Providing advice and assistance on various contractual matters (drafting, licensing, distribution, termination, etc.) regarding pharmaceuticals, cosmetics, etc. both for national and international clients.

## The Team



**José Luís Arnaut**  
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José Luís heads the CMS Rui Pena & Arnaut Lifesciences Group. José specialises in intellectual property law and focuses on patent law, trademarks, enforcement and litigation. He has advised several pharmaceutical companies.

He studied law at *Universidade Lusíada de Lisboa* and received a 'Diplôme d'Etudes Supérieure in Spécialisées in Accords et Propriété Industrielle' from Robert Schuman University in Strasbourg. Since 1996, he has been European Trade Mark Representative for the Office for Harmonization in the Internal Market of the European Union in Alicante and Official Agent of Industrial Property at the National Institute of Industrial Property. José was also involved in the Commission to Monitor and Review the Code of Industrial Property in 1996 and from 1998 to 1999 he was a member of the Revision Committee of the Code of Industrial Property. José has been a member of several associations namely PTMG (Pharmaceutical Trade Marks Group).

Chambers Europe 2011 writes the following: "Department head José Luis Arnaut is widely recognised as an IP specialist, and excels in a number of fields, including patents, trademarks, copyright and technology transfer. Sources describe him as *"a formidable practitioner with supreme international standards."*

### Relevant experience

- Advising companies that focus on the development, production and marketing of a wide range of pharmaceutical products.
- Advising pharmaceutical companies in several arbitration, civil and administrative proceedings related to marketing authorisations of pharmaceutical products.
- Advising one of the biggest Portuguese pharmaceutical companies on proceedings concerning the manufacturing and marketing of pharmaceutical products.
- Advising pharmaceutical companies in administrative proceedings concerning price approval as well as reimbursement.
- Advising pharmaceutical companies concerning marketing strategies, labelling and advertisement.



**João Paulo Mioludo**  
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João Paulo Mioludo specialises in intellectual property law, developing his work mainly in the pharmaceutical sector.

He studied law at *Universidade Católica Portuguesa* with a post graduation degree in industrial property law from *Universidade de Lisboa*. He attended a course on health law and bioethics at the same university in a partnership with the National School of Public Health.

He was awarded by the Portuguese Bar Association with the title: Specialist in Intellectual Property Law. Chambers Europe 2011 writes the following: "João Paulo Mioludo earns praise for his trade mark knowledge and "his ability to develop creative legal strategies."

### **Relevant experience**

- Advising companies that focus on the development, production and marketing of a wide range of pharmaceutical products.
- Advising pharmaceutical companies in several arbitration, civil and administrative proceedings related to marketing authorisations of pharmaceutical products.
- Advising one of the biggest Portuguese pharmaceutical companies on proceedings concerning the manufacturing and marketing of pharmaceutical products.
- Advising pharmaceutical companies in administrative proceedings concerning price approval as well as reimbursement.
- Advising pharmaceutical companies concerning marketing strategies, labelling and advertisement.



**João Leitão Figueiredo**  
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João Leitão specialises in intellectual property law, with a special focus on licencing, litigation, enforcement and patent protection.

He studied law at *Universidade de Lisboa* and attended a course on biotechnology and intellectual property run by the World Academy Organisation of Intellectual Property.

Chambers Europe 2011 writes the following: "João Leitão Figueiredo is recommended for his expertise in the pharmaceutical sector."

#### **Relevant experience**

- Advising companies that focus on the development, production and marketing of a wide range of pharmaceutical products.
- Advising pharmaceutical companies in several arbitration, civil and administrative proceedings related to marketing authorisations of pharmaceutical products.
- Advising one of the biggest Portuguese pharmaceutical companies on proceedings concerning the manufacturing and marketing of pharmaceutical products.
- Advising pharmaceutical companies in administrative proceedings concerning price approval as well as price reimbursements.
- Advising pharmaceutical companies concerning marketing strategies, labelling and advertisement.



**Hugo Monteiro de Queirós**  
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Hugo specializes in IP law and focuses on patent law, trademarks, litigation and enforcement.

He graduated in Law from the Law Faculty of the University of Porto, and obtained a Master's Degree in Private Legal Sciences from the same Faculty.

Hugo was admitted to the Bar in 2004, and is a certified Patent and Trademark Attorney at the Portuguese National Institute of Industrial Property.

He was a lecturer of an Intellectual Property course, and of several Intellectual Property Modules at the University of Porto, and is co-author of "Ipedia", an Intellectual Property Guide for companies, researchers and entrepreneurs.

He is a frequent speaker in several domestic and international conferences and seminars relating to the IP area of practice.

He is a member of APDI – Associação Portuguesa de Direito Intelectual (Portuguese Association of Intellectual Law).

Hugo joined CMS Rui Pena & Arnaut in 2010.

### **Relevant experience**

- Advising a company that focuses on the development, production and marketing of a wide range of generic and branded pharmaceuticals, as well as Active Pharmaceutical Ingredients (API) in civil and administrative proceedings relating to the marketing authorisation of generic products against pharmaceutical companies.
- Advising a pharmaceutical company in several civil and administrative proceedings relating to the marketing authorisation of generic products against pharmaceutical companies.
- Advising the largest Portuguese generic pharmaceutical company on civil and arbitration proceedings relating to the manufacturing and marketing of generic products.
- Patent litigation in civil and arbitration courts.

# Romania: CMS Cameron McKenna

## Scope of services

CMS Cameron McKenna provides access to specialists who have worked in the sector for many years. We have advised on many of the most important transactions in the lifesciences sector in Romania in recent years, including market-changing M&A deals and extensive regulatory work. We offer the advantage of established industry knowledge, solid relationships with major players, and technical skills. We work with many of the world's leading lifesciences companies to deliver integrated services in the pharmaceutical, biotechnology, medical devices and diagnostic areas.

## Recent experience

- Advising Pfizer on clinical trials and related contracts, data protection matters and with regard to the transfer of its consumer healthcare division to another entity.
- Advising Amgen on drug pricing issues, incorporation of its subsidiary in Romania and corporate tax and employment issues.
- Advising Merck on pharma regulatory, employment and distribution matters.
- Advising Takeda in respect to clinical trial regulations, and on implementing a coordinated Global Compliance Policy in Romania.
- Advising J&J on the incorporation of its subsidiary in Romania and on bankruptcy claims.

## The Team



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Loredana has been a member of the CMS Bucharest team since 2001. She was a partner in the Corporate Department between 2008 and 2010, and in 2010 became the Coordinator of the Commercial Department, leading the non-contentious side of the Commercial and Dispute Resolution Team.

With over 13 years' experience, specialising in various areas of commercial law, Loredana has vast expertise in commercial law and corporate law (including M&A and corporate governance).

Loredana's excellent reputation has much to do with her impressive commercial mind and her knowledge in various industry sectors, including lifesciences. Loredana's understanding of the commercial and legal aspects of the sector allows her to tailor her legal advice to clients' specific needs.

### **Relevant experience**

- Advising Advent International in connection with an auction sale of a leading Romanian pharmaceutical company Terapia.
- Advising Advent in connection with an LBO of Terapia.
- Advising Advent International and its Romanian subsidiaries on a number of share and asset acquisitions in Romania in the pharmaceutical and construction sectors (including the acquisition of Deutek SA – former Dufa SA by Advent International and the acquisition of Plantextrakt by Ozone Laboratories Pharma).



**Marius Petroiu**  
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Marius is a senior associate at CMS Cameron McKenna Bucharest. Prior to joining our office, he was a partner in a reputed Romanian law firm. He practises corporate and commercial law and specialises in IP, TMT, lifesciences, data protection and technology transactions.

Marius has significant experience in a variety of IP issues. He has been involved in various projects in respect of litigation and protection of patents, industrial designs and trade marks, data and trade secrets, community trade marks, lifesciences, IT, telecommunication and advertising. Marius is a regular contributor to national and international legal publications, writing on a variety of matters related to intellectual property law, such as infringement of data protection, protection of information and trade secrets and protection of national and community trade marks.

#### **Relevant experience**

- Advising a major multinational chemical and pharmaceutical company in connection with a litigation dispute against a generic pharmaceutical company - seeking enforcement of IP rights with customs authorities and recovery of damages, as a result of infringement of a number of US and Romanian patents.
- Drafting and negotiating an agreement relating to the assignment of trade mark rights for a major pharmaceutical corporation.



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Valentina has been a lawyer with CMS Cameron McKenna Romania since 2003. She practises in commercial law with an emphasis on intellectual property protection, lifesciences and data protection.

She has advised lifesciences companies on a variety of issues including: marketing and distribution of pharmaceutical products; pricing and reimbursement; advertising and promotion; clinical trials; assistance and representation before the competent public authorities; and due diligence in connection with M&A transactions in the pharmaceutical sector.

### **Relevant experience**

- Advising Pfizer on clinical trials and related contracts, data protection matters, and with regard to the transfer of its consumer healthcare division to another entity.
- Advising Takeda on clinical trials regulations and on implementing a coordinated Global Compliance Program in Romania.
- Advising Amgen on pricing and wholesale distribution matters.
- Advising Merck on wholesale distribution and other regulatory matters.
- Advising Fresenius Kabi on marketing, advertising and distribution of their pharmaceutical products.
- Advising GE Healthcare on reviewing commercial contracts in the lifesciences sector.
- Advising a major international Romanian pharma company and its shareholders with respect to the sale of its assets to a private equity owned pharmaceutical company, in what was reported to be the largest pharma transaction of 2009 in Romania.

# Russia: CMS Russia

## Scope of services

Our key experts in Moscow have worked in-house for leading pharmaceutical companies; this means that the team knows the industry regulations and key issues from the inside. The team has collective experience of acting for clients in the lifesciences sector, providing them with comprehensive legal advice on all the aspects of their day-to-day activity, as well as in specific industry-focused projects.

We are recognised leaders in the lifesciences industry – in Moscow we have a team of lawyers specialising in the lifesciences industry that are a part of our global lifesciences group of more than 250 experts across Europe who have significant experience in the sector. The group is equally recognised by Chambers and Partners, Legal 500 and the Practical Law Company who have recommended us in every lifesciences category.

We offer a ‘one-stop shop’ approach – we are a full service law firm ranked in the top 10 in Europe. Our lawyers operate across the majority of legal disciplines across the lifesciences sector; including commercial, intellectual property, corporate, competition and regulatory, allowing us to deliver to all your business needs, both locally and internationally.

## Recent experience

- Advising a major international pharmaceutical company on unfair competition issues and applications to the Federal Antimonopoly Service.
- Representing a leading European homeopathic manufacturer before the Federal Antimonopoly Service in relation to a warning on unfair competition.
- Providing AstraZeneca with legal support for the establishment of a local manufacturing plant in Kaluga.
- Advising a multinational biopharmaceutical company on a local secondary packaging project; drafting and negotiating agreements with local pharmaceutical manufacturers.
- Advising a US pharmaceutical company on regulatory, competition and IP issues arising from a patent licence agreement with a Russian partner.
- Completing due diligence on an international pharmaceutical company as a possible acquisition target for a leading Japanese pharmaceutical company. This included patent analysis, environmental check, corporate due diligence, tax advice and advising on options for establishing a presence in Russia.
- Advising international clinical research organisations on direct payments to healthcare professionals and insurance issues arising in clinical trials in Russia.

