

Lifesciences

Supporting your business in
Central and Eastern Europe

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



"These excellent partners provide outstanding CEE platform."

Chambers Global 2008

We're focused on your sector

CMS Cameron McKenna has a track record of advising lifesciences businesses throughout Central and Eastern Europe (CEE). Working in partnership with clients, we help them take advantage of the many opportunities available whilst minimising their business risks. We have been established in the region for over ten years. This means we never underestimate the differences between local markets, whilst taking into account EU and EEA standards.

Lifesciences regulation in accession countries has undergone significant changes – from the rules on marketing pharmaceutical products to legislation relating to medical devices. The changes have had a profound effect on the way business is conducted in CEE. In light of the recent accession of ten countries into the EU, companies operating in these new member states should ensure that they are fully in compliance with EU regulations.

Facts and figures about the Lifesciences group

- We have advised major pharmaceutical companies for over 70 years – we currently advise more than 50 of the world's top 200 pharmaceutical companies.
- A dedicated team of more than 35 lawyers specialising in lifesciences in Europe.
- Some members of the team are medically as well as legally qualified. Others have worked in-house for leading pharmaceutical companies.
- We are experienced in working with regulatory agencies and governmental departments across Europe – we understand how they work.
- In CEE, we have on-the-ground experts in Bucharest, Budapest, Kyiv, Moscow, Prague, Sofia and Warsaw. Being able to call upon the firm's entire resources from UK and the rest of Europe through the CMS network enables us to provide you with true European coverage.

Our range of services

Our Lifesciences group advises on a wide range of legal issues:

Advertising and promotion

- Providing advice on draft advertising;
- Advising on the industry-wide Code of Pharmaceutical Marketing Ethics;
- Advising on drug sample distribution, the organisation of symposiums and conferences;
- Advising on contracts with advertising agencies;
- Advising on compliance of national promotion and advertising regulations with the Community law;
- Providing training to the management and sales force of pharmaceutical companies;
- Organising training sessions and seminars on promotion and advertising for the pharmaceutical sector;
- Negotiating and drafting promotion and advertising contracts for pharmaceutical companies;
- Providing ongoing legal advice on promotion and advertising to companies in the pharmaceutical sector (in terms of legal compliance of promotion and advertising campaigns, as well as drafting, reviewing and negotiating contracts with providers of promotion and advertising services).

Procedures

- Advising on internal procedures relating to: activities of medical representatives, contacts with public officials, gifts and educational grants;
- Drafting and reviewing internal procedures for pharmaceutical companies in the scope of: (i) promotion and advertising; (ii) execution of contracts with contractors of pharmaceutical companies; (iii) distribution of no-charge products and samples of medicinal products; (iv) donations of medicinal products (including the preparation of complete documentation); (v) processing of personal data by pharmaceutical companies.

Personal data protection

- Database registration, consent to process personal data, data processing contracts, ongoing advice on personal data protection, data processing clauses in clinical trial agreements etc.;
- Personal data processing clauses in business contracts;
- Reviewing policies and other documentation pertaining to personal data processing.

Clinical trials

- Drafting agreements for clinical trials, laboratory and non-intervention studies, including tri-party and preliminary agreements;
- Advising on clinical trial registration and implementation, as well as the early termination of trials and reporting on the adverse effects of medicinal products;
- Preparing forms of informed consent to participate in clinical trials, laboratory and non-intervention studies;
- Negotiating clinical trial agreements for pharmaceutical companies;
- Advising on the compliance of national laws regulating clinical trials with Community law;
- Organising clinical trial training sessions and seminars for the pharmaceutical sector.

Copyright

- Transfer of copyright to advertising materials produced at the behest of pharmaceutical companies;
- Agreements for physicians' participation in advertising, transfer of performance rights and agreements for the use of personal image in audio-visual works;
- Negotiating agreements with authors, drafting agreements transferring commercial copyrights and licence agreements;
- Drafting and negotiating advertising agreements with advertising agencies (including provisions transferring commercial copyrights);
- Drafting and negotiating an agreement to conduct an educational and research programme (including clauses concerning intellectual property rights).

Pricing and subsidising

- Advising on applications to set regulated prices and enter drugs in the register of subsidised drugs;
- Preparing a rationale for setting regulated prices of hospital drugs;
- Advising on the modification of the subsidised drugs register;
- Advising on the available legal means to challenge the decision of the Ministry of Health concerning drug subsidising;
- Advising on production costs.

Lobbying

- Interpreting regulations governing lobbying activities in the legislative process;
- Advising on the obligatory registration in the register of entities professionally conducting lobbying activities;
- Advising on agreements with entities engaging in professional lobbying activities.

Relations with public officials

- Advising on anti-corruption regulations;
- Advising on the establishment of a system of consents to co-operate with the pharmaceutical sector;
- Advising on contractual clauses concerning the absence of conflicts of interest.

Unfair competition

- Preparing responses to queries from the Office for Competition and Consumer Protection;
- Advising on the treatment of certain actions under the unfair competition regulations;
- Advising on legal remedies available under the unfair competition regulations;
- Drafting court pleadings in unfair competition cases;
- Providing PR and business risk advice to pharmaceutical companies;
- Advising on certain types of activities (e.g. promotional and marketing campaigns and product sale strategies, including sale below acquisition or manufacturing costs) in terms of their compliance with unfair competition regulations;
- Assessing competitive practices consisting in using similar labels and trademarks on the packaging of medicinal products.

Public procurement

- Preparing protests and appeals in public procurement cases;
- Advising on agreements between public hospitals and product suppliers;
- Advising on public procurement, including: reviewing tender ToR, reviewing and preparing comments on draft agreements with ordering parties, preparing formal queries concerning the ToR, dealing with the formal and legal aspects of bids, advising on the execution of contracts with ordering parties and in the course of appeal procedures (protests, appeals).

Protection of competition

- Advising on agreements and structures of medicinal product distribution in terms of their compliance with competition protection regulations (including imposition of resale prices, exclusivity clauses, prohibition of competition);
- Advising on certain actions in terms of their compliance with regulations prohibiting the abuse of dominant position (including discounts, price reductions);
- Advising on parallel trading and prohibition of export, including the exhaustion of trademark rights;
- Conducting EU Compliance Audits in clients' companies, including in terms of compliance of their contracts/operations with competition protection regulations;
- Instructing clients on how to behave in the case of dawn raids carried out by competition protection authorities in clients' offices.

Contracts

- Advising on the permitted forms of cooperation between pharmaceutical companies and physicians;
- Drafting civil law contracts regarding cooperation between pharmaceutical companies and physicians, and issuing opinions on such contracts;
- Advising on agreements, including those concerning advertising and promotional campaigns conducted by advertising agencies for pharmaceutical companies;
- Providing comprehensive legal advice in introducing pharmaceutical and life-science companies to the CEE region;
- Providing complex advice on the establishment of domestic distribution, import and intra-Community supply systems;
- Negotiating and drafting a majority of the industry-specific agreements.

Other

- Due diligence and acquisitions;
- PPPs in healthcare sector;
- Regulatory advice (including GMP, permits), dietary supplements, cosmetics;
- Product liability/product recall;
- Advising on EU compliance of the national legislation (issues relating to improper implementation of Union directives and advising on legal remedies available in such situations).

Case studies

Some recent case studies where we have helped clients in Central & Eastern Europe with complex legal issues:

Case study 1

- We helped a major pharmaceutical company dispose of its entire consumer healthcare (over-the-counter) business in the United Kingdom and in multiple jurisdictions across Central and Eastern Europe. We assisted with the due diligence process and in the drafting and negotiation of the sale agreement. We also assisted in dealing with specifically local matters in each jurisdiction (relating to transfer of agreements, transfer of employees and registration of products). We also dealt with all non-US competition aspects of the transaction.

Case study 2

- We helped a major pharmaceutical company establish operations in 10 countries in the region. We assisted with the establishment of legal entities, with local registration and licensing requirements and helped it negotiate and put in place distribution agreements. We also assisted with putting in place employment contracts, internal data protection procedures and have subsequently assisted it in areas ranging from intellectual property to litigation.

Case study 3

- We provide comprehensive legal support to one of the largest American pharmaceutical companies, with regard to the following issues: marketing and promotional projects, pricing and reimbursement of medicinal products (in particular in connection with the possible legal remedies following a negative decision of the Ministry of Health), clinical trials (drafting and negotiating agreements), and advising on cooperation with people performing public functions (doctors, national consultants and members of advisory boards). We also support the company with regard to internal procedures and day-to-day legal advice.

Case study 4

- We advised a major multinational pharmaceutical company in respect of clinical trials conducted in Bulgaria, Romania and CIS. We assisted with the preparation of relevant legal documentation and provided general regulatory advice on clinical trials and associated data protection matters. We received excellent feedback from the client.

Case study 5

- We helped a global medical devices manufacturer in resolving disputes deriving from the alleged defectiveness of its products. We established a coherent system of product liability claims management. The assistance consisted of representation in court disputes and settlement negotiations with individuals. We also advised on the establishment of dispute management agreements with hospitals. Our advice helped to ensure the effectiveness and secrecy of the dispute resolution process.

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Our services

Many international law firms operate in the CEE region primarily as a means of generating large transactional work. We have chosen to take a much broader approach and so our offices in the region have the full-service capability required to provide all the necessary ongoing support to our clients. Our partnership approach means that we develop long-term relationships with our clients as we help them to take advantage of the many opportunities available in Central and Eastern Europe, whilst at the same time working to minimise their business risks.

Our CEE practice covers a range of legal expertise

- Corporate
- Privatisation
- Real Estate
- Private Equity
- Banking
- Competition
- Dispute Resolution
- Major projects – transport and construction
- Energy – oil and gas, electricity
- Telecoms and IT
- Employment
- Tax
- Environment

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