- Advising a European manufacturer of medical devices on the classification of products as medical devices, registration, advertising and pricing of medical devices.
- Advising a leading European pharmaceutical company on the transfer of employees; drafting internal policies on business trips and incentives.
- Representing a European pharmaceutical company in labour disputes and advising on various employment issues.
- Assisting a leading European pharmaceutical company on a Greenfield project for the construction of a manufacturing plant, advising on investment strategy, land issues, construction contracts and related EPC issues.
- Representing a global international chemicals manufacturer in large-scale claims concerning the enforcement of patent rights in Russia.
- Advising a US pharmaceutical company on pricing, advertising, internal policies and procedures, employment matters, IP issues, agency, distribution and license agreements, and drafting standard agreement templates.
- Drafting policies for a leading European pharmaceutical company on relations with healthcare professionals, gifts and donations, conferences, and business trips.
- Advising a European pharmaceutical company on product liability issues.
- Advising a leading European homeopathic manufacturer on the reorganisation of its operations in Russia in relation to human resources, tax planning, licensing and marketing policies, and advising on changes to the Russian import regime for medicines.
- Assisting Pfizer on its US\$ 16.6 billion sale of its healthcare business to Johnson & Johnson in Central and Eastern Europe, Russia and the Baltics. Assisting with the due diligence process and with the drafting and negotiation of the sale agreement.

## The Team



**Vsevolod Tyupa**  
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Vsevolod is the Head of Lifesciences sector group in Moscow. Before joining CMS in 2011, Vsevolod worked for Roche – one of the world’s leading pharmaceutical companies (at first as an attorney, then as head of the legal department and compliance officer). He then worked for a noted law firm as a senior attorney and head of their pharmaceutical practice group.

Besides legal regulation of the lifesciences sector, Vsevolod specialises in contract law, IP, antitrust law, arbitration and enforcement procedures. He has advised many international and Russian companies on the legal regulation relating to the circulation of medicinal products, clinical trials, different civil and corporate law issues, antitrust matters and dispute resolution. Vsevolod is regularly invited to speak at different events in the pharmaceutical field. Vsevolod has a scientific degree PhD in law.

### **Relevant experience**

- Providing full legal support to a major international manufacturer of medical devices for the first stage of a new affiliate company in Russia including the office and warehouse leases, opening branches, creation of a database of template contracts, documenting labour relations, personal data protection, etc.
- Managing a team involved in the support of large due diligence projects for a major international FMSG company.
- Assisting in the restructuring of a business in Russia including the creation of a new subsidiary, transfer of assets, redeployment of the staff and other issues for a major international pharmaceutical company.
- Acting for a major international pharmaceutical company in its successful litigation regarding state and municipal orders - the positive ruling partially changed the court practice in this category of disputes.



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Leonid has been working at CMS, Russia since 1995. He joined the firm as a junior lawyer after graduating from the International Law Department of the Moscow State Institute of International Relations. Leonid became a partner in 2002. He leads the Insurance and Funds practice group.

Leonid advises international companies from various industries on the legal aspects of their operations in the Russian market, including advice on entry strategy, legal establishment, Greenfield and brown-field investments, acquisitions and antimonopoly clearance issues, drafting investment documentation, advising on joint ventures arrangements, labour and immigration issues, licensing and permissions, commercial contracts and IP issues. He also represents clients in disputes.

Leonid advises many Russian and international insurers and re-insurers on market entry strategies and new product entry strategies. He advises on share acquisitions including structuring the transaction, receiving all necessary licences and permissions, long-term life insurance schemes and credit life insurance. Leonid has represented several foreign insurers in disputes over compensation for damage caused by an alleged design defect of a product sold in Russia, Belarus and Ukraine, including the successful defence against the largest claim in Russia to date.



**Gayk Safaryan**  
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Gayk is a senior associate in CMS, Russia. His practice encompasses all areas of domestic and international tax planning and implementation, with a particular emphasis on construction projects and distribution schemes. He also practises in the areas of currency regulation, international trade, customs and transportation law. Gayk advises international pharmaceutical companies on: set-up schemes in Russia; obtaining pharmaceutical licences; the choice of import schemes to Russia; transfer pricing; taxation issues in the pharmaceutical sector; and assisting with tax issues in relation to wholesale trade.

Gayk used to be in-house counsel and deputy chief accountant for a Russian company in the retail industry. He holds an LLM (DEA) in public law from the University of Aix-Marseille III, a Franco-Russian Masters in International Management from the Chamber of Commerce and Industry of Paris and Moscow State University (MGU) and an Economics degree from Moscow State University (MGU). In addition to being an Armenian native speaker, he is fluent in Russian, French, and English.

### **Relevant experience**

- Advising major European pharmaceutical companies in relation to their start-up operations in Russia.
- Advising on legal and tax structuring of the activities of pharmaceutical companies in Russia.
- Advising on certification and registration of medicines in Russia.
- Assisting with obtaining pharmaceutical licences for the Russian subsidiaries of European pharmaceutical companies.
- Advising on tax issues in relation to the distribution scheme chosen by pharmaceutical companies in Russia.
- Assisting pharmaceutical companies in negotiating contracts with distributors and dealing with the public authorities in Russia.
- Advising on customs-related matters, including import and export controls, economic sanctions, tariff classification, valuation, rules of origin, and customs audits.

# Slovakia: CMS Cameron McKenna

## Scope of services

The Slovakian Lifesciences Team comprises a partner and an associate consultant in the Bratislava office. The team has a wealth of experience in advising clients from the pharmaceutical and medical device sectors on numerous regulatory issues, such as advertising, registration and parallel import, reimbursement, and distribution schemes including exclusive distribution. The team also has significant experience relating to various aspects of conducting clinical trials, negotiating with clinical trial institutions on the terms and conditions of medical trial agreements, along with insurance and labelling of investigational medicinal products. The team also provides services related to personal data protection, IP, and public procurement issues with respect to specific activities undertaken by pharmaceutical and medical device companies.

## Recent experience

- Advising Pfizer on transfer of its Consumer Healthcare business.
- Advising a leading biotechnology company on general commercial matters including drafting and review of commercial contracts, data protection issues, transfer of personal data, consent with processing of data, registration of filing system.
- Advising Outcome Europe Sarl on Clinical Trials/Non Clinical Trials (observational studies) – drafting a three party agreement with the Site and the Investigator.
- Advising a major Swiss pharmaceutical company on drafting ethical codes for testing and marketing medicinal products and the related advertising in Slovakia.
- Advising a major Swiss pharmaceutical company on medicinal products distribution and obtaining a licence with respective conditions for export, import storage, and transport of drugs, marketing authorisation and transfer with respect to the EC Regulations, clinical trials and rights of clinical trial subjects.
- Advising a major pharmaceutical company on requirements for cosmetic product labelling, marketing authorisation and transfer, and personal data protection.
- Advising a major pharmaceutical company on product liability, consumer protection, and liability for defects.
- Advising a major pharmaceutical company on competition protection.
- Advising a biotechnology company on transfer of brand certificates.
- Advising a pharmaceutical project on employment issues.

## The Team



**Sylvia Szabó**  
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Sylvia has over ten years' experience in 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. Sylvia has participated in a number of due diligence processes and has prepared and reviewed various legal documents and legal opinions. She is fluent in English, German, and Hungarian.

### **Relevant experience**

- Advising Pfizer on the transfer of its Consumer Healthcare business.
- Advising Outcome Europe Sarl on Clinical Trials/Non Clinical Trials (observational studies) – drafting a three party agreement with the Site and the Investigator.
- Advising a leading biotechnology company on special clinical trial issues especially on liabilities of the Sponsor and insurance, on collecting of various patients' data during clinical trials and or outside of clinical trials, general commercial matters including drafting and review of commercial contracts, data protection issues, transfer of personal data, consent with processing of data, registration of filing system.
- Advising a major Swiss pharmaceutical company in drafting ethical codes for testing and marketing of medicinal products and the related advertising in Slovakia.
- Advising a major Swiss pharmaceutical company on medicinal products distribution and obtaining a licence including advising on the conditions for export, import storage and transport of drugs, marketing authorisation and transfers with respect to EC Regulations, clinical trials and rights of clinical trial subjects.
- Advising a major pharmaceutical company on labelling requirements for cosmetic products, marketing authorisation, transfer, and personal data protection.
- Advising a major pharmaceutical company on product liability, consumer protection, and liability for defects.
- Advising a major pharmaceutical company on competition protection.



**Hana Supeková**  
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Hana is a junior associate consultant in our Bratislava office. She specialises in lifesciences and advises clients on commercial law, especially contractual documentation, and employment and administrative law. In addition to representing business groups and pharmaceutical companies, she frequently advises international corporations on various data protection issues. Hana is often a member of due diligence teams. She is fluent in English.

### **Relevant experience**

- Advising Pfizer on the transfer of its Consumer Healthcare business.
- Advising a leading biotechnology company on collecting of various patients' data during clinical trials and or outside of clinical trials, general commercial matters including drafting and review of commercial contracts, data protection issues, transfer of personal data, consent with processing of data, registration of filing system.
- Advising a major Swiss pharmaceutical company on the status of health service institutions and their employees, and bribery laws regarding physicians, legal advice in general commercial matters including preparation of contracts.
- Advising a major pharmaceutical company on product liability, consumer protection, personal data protection, and competition protection, labelling requirements for cosmetic products, marketing authorisation, registration of drugs, advising on general matters with regards to drugs and medical devices, advising on the issues of packaging of drugs and related labelling and insert requirements.
- Advising a pharmaceutical project on employment issues.
- Advising a European biopharmaceutical company regarding the labelling and preparation of drugs and on the advertisement on drugs.

# Spain: CMS Albiñana & Suárez de Lezo

## Scope of services

The Spanish Lifesciences Team comprises 1 partner and 4 senior associates. It has a highly regarded reputation in the Spanish lifesciences market, covering a full range of legal services required by our clients, including corporate and commercial, regulatory, IP, data protection, competition, disputes, and any other specific lifesciences issues.

## Recent experience

- Advising Laboratorios Intervet /Shering Plough on distribution claims in process of resolution.
- Advising Invertis SGPS, S.A. on the acquisition of the Spanish laboratory Acyfabrik SA. Advice to the purchaser in the due diligence process and the share purchase agreement.
- Advising Cegedim-Dendrite on the creation of a database for the use of medical personnel, and the transmission of intellectual property rights of the medical reports to the owner of the database.
- Advising Unilabs on a joint venture with various companies to manage hospitals in Valencia.
- Advising a group of investors on the purchase of Laboratorios Perez-Gimenez, with debt refinancing and company injection of EUR 10m.
- Advising on the acquisition of the Spanish subsidiary Valeant Pharmaceuticals Iberica, S.A. from a Dutch company belonging to the Group Meda Pharma.
- Advising Bayer Hispania, S.L. on the procedure for the delisting of shares of a foreign company (Bayer) quoted on the Spanish stock exchange.
- Advising Biobanc Group on the Spanish conditions for the incorporation of a subsidiary in Andalusia.
- Advising Camlog Biotechnologies AG on the incorporation of the Spanish subsidiary of the German group and on general corporate matters, particularly the secretary to the Board of Directors.
- Advising BTG Industries et Sante on the acquisition of Vitapharma, a company located in the Basque region.
- Advising Onex Corporation on the purchase of Health Division assets from Eastman Kodak and on a regular basis on regulatory issues.
- Advising Dendrite SA on the acquisition of the healthcare website Saludalic.com and on the restructuring of Cegedim and Dendrite in Spain.

## The Team



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Mariano is responsible for the areas of M&A and restructuring of companies. He has wide professional experience in corporate law and in business acquisitions and joint ventures in the lifesciences sector. As a member of the Corporate Department, he has worked in transactions giving legal advice to international and local clients.

### **Relevant experience**

- Advising Invertis SGPS, S.A. on the acquisition by the Portuguese family group Invertis SGPS, SA of the Spanish laboratory Acyfabrik SA. Advice to the purchaser in the due diligence process and the share purchase agreement.
- Advising Takeda on pharmaceutical patent licensing issues.
- Advising Cegedim Dendrite España on the merger between Cegedim and Dendrite in Spain and generally on corporate, IP (data protection), labour, litigation and tax matters.
- Advising Daiichi Sankyo España, S.A. on corporate and competition issues and especially on the transfer of products, distribution, and regulatory matters.
- Advising Intervet /Shering Plough on distribution claims in process of resolution.



**Blanca Cortés**  
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Blanca is an expert in legal advice and litigation in intellectual property, industrial property, unfair competition, fundamental rights to honour, privacy and image, advertising, new technologies and data protection related matters with particular emphasis in the lifesciences sector.

### **Relevant experience**

- Advising Takeda on pharmaceutical patent licensing issues.
- Advising Merck on the transfer of image rights for drug advertising.
- Advising Medicap Holding International (laboratory of homeopathy) on the replacement of a technical and product director.
- Assisting Smith and Nephew with a contract review and the negotiation of distribution agreement.
- Advising Cegedim-Dendrite with regards to the creation of a database and the transmission of intellectual property rights of medical reports.
- Advising Smith & Nephew on the distribution of pharmaceutical products.
- Providing advice to Takeda on pharmaceutical patents' issues, transparency legislation and the implementation of a global anti-corruption policy in Spain.
- Advising Otsuka Pharmaceuticals on a semi-exclusive distribution agreement signed with a Spanish Company, and its suspension.
- Advising Santhera in an administrative trademark proceeding.
- Representing pharmaceutical companies before Customs for the retention of counterfeit and pirated goods.



**Nuria Serrano**  
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Nuria is part of the Litigation Department. She specialises in economic criminal law including consumer law, insurance, breach of contract, and actions against directors. She has extensive knowledge of the lifesciences sector and she advises clients on issues arising from defects in manufacturing and distribution. Nuria combines her position at the firm with her role as professor of Economic Criminal Law at the Universidad de Nebrija.

### **Relevant experience**

- Successfully defending an American Pharmaceutical Company before the courts as a result of the alleged contamination of animal health vaccinations.
- Advising Onex Corporation - Carestream Health (medical and dental imaging products) on general dispute resolution issues.
- Advising Cultek - Transgenomic, Inc (biotechnology) on a dispute resolution matter.
- Advising Dendrite, S.A. (healthcare products and services provider) on litigation matters.
- Successfully defending an American Pharmaceutical Company before the court, versus local distributors in Spain, in claims regarding the distribution process.
- Advising an American Pharmaceutical Company against the Spanish Medicine Agency regarding the commercialisation of medicines.



**Patricia Liñán**  
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Patricia is senior associate specialising in EU and Competition law including merger control, restrictive agreements and abuses of dominant position. Patricia advises companies regarding the implementation of compliance programs of competition law, distribution contracts, unfair competition (proceedings before courts) and European Union law (proceedings before the EU institutions, preparation of opinions on restrictions on freedom of movement).

### **Relevant experience**

- Advising Schering – Plough, S.A. (pharmaceutical) on competition matters (antitrust issues and representation in litigation related to product liability and negotiation).
- Advising Pfizer on the regulation of clinical trials of medical products.
- Advising Esai on Spanish regulations regarding antitrust and pharmaceutical law.
- Advising Cofares on Spanish regulations regarding antitrust and pharmaceutical law.
- Advising Meda (pharma company) on the concentration created by the acquisition of Viartis by Meda. Filing before the Spanish Competition Authorities.



**Pedro Merry**  
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Pedro specialises in legal advice and litigation in intellectual property, industrial property, unfair competition, fundamental rights to honour, privacy and image, advertising, new technologies and data protection related matters with particular emphasis in the lifesciences sector.

### **Relevant experience**

- Advising Takeda on pharmaceutical patent licensing issues.
- Advising Cegedim Dendrite España on IP and data protection matters.
- Advising Merck on transfer of image rights for drug advertising.
- Advising Medicap Holding International (Laboratory of Homeopathy) on the replacement of a technical and product director.

# Switzerland: CMS von Erlach Henrici

## Scope of services

The Swiss Lifesciences team consists of four partners and three associates. The Swiss team has a strong foothold in the pharmaceutical, medical devices, and laboratory industry. The legal services rendered to its clients in the Lifesciences industry range from corporate, commercial, competition and tax law issues to the more industry-specific areas such as intellectual property law, food and drug law and related regulations

## Recent experience

- Advising Takeda Pharmaceutical on its €9.6 billion acquisition of Swiss drug company Nycomed.
- Acting for a listed Canadian venture capitalist on the acquisition of a business division trading in medical devices for USD 2.5 billion, including completion of corporate transactions in Switzerland and advice on Swiss commercial and regulatory aspects.
- Advising Bayer AG on the investigation of the Swiss competition authorities on the pharmaceutical market.
- Advising a pharmaceutical company with regard to the implementation of a distribution system.
- Advising a biotechnology company on clinical trial agreements and related insurance agreements.
- Advising on various research and development agreements and sponsorship agreements for lifesciences clients.
- Advising clients in the pharmaceutical sector in regulatory and advertisement law matters, trade mark and patent law.
- Representing clients in the lifesciences industry in trade mark disputes in front of the Swiss Federal Institute of IP as well as the trade mark appellate board.
- Advising clients in the pharmaceutical sector regarding trade secrets and their protection, competitor relations and on labor law.
- Providing training to staff of pharmaceutical companies regarding legal compliance and behaviour in the event of government action.
- Acting as arbitrator in a large arbitration between two pharmaceutical companies.
- Advising clients in the pharmaceutical sector in operational matters such as logistics organisation or wholesale distribution.

- Advising various organisations in the health care industry on contractual and regulatory matters.
- Advising clients in the pharmaceutical and health care industry in connection with data protection, trade mark and licensing matters (in- and out-bound).
- Advising clients in the biotech and pharmaceutical sector (including leading US firms) in various corporate, commercial, and regulatory law matters.

## The Team



**Dr Robert G. Briner**  
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Robert joined CMS von Erlach Henrici AG in 2006 where he currently heads the IP team. He holds a degree (Dr.iur.) from Zurich University and is admitted to all Swiss bars. His main practice areas are intellectual property and technology law. In addition, he advises clients in the pharmaceutical sector, and advises on e-commerce and the legal compliance of websites, particularly in sectors with pronounced regulatory frameworks such as the pharmaceutical and finance sector. His work regularly involves trade mark law, as well patent law. In heavily regulated sectors, his focus is on compliance and advertising issues. Other activities include assisting in M&A deals, criminal prosecution of IP rights violations, and contractual liability, both as an advisor and as a litigator.

### **Relevant experience**

- Advising clients in the pharmaceutical sector (including leading US firms) on regulatory and advertisement law matters.
- Advising clients in the pharmaceutical sector on trade mark and patent law, and on contract law, for example regarding clinical trial contracts.
- Advising clients in the pharmaceutical sector in operational matters such as logistics organisation or wholesale distribution.
- Advising clients in the pharmaceutical sector regarding trade secret protection in relation to competitors and employees who leave the company.
- Providing advice regarding the legal compliance of websites, in particular with a view to links to websites of subsidiaries in a less-regulated environment.
- Providing training to staff of pharmaceutical companies regarding legal compliance and correct behaviour in the event of government action, e.g. for suspected regulation violations.
- Assessing risks associated with the US FCPA (Foreign Corrupt Practices Act).



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Rudolf is a partner in the Lifesciences Group of CMS von Erlach Henrici AG. He is a graduate from the University of Zurich, Switzerland (LL.M and LL.D, both magna cum laude) and holds a postgraduate degree (M.C.L) from the University of Michigan, USA. He frequently advises on corporate, contractual and regulatory issues in the healthcare industry. He also serves on the board of Swiss corporations operating in the area of lifesciences, medical devices and healthcare services. Rudolf also has extensive experience in employment and business immigration matters. He frequently assists in trade mark protection matters, including criminal prosecution.

#### **Relevant experience**

- Advising the largest laboratory group in Switzerland on their Swiss corporate, contractual, and regulatory matters.
- Advising a multinational pharmaceutical group on Swiss contractual and regulatory matters.
- Advising a multinational lifesciences and medical device group on Swiss contractual and employment law and business immigration matters.
- Advising various organisations in the healthcare industry on contractual and regulatory matters.
- Advising multinational groups on acquisitions of shares and businesses in the Swiss healthcare industry.



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Tobias is a partner in the Lifesciences Group of CMS von Erlach Henrici AG. He is a graduate from the University of Zurich and took the Zurich bar and Swiss bar in 2000. Tobias holds a postgraduate degree (LL.M) from Stanford University. His work covers the fields of commercial law, general contract law (negotiating and drafting agreements), healthcare laws (pharmaceuticals and medical device regulations), intellectual property laws (mainly trade mark laws) as well as dispute resolution (litigation, arbitration, and administrative proceedings).

#### **Relevant experience**

- Advising pharmaceutical and medical device companies on a wide range of regulatory matters.
- Advising on clinical trial agreements and related insurance contracts.
- Advising on marketing, promotion and advertising regulations.
- Advising clients in the pharmaceutical and healthcare industry in connection with data protection, trade mark and licensing matters (in- and out-).
- Assisting a Swiss biotechnology company in developing its intellectual property portfolio and advising on the strategy for protecting and exploiting their IP rights.
- Representing clients in administrative court proceedings and obtaining judicial review of regulatory authorities' decision (e.g. healthcare regulators on local and national levels).



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Patrick graduated from the University of St. Gallen in 1987 and was admitted to the bar in 1989. He wrote his doctoral thesis on Switzerland's relationship to the European Union and completed postgraduate studies at the Collège d'Europe in Brugues with the H.E.E. diploma. He then worked for seven years in the legal department of a Swiss multinational group where he was promoted to the offices of General Counsel and Secretary to the Board of Directors. Patrick Sommer is a member of the international advisory board of the St. Galler Internationales Kartellrechtsforum and of the Studienvereinigung Kartellrecht. Among his main responsibilities are the areas of corporate and commercial law, EU and Swiss competition law, advice on legal issues in the lifesciences industry as well as regulatory matters.

### **Relevant experience**

- Advising a pharmaceutical company on an investigation by the Swiss competition authorities.
- Advising several Swiss companies on various investigations of the market.
- Advising several Swiss and international companies on multi-jurisdictional merger control filings.
- Advising several major foreign companies on various Swiss merger control filings.
- Advising a pharmaceutical company with regard to the implementation of a distribution system.
- Advising several major industrial companies and service providers on the implementation of dawn raid policies.
- Advising several companies in dawn raids by the Swiss competition authorities.
- Advising a major industrial company in a damage claim based on alleged infringement of competition law.
- Advising Takeda Pharmaceutical on its €9.6 billion acquisition of Swiss drug company Nycomed.
- Acting for a listed Canadian venture capitalist on the acquisition of a business division trading in medical devices for USD 2.5 billion, including completion of corporate transactions in Switzerland and advice on Swiss commercial and regulatory aspects.



**Amr Abdelaziz**  
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Amr graduated magna cum laude from the University of Zurich (MLaw UZH) in 2003. He spent one academic year at the University of Geneva (Certificat de droit transnational) and completed a postgraduate degree in advanced European studies at the College of Europe in Bruges (LL.M., Master of European Legal Studies). After working in a major Zurich law firm as a junior associate, he took the bar exam and joined CMS Switzerland in 2007 as an associate.

Amr has advised many of our lifesciences clients on commercial, competition, corporate and employment matters. He heads the CMS Commercial Team in Switzerland and is a member of the CMS Competition and Lifesciences Groups.

#### **Relevant experience**

- Advising Takeda, the largest Japanese pharmaceutical company, on post-merger integration issues following its €9.6 billion acquisition of Swiss drug company Nycomed.
- Advising and representing Bayer in an antitrust investigation conducted by the Swiss competition authorities.
- Advising a Norwegian pharmaceutical company on employment matters in Switzerland.
- Advising a US pharmaceutical company in terminating its exclusive distribution arrangement in Germany.
- Advising a German producer and processor of raw materials for the food industry in negotiating sales contracts governed by Swiss law.



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Franziska graduated magna cum laude from the University of St. Gallen in 1997. Having gained experience as a trainee with the Department of Justice and Police of the Canton of St. Gallen and with a leading law firm in Zurich, she was admitted to the bar in 1999. In December 1999 she joined the firm and was seconded to CMS Cameron McKenna in London in 2001 and to the biotech firm Amgen (Europe) AG in Lucerne in 2003. The emphasis of her practice is corporate and lifesciences law.

#### **Relevant experience**

- Advising clients in the biotech and pharmaceutical sector (including leading US firms) in various corporate, commercial, and regulatory law matters.
- Advising on various research and development agreements and sponsorship agreements for lifesciences clients.
- Advising on advertising restrictions under Swiss law in the health sector.
- Acting for a listed Canadian venture capitalist on the international acquisition of a business division trading in medical devices for USD 2.5 billion, including completion of corporate transactions in Switzerland and advice on Swiss commercial and regulatory aspects.



**Denise Mathieu**  
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Denise joined CMS von Erlach Henrici AG in 2007. She graduated from the University of Zurich in 2001 (lic. iur.). Prior to joining CMS von Erlach Henrici AG, she worked with a leading law firm in Zurich for five years. Her main practice areas are trade mark, design and domain-name prosecution and administration, including the filing of national and international applications and the monitoring of trade marks and designs. She also conducts and analyses searches in these areas. In addition, she advises clients on trade mark strategies and on the enforcement of national and international trade mark portfolios.

#### **Relevant experience**

- Advising various clients in the pharmaceutical sector on trade mark matters.
- Advising clients in the biotechnology sector on trade mark matters.
- Managing the extensive international trade mark portfolio of a Swiss manufacturer of luxury goods.
- Representing clients in objection and opposition proceedings before the Swiss Patent and Trade Mark Office.
- Assisting clients in fighting trade mark and product counterfeiting, including customs assistance.

# UK: CMS Cameron McKenna

## Scope of services

The UK Lifesciences Team comprises over 15 partners and 30 associates in London. We have a wealth of experience advising on a full range of legal services impacting the lifesciences sector including:

- Advertising and marketing
- Anti-counterfeiting
- Collaboration and licensing
- Compliance including bribery risks
- Competition and tendering
- Data protection
- Employee incentive schemes
- Employment
- Environmental issues
- Health and Safety
- Intellectual property including patent and trade mark issues
- IPOs and fundraising
- Litigation
- M&A
- Private equity, MBOs and venture capital
- Product liability
- Regulatory
- Specialist industry agreements

The UK Lifesciences Team is actively involved in the lifesciences community through their work with and sponsorship of the BioIndustry Association (BIA) and their active membership of the ABPI, the ABHI, the BIVDA, the PAGB and EFPIA, allowing the group to have a deep involvement in the lifesciences sector. Our formal representation includes David Marks on the Legal Committee of the ABPI, Nick Beckett on the Research and Innovation Committee of the ABHI and Shuna Mason on the ABHI Legal Issues and Compliance Committee of ABHI and on the Legal Affairs Focus Group of EUCOMED and the EUCOMED Code Committee.

## Recent experience

- Advising Takeda Pharmaceutical on its €9.6 billion (debt-free cash free) acquisition of Swiss drug company, Nycomed.
- Advising Pfizer on the UK and Central European aspects of the disposal of its consumer healthcare division to Johnson & Johnson for \$16.6 billion.
- Advising Wellcome Trust on its issue of £550 million bonds, listed on the London Stock Exchange.
- Advising Medtronic, Inc. on the disposal of stock and intellectual property relating to urology diagnostics to Mediwatch Plc.
- Advising Erbe on the first ever UK streamlined patent infringement proceedings to deal with issues of infringement and validity separately.
- Advising Otsuka on the co-promotion arrangements with Schwarz Pharma of Otsuka's product Pletal.
- Advising Eli Lilly on a leading pharmaceutical repackaging case before the ECJ.
- Advising one of the principal shareholders in Ionix on the sale to Vernalis.
- Advising Baxter Healthcare on UK aspects of the sale of its transfusion therapies business to Texas Pacific.
- Acting for Onex on and coordinating European aspects of the \$2.6 billion purchase of the Eastman Kodak medical imaging division.

## The Team



**Nick Beckett**  
**Partner, Head of IP**  
**Head of Lifesciences**  
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Nick heads up the IP team and has extensive experience in advising on all aspects of intellectual property. His practice spans both contentious and non-contentious issues in relation to trade mark, patent, design, copyright, passing off and confidentiality matters. He focuses in particular on the pharmaceutical, biotechnology and medical device industry sectors. Nick has substantial experience in coordinating complex multi-jurisdictional litigation, regularly working with IP colleagues throughout the CMS network and elsewhere. In particular his work in the areas of patent litigation, as well as parallel trade, anti-counterfeiting and trade mark litigation, often spans national borders.

### Relevant experience

- Advising Takeda Pharmaceutical on its €9.6 billion (debt-free cash free) acquisition of Swiss drug company, Nycomed, including substantive IP and patent due diligence. Nick is Client Relationship Partner for Takeda, having acted on many due diligence exercises, in disputes and EPO oppositions and providing many validity and FTO opinions.
- Acting with a Japanese pharmaceutical company in a very significant ICC arbitration, with damages of up to \$1 billion, concerning a dispute under a worldwide patent licence agreement in the pharmaceutical sector as a result of the wrongful withdrawal of a licensed pharmaceutical product from the market.
- Acting for Erbe Elektromedizin in UK patent litigation concerning argon plasma coagulation, coordinating with CMS on equivalent litigation in Germany, and other patent attorneys on litigation in the US and before the EPO.
- Acting for Japan Tobacco, Eagle Technologies and Asahi Medical in patent litigation in the UK, including co-ordinating multi-jurisdictional litigation.



**Sarah Hanson**  
**Partner, Commercial**  
**Deputy Head of Lifesciences**  
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Sarah has over 15 years' experience of providing lifesciences 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, outsourcing, 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).

### **Relevant experience**

- Advising Takeda Pharmaceutical on its €9.6 billion (debt-free cash free) acquisition of Swiss drug company, Nycomed.
- Advising Futura Medical, an AIM listed company, on a global development, marketing and distribution agreement with Reckitt Benckiser for worldwide rights to the company's topically applied gel for erectile dysfunction.
- Advising UCL Business plc on the licensing of samples to Becton Dickinson in certain prescribed fields relating principally to cancer.
- Advising Proximagen, an AIM listed company, on the disposal to the US company BrainCells Inc of a development programme in respect of the compound sabcomeline for an upfront fee and development and sales milestone payments together worth up to \$51 million, as well as a royalty on sales.
- Advising Medtronic on the distribution agreement with Tissuemed for Medtronic to be appointed as exclusive distributor of Obex NeuroFilm™ Cerebrospinal Fluid Barrier in markets outside the US.
- Advising Pfizer on corporate and commercial aspects of its acquisition of PowderMed Ltd, a company specialising in the emerging science of DNA based vaccines.
- Advising Otsuka in relation to a co-promotion arrangement with Schwarz Pharma for Pletal for the treatment of peripheral vascular disease.
- Advising Bayer on its disposal of its manufacturing site in Norwich to Aurelias Group.



**Shuna Mason**  
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Shuna is one of the few lawyers specialising in the law and regulation of lifesciences products, covering pharmaceuticals, medical devices, in vitro diagnostic devices, and human tissue and crop protection products. She advises and represents lifescience manufacturers in relation to pre-market development, market authorisation or conformity assessment as well as in relation to vigilance and other post-market compliance issues (including post-market surveillance, field safety corrective action, labelling/IFU and all types of promotional materials and activities). 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. She is a member of the ABHI Technical Policy Group and the Legal Issues and Compliance Committee as well as an invited member of EUCOMED's Legal Affairs Focus Group and its Code Committee. She is also a member of the ABPI's Bribery Act Working Group.

### **Relevant experience**

- Advising on advertising compliance and challenge issues in relation to the ABPI Code of Practice and the EUCOMED and ABHI Codes of Ethical Business Practice.
- Helping major pharmaceutical and medical device companies prepare and implement ethical business standards policies and procedures, especially post-Bribery Act 2010. Also advising on related promotional strategies around discounting and rebate practices, interactions with health professionals and off-label promotion.
- Advising a major US-based pharmaceutical company on the wholesale dealing regime and implications for EU distribution practices and potential market openings through NHS reforms.
- Advising a US clinical trial insurer and various global trial sponsors on clinical trial insurance requirements across multiple EU and ex-EU jurisdictions.
- Advising pharmaceutical EU legal representatives on their potential liability exposure and advising on contractual arrangements to minimise exposure.
- Advising a multi-national medical devices manufacturing group in connection with transfer pricing and regulatory compliance arrangements for manufacturing and selling in China and preparing the suite of transfer pricing agreements.



**David Marks**  
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Having 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.

### **Relevant experience**

- Advising Takeda Pharmaceutical on its €9.6 billion (debt-free cash free) acquisition of Swiss drug company, Nycomed.
- Advising on joint ventures, co-promotion, co-marketing, licensing and other forms of strategic alliance in the industry.
- Advising on market-facing strategies including supply chain management, parallel trade, discounting and rebate policies.
- Advising on tendering procedures to the UK health services, including pricing strategies and bid protesting.
- Advising on merger control issues affecting transactions in the industry.
- Clients include major US and Japanese pharmaceutical, biotech and medical device companies.



**Sandra Rafferty**  
**Partner, Corporate**  
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Sandra has been a partner in our corporate department since 2001 and advises on a wide range of corporate matters including domestic and cross-border M&A, corporate finance, joint ventures, restructurings, structuring and establishing limited partnerships.

Her work has covered a range of sectors including lifesciences, infrastructure, construction and banking. Sandra is praised by clients for her project management skills and her commercial approach on corporate transactions. During her time as a partner, Sandra has spent 12 months in the corporate department of our Moscow office.

### **Relevant experience**

- Advising Takeda Pharmaceutical on its €9.6 billion (debt-free cash free) acquisition of Swiss drug company, Nycomed.
- Advising Vanguard Medica Group plc on a placing and open offer.
- Advising Cerebrus Limited on a private placing and subsequent reorganisation.
- Advising the shareholders on the disposal of Hexagen Limited to Incyte Pharmaceuticals Inc.
- Advising on the acquisition of Vacs of Life PLC by Evolutec Limited (a research and development spin-out company from Oxford University), and an equity investment by 3i.
- Advising PPL Therapeutics plc on various fundraisings, the entering into of various manufacturing facility agreements and a subscription by Bayer.
- Advising Neurovex Limited, a spin-out company for University College London for research and development of viral based vectors for therapeutic use, on a private placing.
- Advising Celoxica Holdings plc, on general corporate matters, and a proposed placing and acquisition.
- Advising the Department of Trade and Industry on its £500m outsourcing of the science services contract for the National Physical Laboratory.
- Advising various investors in acquiring and disposing of interests in various Private Finance Initiative healthcare projects in the UK.



**Gary Green**  
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Gary is a senior partner in our Corporate Department. Gary has extensive experience of a wide variety of corporate matters including corporate finance, domestic and cross-border M&A, restructurings and joint ventures. He has often been involved in very large and complex transactions. Gary has advised many of his clients over long periods and is regarded as a trusted business adviser. He is praised by clients for having a very calm demeanour and targeting the core issues.

#### **Relevant experience**

- Advising Biotrace on 3M's recommended cash offer.
- Advising Corin on acquisitions and restructurings.
- Advising PuriCore on a placing and open offer.
- Advising PuriCore on a placing to partially fund the acquisition of Labcaire.
- Advising PuriCore on an issue of secured convertible loan notes.
- Advising Antisoma on a placing in relation to the funding of the acquisition of Xanthus Pharmaceuticals.
- Advising Antisoma on its move from the Main Market to AIM.
- Advising Carestream, Pfizer and Proximagen on various matters.



**Nick Hadley**  
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Nick has worked on all aspects of commercial and residential property development, institutional investment and disposal, and the acquisition, sale and letting (for both landlords and tenants) of all types of commercial property. His clients include companies, institutions, regional development agencies, public bodies, national museums and developers. He has wide experience of representing clients undertaking regeneration projects and in acting for bodies formerly in public ownership, involving clawback and overage considerations.

Nick has advised regularly on the real estate aspects of corporate acquisitions and disposals and on real estate matters for lifesciences clients. He represents the team on the CMS real estate and construction practice area group.

#### **Relevant experience**

- Acting for Abbott Laboratories in connection with their leases of office premises
- Acting for Eli Lilly on a number of transactions, including their acquisition of office premises and the disposition of operational real estate in Basingstoke
- Acting for Du Pont on the UK real estate aspects of their acquisition of ICI's nylon business and on other property transactions
- Acting for Vertex in their taking of a lease of premises at Milton Park
- Acting for a subsidiary of Wyeth in relation to office premises in London
- Advising Proximagen in connection with their office premises
- Acting for a number of other companies (including Honeywell, LGC, TRL, Wells Fargo and Caradon/Novar) on a wide variety of real estate transactions relating to their operational real estate



**Paul Smith**  
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Paul is a partner in the Infrastructure & Project Finance team and has extensive experience in PFI projects in a variety of sectors, including health, education and custodial, and has recently contributed a chapter on health PPPs that was included in a book on PPPs. Before joining the firm, Paul was a development manager for PFI health transactions. Paul is also a member of the Royal Institution of Chartered Surveyors.

### **Relevant experience**

- Advising Clinicenta on the first independent sector diagnosis and treatment centre projects, including arrangements in relation to the provision of a private patient unit at the Lister site in Hertfordshire.
- Advising Nuffield Hospitals in relation to business reorganisation.
- Advising Imperial College in relation to the creation of a centre of excellence for the provision of clinical services and research.
- Advising The Hospital Company on the Swindon diagnostic treatment centre.
- Advising Ramsay Healthcare in relation to the Hinchingsbrooke Hospital franchise.
- Advising Carillion Construction on a variation to provide a new diagnostic and treatment centre at Darenth Valley Hospital in Dartford.
- Advising Biomnis in relation to various outsourced pathology projects.
- Advising The Laing / Laing O'Rourke / Interserve consortium in relation to the Alder Hey PFI Children's Hospital Project.
- Advising FCC / Interserve in relation to the Royal Liverpool PFI Hospital project.
- Advising Skanska in relation to the Papworth PFI Hospital project.
- Advising FSA (funders to the Carillion consortium) on the Portsmouth NHS PFI Project.
- Advising MBIA, EIB and HSBC (funders to the Laing/Sodexo consortium) on the North Staffs NHS PFI Project.
- Advising HBOS and EIB (the funders to the Laing/Serco consortium) on the Forth Valley Health Project.

- Advising XL Capital, EIB and RBC (the funders to the Laing/Interserve consortium) on the Newcastle NHS Health Project.



**Nicholas Stretch**  
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Nicholas advises on employee share plans for both listed and private companies. Advice focuses mainly on the tax, employment, company law and regulatory positions, but advice is tailored as he does work with all sizes of company - whether the company is a small private spin-out able to benefit from the research spin-out exemption or a “big pharma” quoted company with employees in various jurisdictions. Nicholas is a member of the Share Plan Lawyers group and is ranked as a leading practitioner in his area by Chambers and Legal 500.

### **Relevant experience**

- Advising Pfizer on the employee share scheme aspects of its acquisition of PowderMed, a company specialising in the emerging science of DNA based vaccines.
- Advising Eli Lilly on the Prospectus Directive requirements affecting the offer of shares to employees in the UK and the Republic of Ireland.
- Establishing a UK Revenue-approved share plan for employees at Coopervision.
- Advising Corin on its long-term incentive plan and the departure arrangements for a chief executive.
- Advising Syntaxin on holdings by employees of shares in this spin-out from the Health Protection Agency.
- Advising Puricore on the employee share plans for a UK listed company, which provides natural solutions to control the spread of infectious pathogens.
- He has also advised on the treatment of scientists' shares in the spin out of Crysalin Limited (a spin out from ISIS Innovations, the technology transfer arm of Oxford University).



**John Armstrong**  
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John is a partner in the CMS Cameron McKenna lifesciences practice. He has 24 years' experience advising on all aspects of non-contentious intellectual property and biotechnology law. His expertise includes technology transfer, patent and know-how licensing and all types of commercial contracts for the Biotechnology industry including agreements for product distribution, agency, joint ventures, manufacture, supply and purchase, outsourcing logistics and other services, co-promotion, research and development, evaluation, consultancy, confidentiality, data protection, sponsored research, clinical trials and asset sales.

#### **Relevant experience**

- Advising Medtronic in relation to the use of clinical trial data.
- Advising Pfizer in relation to IP licensing, outsourcing, data protection and asset sales.
- Advising Nuffield Hospitals in relation to IT licences, service agreements, outsourcing agreements and data protection.
- Advising Pru Health in relation to its tender to the National Health Service.
- Advising ABPI in relation to the application of the Freedom of Information Act to pharmaceutical data.
- Advising Coopervision in relation to data protection and commercial agreements.
- Advising Biocontrol on IP licensing and commercial contracts.
- Advising PRA in relation to data protection issues relating to clinical trials.



**Mark Atkinson**  
**Partner, Pensions**  
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Mark became a partner in CMS Cameron McKenna in 2001. Mark has acted for claimants and defendants in relation to professional negligence claims against pension scheme advisers. A member of the Association of Pension Lawyers and qualified as an associate of the Pensions Management Institute, he is named in the top tier of specialists in the pensions field (“energetic client man”) and pensions litigation field (“keen as mustard and extremely clever”) in Chambers Guide to the Legal Profession and The Legal 500. Mark is immediate past Chair of APL’s Legislative & Parliamentary sub committee (the body responding to Government consultation on behalf of pension lawyers).

#### **Relevant experience**

- Acting on the merger of the Bayer Group Pension Plan/Schering Healthcare Limited/Bayer CropScience Pension Scheme.
- Settling, on advantageous terms for the client, a significant claim relating to the documentation of changes to retirement ages in the mid-1990s.
- Acting for trustees in relation to one of the largest and most complicated corporate refinancings in the UK market, a role which included negotiating intercreditor rights for the pension scheme trustees in the security structure.
- Advising in relation to a buy-in and reinsurance structure across four countries that gave additional security to trustee clients and control of investment risks more directly to the sponsoring group.
- Acting for the Coloroll schemes in winding up, including taking an application to the European Court of Justice in relation to sex equality issues.



**Susan Barty**  
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Susan is a partner in the Technology and Litigation team. She is a commercial litigator with particular experience in the management and resolution of outsourcing, software and hardware development and other IT related disputes, both within private and government sectors and acting for both suppliers and customers. Susan also specialises in media and reputation management, where she has represented clients across all industry sectors. Susan is an accredited mediator and has substantial experience in alternative dispute resolution procedures.

Susan is a board member of ITechLaw (International Technology Law Association) and a member of the Society for Computers and Law. Susan is also a regular speaker at conferences and seminars. Recent topics include Managing your Contractual Rights, IT Crime Update, Developments relating to Confidential Information, Dispute Avoidance in Outsourcing and Brand Protection Strategies on an International Level.

### **Relevant experience**

- Advising Pfizer in defending an application for an interim injunction brought by a trade body, seeking to prevent the introduction of a new model for distribution to pharmacies.
- Acting for Pfizer on a significant claim against a major pharmacy chain for breach of a discounted supply agreement.
- Acting for Pfizer on a claim made in connection with the termination of long term distribution arrangements within Europe.
- Advising Bizda, a trade body, on potential judicial review proceedings in relation to Government pricing mechanisms.
- Advising the PSNC on potential judicial review proceedings in relation to fee increases imposed by the RPSGB.
- Acting for Pfizer in connection with licensing arrangements in Japan and the termination of licensing arrangements, including advising on proceedings in both the Japanese and English Courts.



**Tom Scourfield**  
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Tom is a Partner in the IP team in London, with substantial experience of the protection and enforcement of all intellectual property rights. As a solicitor advocate, Tom has particular expertise in contentious matters and has acted on a number of leading cases in the High Court, the Patents Court and Patents County Court, the Court of Appeal, the European Court of Justice and the Privy Council. Many of his cases are the leading authority on particular issues, including dilution (INTELMARK), post-sale confusion (Datacard v Eagle Technologies) and split trials in patent cases (Canady v Erbe).

Tom has been widely published and is responsible for the chapter on Patent Enforcement and Revocation in the leading practitioners' text, The European Patents Handbook, as well as the chapter on infringement in the Trade Marks Handbook. Tom has a post-graduate diploma in IP Law and Practice from one of the UK's leading IP schools.

Chambers and Partners 2011 (IP) described Tom as one to watch, noting he was "very strategic and pragmatic in his advice".

### **Relevant experience**

- Acting for the lead defendant in a medical device case involving accessories for therapeutic endoscopy in Canady v Erbe (and others).
- Advising on defending patent infringement proceedings brought by SmithKlineBeecham for alleged infringement of formulation patents relating to the SSRI paroxetine, then SKB's second best selling drug in the UK in SKB v Alparma Limited.
- Advising on the defence of patent infringement proceedings as a result of the proposed launch of Sebomin MR (a form of minocycline) in Wyeth v Alparma Limited.
- Advising a leading medical device manufacturer on defending a claim for breach of contract and inventorship from a former consultant, regarding the entitlement to technology related to spinal implants.
- Investment due diligence on various complex patent portfolios involved with corporate investments, shares sales and research collaborations.
- Acting for a leading pharmaceutical company as the claimant in a trade mark and design infringement case in Central and Eastern Europe.



**Karen Clarke**  
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Karen is a partner in the Construction team specialising in the drafting of construction and facilities management contracts. She has experience of drafting, negotiating and advising on construction contracts, consultant appointments for developers, institutions and public sector clients on various office, commercial premises and research facility projects. She has also drafted and advised on operational and facilities management documentation and recently assisted the Chartered Institute of Building in revising their Standard Form Facilities Management Contract.

#### **Relevant experience**

- Drafting and negotiating construction documentation on a number of development and refurbishment projects for the Wellcome Trust.
- Advising the Wellcome Trust in connection with a major academic, research facility and commercial innovation centre, at Genome Campus, Hinxton.
- Advising the Wellcome Trust on a facility developed in connection with European Bioinformatics Institute.
- Advising the Wellcome Trust on supply and facilities agreements.
- Advising Imperial College on the drafting of construction contracts (based on NEC/ECC forms) and appointments for a number of projects procured under Framework Agreements for research and laboratory projects.
- Advising Imperial College on research facility supply, operational and facilities management agreements.



**Sam Dames**  
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Sam is a partner in the Tax team. Sam is primarily involved in the tax aspects of UK and cross-border structured finance, M&A, and general corporate tax including stamp taxes and VAT. Sam has advised on a wide range of tax issues across a variety of industry sectors, in particular advising clients in the financial services, lifesciences and hotels sectors.

Sam is currently involved in an initiative with the lifesciences and technology sector groups in relation to the new Patent Box regime which will allow companies to apply a 10% corporation tax rate to profits attributed to patents from 2013 and will also raise significant issues in relation to transfer pricing arrangements and IP litigation planning.

#### **Relevant experience**

- Advising a US pharmaceutical company on the tax aspects of the proposed acquisition of a global pharmaceutical group.
- Advising the Wellcome Trust on the finance leasing of their headquarters at Euston Road, London and their research centre at Hinxton near Cambridge.
- Advising Evolutec plc on the tax aspects of different joint venture arrangements.
- Advising Nuffield Hospitals on the tax aspects of the acquisition of Vanguard Healthcare Solutions.
- Advising various private companies on the availability of Enterprise Investment Scheme relief.



**Caroline Hobson**  
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Caroline advises on a wide range of EU and UK competition law issues in a variety of industry sectors, in particular advising clients in the lifesciences and consumer products sectors. Caroline has considerable experience of advising on competition issues affecting the pharmaceutical sector.

**Relevant experience**

- Advising pharmaceutical companies on UK, EC and worldwide merger clearances.
- Advising on product distribution strategy, licensing, collaboration and joint venture agreements, pricing and sales strategies for major pharmaceutical companies and multi-national consumer products companies.
- Advising a multi-national pharmaceutical client in the European Commission's pharmaceutical sector enquiry.
- Preparation of numerous compliance programmes, compliance training and dawn raid response policies for pharmaceutical companies.



**James Parkes**  
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James is a partner in our Corporate Department.

James has extensive experience of advising clients on a wide range of corporate transactions and specialises in public and private M&A, equity fundraisings and corporate restructurings, with a particular focus on the lifesciences sector.

### **Relevant experience**

- Advising Takeda Pharmaceutical Company on its €9.6 billion acquisition of Swiss drug company, Nycomed.
- Advising Biotrace on 3M's recommended cash offer of approximately £52 million.
- Advising Pfizer on its €135 million sale of European OTC and personal care brands to Omega Pharma.
- Advising Paragon Healthcare on its £322 million sale to Hg Capital.
- Advising PuriCore on an issue of secured convertible loan notes to raise £8 million.



**Arundel McDougall**  
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Arundel has over thirty years of general commercial litigation experience in the UK, covering a very broad range of casework, and much of it involving an international element. He has specialised in the lifesciences sector for many years and has been ranked in the directories as a leader in the Product Liability (Defendant) field for many years.

Over his practising career he has defended some of the best known pharmaceutical Group Actions and a number of ground breaking competition cases from 2001 to the present.

**Relevant experience:**

- Advising Hoechst Marion Roussel in the Norplant Group Litigation 1995 – 1999.
- Advising Sanofi Aventis in the Sabril Group litigation: 2000 – 2010.
- Advising Aventis Animal Nutrition, Sanofi Aventis and Rhodia in defence of EC Competition Law claims; resulting in a series of ground breaking decisions in the UK, see *Provimi Ltd v Aventis Animal Nutrition SA and Ors* [2003] EWHC 961 (Comm), *BCL Old Co Ltd and Ors v Aventis SA and Ors* (Competition Appeal Tribunal [2005] CAT 1, *Devenish and Ors v Sanofi Aventis SA and Ors* [2007] EWHC 2394 (Ch), *Grampian Country Food Group Ltd and Ors v. Sanofi-Aventis SA and Ors* [2009] CAT 29.
- Advising Sanofi in defence of the methionine cartel damages action in the UK.
- Advising Merck KgAa.
- Advising Imperial Tobacco in relation to smoking and health-related matters since 2010.
- Advising Total in defence of the Wax Cartel damages action in the UK .
- Advising Shire Pharmaceuticals in its successful challenge, by way of judicial review, to NICE Guidance on the use of acetylcholinesterase in patients with Alzheimer's Disease, *The Queen (on the Application of Eisai Limited) and the National Institute of Clinical Excellence* [2008] EWCA Civ 438.
- Advising the Prescriptions Medicines Code of Practice Committee (PCMPA) of the ABPI.



**Amy Bird**  
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As an associate in the Employment team, Amy has worked with clients across a wide range of sectors, but has a focus on lifesciences. She has completed post-qualification secondments to the in-house legal teams of two FTSE 100 companies. She supports clients by formulating service agreements and negotiating board-level exits, drafting staff handbooks and policies, advising on individual disciplinary issues, providing staff training and advising on TUPE and other employee aspects of corporate transactions. Her litigation experience includes handling Employment Tribunal claims for unfair dismissal, discrimination and whistleblowing, at first instance and on appeal. She also has experience of High Court litigation, including seeking injunctive relief for misuse of confidential information. Amy is a regular contributor to the Workplace Law Handbook and serves on the Employment Lawyers' Association Training Committee.

#### **Relevant experience**

- Advising on employment issues in acquisition of major pharmaceuticals group, including drafting appointment and termination documentation for senior personnel.
- Defending biomedical research institute in employment tribunal proceedings brought by senior executive.
- Advising Pfizer on the employee aspects of its acquisition of PowderMed, a company specialising in the emerging science of DNA based vaccines.



**Louise Boswell**  
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Louise has varied liability, compliance and dispute resolution experience. She has advised clients in the medical devices and pharmaceutical industries in relation to compliance with product liability and anti-bribery and corruption laws, and assisted with the resolution of complex disputes arising from allegations of negligence, fraud, abuse of process and misrepresentation, as well as regarding contractual disputes.

**Relevant experience**

- Advising a global pharmaceutical company on the resolution of multiple product liability claims and claims of negligence, including achieving satisfactory settlement where appropriate.
- Advising clients in the lifesciences sector on compliance with anti-bribery and corruption laws, including the Bribery Act 2010.
- Advising a multi-national company concerning a potential dispute arising out of corporate structure and financing agreements and alleged misrepresentation.
- Advising on various aspects of third party contracts (with both customers and suppliers) and identifying risk areas (including in relation to bribery and corruption) in order to prevent and/or resolve potential disputes.



**Alex Bowtell**  
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Alex is an associate in the intellectual property and advertising and marketing team. She has experience in advising on all aspects of intellectual property work. Her practice covers both contentious and non-contentious issues relating to: patents; trade marks; designs; copyright; passing off; and confidentiality. She also provides advice on general commercial agreements. In particular she has worked on matters involving: intellectual property due diligence; patent validity and infringement opinions; trade mark clearance; product-specific marketing advice; patent licensing issues and disputes; and customs and counterfeiting. Alex also has experience in coordinating multi-jurisdictional advice, working regularly with colleagues throughout the CMS network and in other jurisdictions worldwide. Alex has a range of in-house experience, having completed secondments at, inter alia, GlaxoSmithKline and Takeda. Alex graduated from the University of Sheffield with a BSc in Psychology with an emphasis on neuro and cognitive psychology.

### **Relevant experience**

- Advising Takeda Pharmaceutical on its €9.6 billion (debt-free cash free) acquisition of Swiss drug company, Nycomed.
- Assisting in the intellectual property aspects of several large due diligence projects, including document review, review of existing intellectual property rights and protection and assessment of validity and freedom to operate.
- Assisting several companies in relation to customs applications for the protection against counterfeits.
- Assisting Erbe Elektromedizin in UK patent litigation concerning argon plasma coagulation in relation to therapeutic endoscopy involving proceedings in the Patents Court and the Leeds Magistrates Court.
- Assisting a leading international agrochemical company in the co-ordination of patent infringement and regulatory dispute advice from other CMS offices regarding restrictions on the marketing and labelling of agrochemicals.
- Assisting Eli Lilly in a parallel trade re-packaging case.
- Assisting a major UK pharmaceutical company in intellectual property litigation in relation to the obtaining of injunctions on an international basis.



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Elizabeth is a senior associate in the Commercial team and is a member of the firm's Lifesciences Sector Group. Elizabeth's experience includes advising on a broad range of commercial agreements, in particular those with an intellectual property focus, providing commercial advice to pharmaceutical clients, and assisting with due diligence exercises within the lifesciences sector. During her time with CMS, Elizabeth has been on secondment at CooperVision Manufacturing Limited, a manufacturer of medical devices. Elizabeth graduated from The University of Melbourne, Australia with a LLB (Hons) and a BSc, specialising in Biochemistry.

#### **Relevant experience**

- Advising pharmaceutical companies on research and development agreements, and clinical trial agreements.
- Advising Takeda Pharmaceutical on its €9.6 billion (debt-free cash free) acquisition of Swiss drug company, Nycomed.
- Drafting purchase and transitional services agreements for, and advising on, the acquisition of a Central European manufacturer by a UK medical devices manufacturer.
- Drafting supply agreements for the supply of products to an agrochemical company and the supply of raw materials to a medical device company.
- Advising on the sale of a manufacturing site and related IP for an agrochemical company.
- Drafting agreements for the supply and manufacture of bulk product and the supply of raw material for a pharmaceutical manufacturer.
- Advising in relation to the interpretation of a licence and supply agreement between two global pharmaceutical companies in respect of royalty payments and an ongoing obligation to procure licensed product.



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Siobhan qualified in 2004 and joined CMS Cameron McKenna in 2006. Siobhan advises on a wide range of EU and UK competition issues in a variety of industry sectors, including the pharmaceutical and medical devices sectors. Siobhan has advised clients on all aspects of public procurement law. She advises extensively on EU and UK merger control and has worked on numerous multi-jurisdictional merger filings.

### **Relevant experience**

- Advising a well-known medical devices company in relation to a complaint to the Office of Fair Trading.
- Advising clients in the medical devices and pharmaceutical sector on all aspects of public procurement law.
- Delivering bespoke competition compliance training to trade associations in the medical devices and in-vitro diagnostics industries.
- Advising on tendering procedures to the UK health services, including pricing strategies and bid protesting.
- Advising on the competition aspects of numerous distribution arrangements.
- Advising on merger clearance at EU, UK and multi-jurisdictional level.



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Hannah is an associate in the Commercial team and is a member of the firm's Lifesciences Sector Group. Hannah's experience includes advising on a broad range of commercial agreements, in particular those with an intellectual property focus, providing commercial advice to pharmaceutical clients, and assisting with due diligence exercises within the lifesciences sector. During her time with the firm Hannah has been on secondment with the Wellcome Trust and Pfizer Limited. Prior to commencing her legal studies, Hannah graduated from Imperial College with a BSc in Biology, specialising in microbiology.

#### **Relevant experience**

- Advising Takeda Pharmaceutical on its €9.6 billion (debt-free cash free) acquisition of Swiss drug company, Nycomed.
- Advising in relation to a research, licence and collaboration agreement with a global pharmaceutical company.
- Advising in relation to the interpretation of a licence and supply agreement between two global pharmaceutical companies in respect of royalty payments and an ongoing obligation to procure licensed product.
- Advising in relation to the Innovative Medicines Initiative (IMI), appropriate marketing and development strategies for new product launches and compliance with relevant codes of practice.
- Advising a global medical devices company on commercial aspects of its investment in another lifesciences organisation including the drafting and negotiation of associated distribution agreements.
- Advising in relation to the commercial and intellectual property issues relevant to an investment in a privately held pharmaceutical company.
- Drafting revenue sharing agreements for the commercial exploitation of grant-funded projects at the Wellcome Trust and advising the Trust's Investment Division on its funding of a biopharmaceutical company.
- Drafting, advising on and negotiating agreements for start-up companies to commercialise developed technology such as IP licences, IP assignments, services agreements and software (support, training and hosting) agreements.



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Stuart is a Senior Associate in our intellectual property team. He advises on IP disputes in the lifesciences sector, including in particular parallel trade matters, where his experience includes acting for Eli Lilly in the leading pharmaceutical repackaging case of *Eli Lilly v Dowelhurst*. Stuart also advises on IP and commercial issues in transactions in the lifesciences sector, and on advertising and marketing and consumer protection issues.

### **Relevant experience**

- Advising Takeda Pharmaceutical on its €9.6 billion (debt-free cash free) acquisition of Swiss drug company, Nycomed.
- Acting for Enigma Diagnostics in its negotiations for a patent licence and collaboration agreement with The Tecan Group, for the development and manufacturing by Tecan of a diagnostics platform based on Enigma IP.
- Advising Proximagen plc on a range of commercial transactions, including patent licensing agreements and acquisitions and disposals of development programmes.
- Acting for UCL Business plc on the licensing of UCL's "biobanks" of human serum samples to Becton Dickinson & Company.
- Acting for Eli Lilly in the Court of Appeal in Eli Lilly's dispute with the parallel importer Dowelhurst, in one of the leading cases in the field of repackaging of pharmaceutical products.
- Advising Abbott Laboratories on the termination of distribution agreements.
- Advising Johnson & Johnson on a range of advertising and marketing and consumer issues.
- Advising the Proprietary Association of Great Britain on the redrafting of its Advertising Codes in light of the implementation of the Unfair Commercial Practices Directive.
- Advising on AAC's acquisition of Martindale Pharmaceuticals.



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John qualified into the CMS Cameron McKenna competition team in 1998, having trained with the firm. Since then, John has advised exclusively on a wide range of EC and UK competition and merger control issues across a variety of industry sectors, in particular advising clients in the lifesciences and consumer products industries.

John has considerable experience of dealing with the European Commission and (in the UK) with the Office of Fair Trading, the Competition Commission and the Competition Appeal Tribunal, advising clients on investigations into cartels and into alleged abuse of dominance as well as on merger control procedure (including appeals of mergers) and market-wide investigations. John frequently co-ordinates multi-jurisdictional filings to merger control authorities world-wide. John has particular expertise in advising on the application of the rules on distribution, supply and licensing agreements and in advising and presenting on product distribution strategy and pricing issues.

#### **Relevant experience**

- Advising Takeda Pharmaceutical on its €9.6 billion (debt-free cash-free) acquisition of Swiss drug company, Nycomed.
- Providing advice on distribution strategy to a leading global pharmaceutical supplier in the context of an Office of Fair Trading enquiry (2004 to the present).
- Advising a leading global pharmaceutical supplier on merger control proceedings (including remedies) before the European Commission.
- Advising a major food company from 1999 to 2004 on a wide variety of agreements and compliance issues and disputes and on compliance strategies (including regular seminars). The largest of many matters during this period was a Competition Commission monopoly investigation.
- Representing a UK company in the Office of Fair Trading's ongoing industry-wide cartel investigation, including representing the client during dawn raids, leniency application and interviews (2006 to the present).



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Kate qualified in 1999 and joined CMS Cameron McKenna in 2004. Kate advises the private healthcare sector, including insurers, on all types of claims and disputes including professional negligence and third party liabilities.

### **Relevant experience**

- Advising a private laboratory and their insurers in relation to a wrongful birth claim which went to trial in 2008 and to appeal in 2009. The case involved complex factual and expert issues concerning the culture and testing of CVS and a duty to communicate between an NHS Trust Hospital and a private laboratory.
- Advising on claims arising from a product liability matter involving a machine malfunction resulting in false negatives being given to patients.
- Advising on claims arising from breach of confidence concerning paternity testing.
- Advising on data protection issues relating to medical records.
- Advising on potential claims arising from the miscommunication of DNA test results.
- Advising on issues arising from police investigations concerning a third party who was impersonating our clients and fraudulently issuing test results in their name.
- Advising on issues relating to sexual abuse investigations by the police arising from a positive chlamydia test on a child.



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Odette is a lawyer in the Commercial team and is a member of the firm's Lifesciences Sector Group. Odette's experience includes assisting with and advising on a broad range of commercial agreements, providing commercial and data protection advice and assisting with IT, IP and material contracts due diligence for companies in the lifesciences sector, among others.

### **Relevant Experience**

- Advising Takeda Pharmaceutical on its €9.6 billion (debt-free cash free) acquisition of Swiss drug company, Nycomed.
- Assisting a multi-national medical devices manufacturing group with the preparation of a suite of transfer pricing agreements relating to manufacturing and selling in China.
- Advising a UK-headquartered pharmaceutical company on the drafting and amending of a formulation agreement and a tripartite development agreement.
- Advising a supplier of medical and surgical disposables on its termination rights under a purchasing agreement.
- Advising a clinical research charity on the drafting of a research grant agreement.
- Advising a price comparison website in the healthcare sector on its website terms of use and privacy policy.
- Advising a global pharmaceutical company on the co-ordination of a multijurisdictional review of pan-European terms of business.
- Drafting IP licences and IP deeds of assignment for companies in the lifesciences sector.



**Robert Patterson**  
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Robert is a Senior Associate in the Real Estate team. He is involved in institutional sales, purchases and lettings and general management work. In particular, he has been involved on the following transactions advising lifesciences clients and other clients.

**Relevant experience**

- Acting for the Wellcome Trust on the sale of the Wellesbourne Industrial Estate for £49,000,000.
- Acting for the Wellcome Trust on numerous lettings at Stadium Way Industrial Estate, Reading.
- Acting for De Novo Pharmaceuticals Limited on various lettings.
- Acting for Hartest Holdings Plc in respect of various sales and lettings.
- Acting for Derwent London Plc on the letting of the whole of 80-85 Tottenham Court Road to MWB Business Exchange Centres Limited at a rent of over a million pounds per annum.
- Acting for Abbott Laboratories Limited on various lettings.



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Isabel is a senior associate in the Tax Team, specialising in employee incentives. Isabel joined the team in June 2007 after practising for nearly four years at a large firm in Cambridge, the leading biotechnology centre in the UK, where she specialised in corporate tax and employee incentives.

Isabel's experience includes advising quoted and unquoted companies, including biotech companies, on a broad range of incentives for their employees to participate in company shares, other equity and cash schemes, including advising on tax, company law, corporate governance and employment issues. She also advises both companies and trustees on employee benefit trust matters.

Isabel has written a number of articles, including for Executive Compensation Briefing, and participates in the work of the Share Plan Lawyers group and ifsProShare.

### **Relevant experience**

- Advising Proximagen, a UK quoted company and a number of other quoted companies on their employee incentive arrangements.
- Advising Puricore, a UK listed company, which provides natural solutions to control the spread of infectious pathogens, on its employee share plans. This included the share option aspects of an open offer.
- Acting for a number of biotech companies in relation to the establishment of employee share plans and university spin outs on the treatment of scientists' shares.
- Advising the trustee of an employee benefit trust on significant changes to the trust arrangements following the takeover of a listed company by a private equity firm.



**Dr David Pountney**  
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David provides technical support and assistance to lawyers in the Lifesciences Sector Group on a number of matters, including patent litigation, patent due diligence, regulatory matters, and M&A and commercial deals where there is a need to review scientific and technical issues. Prior to joining CMS Cameron McKenna, David held research positions in both academia and the pharmaceutical industry. David has conducted scientific research across several therapeutic areas in medical centres in Paris and New York, and for many years led a pre-clinical drug discovery team at GlaxoSmithKline. David graduated from University College Swansea in Biochemistry and obtained a PhD degree in Clinical Biochemistry from King's College London.

#### **Relevant experience**

- Advising Takeda Pharmaceutical on its €9.6 billion (debt-free cash free) acquisition of Swiss drug company, Nycomed.

#### **Drug discovery**

- GlaxoSmithKline – David led trans-national matrix drug discovery projects across several areas of the Molecular Discovery Research Division and acquired a detailed understanding of the pre-clinical drug discovery process. David also conducted technical due diligence, evaluating external technology for potential in-licensing.
- New York University Medical Centre – David was part of a team investigating novel cardiac genes important in regulating the heartbeat and involved in cardiovascular disease.
- Hôpital Bichat, Paris, France – David was part of a team discovering and characterising novel genes and proteins involved in nutritional and blood disorders.

#### **Scientific communication**

- David has published technical and research papers in scientific journals including Developmental Biology; The Journal of Molecular and Cellular Cardiology; The Proceedings of the National Academy of Sciences (PNAS); The Journal of Cell Science; Annals of the New York Academy of Science; and FEBS Letters.
- David has for many years worked as a freelance science and health writer, contributing to the British Medical Journal (BMJ), Cancer Nursing Practice, Chemistry & Industry; and Nursing Older People.



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Karma advises a wide range of corporate and management teams on M&A, fundraisings, private equity and venture capital transactions, joint ventures and re-organisations. Karma focuses primarily on transactions in the lifesciences and technology sector groups.

### **Relevant experience**

- Advising Takeda Pharmaceutical on its €9.6 billion (debt-free cash free) acquisition of Swiss drug company, Nycomed.
- Advising Ventech, a Paris-based venture capital firm on its participation in the Series B financing round undertaken by Funxional Therapeutics Limited, a Cambridge-based clinical stage pharmaceutical company which focuses on the discovery and development of novel anti-inflammatory therapies.
- Advising Pfizer Inc. on its acquisition of PowderMed Limited, a UK-based start-up focusing on developing vaccine technology involving needle-free administration of DNA-coated microscopic gold particles into the skin using pressurised helium gas.
- Advising Pfizer Inc. on its disposal of its consumer healthcare business, comprising interests in numerous European jurisdictions, to Johnson & Johnson for a consideration in excess of US\$1 billion as part of a global disposal programme for an aggregate consideration of US\$16.6 billion.

Advising Pfizer Inc. on the disposal of its Adams confectionery business to Cadbury Schweppes Plc for a consideration of US\$165 million. The transaction formed part of a global disposal programme to Cadbury for an aggregate consideration of US\$4.2 billion.



**Joanna Hook**  
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Joanna is a senior associate and works on regulatory matters for pharmaceutical, medical device, cosmetic, consumer product and food companies in the Lifesciences and Consumer Products Sector Groups. She also assists clients with compliance matters arising under the UK Bribery Act. Joanna is personally recommended in Chambers UK Legal Directory. Joanna's advice on general pharmaceutical regulatory matters includes: applications for approvals of medicinal products, adverse event and other reporting obligations, manufacturing controls, pricing and reimbursement, labelling and promotion, and data protection. She has also advised extensively on EC and national laws governing clinical research and the regulatory status of borderline products. She has developed considerable expertise in coordinating regulatory projects covering jurisdictions outside of Europe, including South America, Eastern Europe, the former Soviet Union, and Asia.

### **Relevant experience**

- Advising Takeda Pharmaceutical on its €9.6 billion (debt-free cash free) acquisition of Swiss drug company, Nycomed.
- Advising on potential commercial and regulatory procedural and transitional issues surrounding the sale of a multinational company's European pharmaceutical business.
- Assisting with compliance-related investigations and initiatives in respect of alleged breaches of medicines advertising, anti-bribery, clinical trials, and pharmacovigilance rules. Includes representing several major European clients in investigations under the U.S. Foreign Corrupt Practices Act, the UK Bribery Act and the UK Proceeds of Crime Act.
- Advising various pharmaceutical companies on advertising compliance with the ABPI Code of Practice, including in relation to advertising challenges.
- Advising on product defence resulting from regulatory challenges to product claims and borderline product classifications.
- Advising various companies on inspection and enforcement activities regarding medicinal products, cosmetics and foods in the UK and mainland Europe.
- Conducting a due diligence review and advising on the potential European commercial and regulatory issues surrounding the sale of several international food companies.
- Advising a UK insurer on product liability and clinical trial insurance requirements in the UK.

# Ukraine: CMS Cameron McKenna

## Scope of services

The Kyiv office Lifesciences Team consists of 1 partner and 2 associates. The team has extensive experience of advising major pharmaceutical companies in Ukraine on various regulatory issues, protection of IP rights, clinical trials and other issues relevant to the lifesciences sector.

The Kyiv office has significant experience of advising clients on regulatory issues, protection of IP rights, advising on relations with distributors and pharmacies and on legal aspects of conducting clinical trials as well as on the import of medicines into Ukraine.

## Recent experience

- Advising Takeda Pharmaceutical on its €9.6 billion (debt-free cash-free) acquisition of Swiss drug company, Nycomed.
- Advising international and local medicine producers on conducting clinical trials in Ukraine, including drafting clinical trial agreements between trial institutions, investigators and Pharma companies.
- Advising foreign pharmaceutical companies regarding the import of medicines into Ukraine.
- Representing several major international pharmaceutical companies on a number of contentious matters relating to the protection of their patent and trade mark rights to various active substances in Ukraine and in actions against generic companies.
- Representing major international pharmaceutical companies in ongoing corporate and commercial matters.
- Representing a major pharmaceutical company on the protection of patent rights and counterfeiting matters.
- Advising a major pharmaceutical company on a dispute with the local distributor of this company in Ukraine.
- Assisting APRaD (Association of Pharmaceutical Research and Development) in establishing a major lobbying organisation of international pharmaceutical companies in Ukraine (the headquarters are located in Switzerland and there is a representative office in Ukraine).
- Advising major international clinical trial companies on clinical trial agreements in Ukraine.
- Conducting IP due diligence of the Ukrainian IP portfolio of a major international pharmaceutical manufacturer.
- Advising a global private equity fund on the acquisition of a stake in one of Ukraine's cutting edge medical treatment and healthcare providers.

## The Team



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Olexander joined CMS Cameron McKenna from the Kyiv office of Baker & McKenzie. His practice includes a broad experience in advising multi-national and local companies, institutions and organisations on their business activities in Ukraine, on corporate and competition law, with a particular emphasis on anti-counterfeiting and unfair competition, and corporate restructuring, as well as M&A and telecommunications. Olexander was recognised as Band 1 lawyer in Corporate/Commercial by Chambers Europe 2008-2011 as a leading specialist in Corporate and M&A by PLC Which Lawyer? He was also recommended in Competition/Antitrust and Dispute Resolution by the same directory. Chambers Europe 2008 says: "He is known as a seasoned veteran of the Ukrainian market, but don't underestimate the extent of his US education and Western-style knowledge of commercial issues".

### Relevant experience

- Advising Takeda Pharmaceutical on its €9.6 billion (debt-free cash-free) acquisition of Swiss drug company, Nycomed.
- Representing several major international pharmaceutical companies on a number of contentious matters relating to the protection of their patent and trade mark rights to various active substances in Ukraine and in actions against generic companies.
- Representing major international pharmaceutical companies in on-going corporate and commercial matters.
- Representing a major pharmaceutical company on counterfeiting matters in Ukraine.
- Representing a major pharmaceutical company on the protection of patent rights and counterfeiting matters.
- Assisting APRaD (Association of Pharmaceutical Research and Development) in establishing a major lobbying organisation of international pharmaceutical companies in Ukraine (the headquarters are located in Switzerland and there is a representative office in Ukraine).
- Advising major international clinical trial companies on clinical trial agreements in Ukraine.



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Olga joined CMS Cameron McKenna from the Kyiv office of Baker & McKenzie. Olga's practice includes competition and general commercial issues.

As a competition lawyer, Olga advises foreign and local clients on merger control issues, concerted actions, anti-competitive conduct on the market, etc.

Her general commercial practice combines a broad experience in drafting and negotiating different types of commercial contracts, including sale and purchase, logistics, supply, recruitment and advertising services, etc., as well as advising clients on regulatory issues related to their commercial activity.

#### **Relevant experience**

- Advising international and local medicine producers on conducting clinical trials in Ukraine, including drafting a clinical trial agreement between trial institutions, investigators and pharma companies.
- Advising foreign pharmaceutical companies regarding the import of medicines into Ukraine.
- Advising pharmaceutical companies regarding insurance issues related to the clinical trials.



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Prior to joining CMS Cameron McKenna, Oleksandr headed the IP Department at Khortytsya, Ukraine's major producer of alcoholic beverages. He has over seven years of practice in various aspects of intellectual property and unfair competition law. Oleksandr's experience embraces a range of issues related to intellectual property, such as drawing up and deploying of IP protection strategies for various types of businesses, IP portfolio management, structuring of transactions that involve IP assets (transfer and licensing of technology and goodwill), suppression of unfair business practices and litigation of IP-related disputes. He has been advising clients representing a broad variety of business sectors, including lifesciences, financial institutions, media and advertising companies, manufacturers of consumer products, accommodation, leisure and entertainment facilities, oil and gas, etc.

#### **Relevant experience**

- Prosecution of trade mark portfolio of a Ukrainian leading manufacturer of insulin.
- IP Due diligence of a Ukrainian pharmaceutical company.
- Representing a major international producer of agricultural seeds in criminal proceedings instigated by the client against a counterfeiter of its sunflower seeds in Ukraine.
- Representing a major international producer of agricultural seeds in a trade mark infringement matter that involved manufacture of counterfeit packaging for the client's products in Ukraine.
- Representing various international companies from the lifesciences sector at the Ukrainian Patent and Trade mark Office in various trade mark and patent prosecution matters, such as filing and prosecution of applications, opposing bad faith applications, patent maintenance, assignment and licensing.

# CMS Office Contacts

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