



# HEALTHCARE INDUSTRY, INSTITUTIONS AND PRODUCTS

## A cross-functional expertise

The Firm advises and assists its French and international healthcare industry clients throughout the life cycle of their products: from clinical trials to post-marketing litigation, including product liability litigation and litigation with health authorities, thanks to LexCase's team of lawyers with interrelated expertise.

Through our previous experience as *in-house lawyers* in the health and pharmaceutical sectors, and frequent contact with the French health authorities, regulators, courts, tribunals and specialist commissions, we have intimate knowledge of the actors in this field and detailed experience of relevant procedures, enabling us to manage all your legal issues effectively.

Our team has expertise covering all types of health products and other regulated products:

- Drugs, Medicines and Vaccines
- Medical Devices and IVDs
- Cosmetics
- Food supplements
- Frontier products
- Foods for special medical purposes
- Biocides
- Connected Health Solutions



## PRACTICE AREAS

- R&D and pharmaceutical patents / Clinical trials
- Marketing: marketing authorisation, CE marking (new medical device regulation), definition of borderline products
- Market access: price & reimbursement, early access to medicine scheme
- Anti-bribery, gift regulation & transparency
- Business structures, projects or companies
- E-health: telemedicine, software, websites, data (GDPR), quantified self tracking (remote medical services)
- Contracts with business partners: distribution, subcontracting, national and international marketing
- Hospital public procurement and legal challenges to awards
- Promotion and advertising of medical product information
- Advice and assistance in relation to regulatory inspections
- Vigilance: drafting of appropriate tools / assistance in determining and defining processes
- Health product liability, class actions, image risk management
- Negotiation with authorities, medicine and health regulatory agency decisions
- Commercial and competition law disputes between business operators in the sector

## OUR STRENGTHS

We are referenced by industry federations (SNITEM, FEBEA, COMIDENT) and actively collaborate with associations in the health field. In particular, **we chair the working group on medical device advertising of the AFAR** (French Association of Regulatory Affairs). As French representatives of the Blue Conference (a multi-jurisdictional network of specialist European law firms in the health sector), listed by **Chambers & Partners, LEGAL 500 and Décideurs rankings**, we also have a large network of international partners, experts in health law.

### WHAT WE DO

- Structuring regulated activities of international groups (in particular multi-products) and assistance in the creation of new activities in France and Europe
- Negotiations with the authorities and appeals against decisions of the French Health Regulator (ANSM) (suspension of marketing authorizations in the context of a health crisis, modification and withdrawal of marketing authorizations, expiry, suspension of marking) or against decisions of regulatory authorities, refusing reimbursement of health products or delisting
- Implementation of operational tools for the management of regulatory constraints related to the law on gifts, transparency and conflicts of interest
- Defense of manufacturers of drugs, medical devices, cosmetics and borderline products in individual or class actions based on product liability
- Advice on digital communication, in particular by validating content according to the type of broadcasting media and the target audience, or the development of tools to support operational decision making
- Litigation between business operators in the sector (unfair competition, illegal comparative advertising, termination of established business relations...)
- Advice and support on market access strategy (including early access, pricing and reimbursement)

### WHAT WE PUBLISH

- France chapter of "Healthcare Enforcement & Litigation 2022", Lexology (Getting the deal through), updated in August 2021
- Combatting health product shortages: a changing regulatory environment in the context of a health crisis, Panorama de droit pharmaceutique 2020, Revue général de droit médical n°29, 2021
- Health product liability in a pandemic context, Editions Législatives, June 2020
- Launching an e-health project - Acquiring the legal reflexes, Editions Législatives, Dec. 2019
- Health Industries and Products monitoring and legal update service

# PRESENTATION OF LEXCASE

LexCase was born from an entrepreneurial project: to create a multidisciplinary law firm, present in Paris, Lyon and Marseille and developing close links with foreign law firms.

Regional, national and international, LexCase has chosen to anticipate the Europe of Regions by focusing on proximity to its clients while maintaining a concern for excellence.

LexCase has more than 50 lawyers, including 14 partners specialized in the various disciplines of business law.



Associations and foundations



Commercial Litigation



Personal data



Health Industries, healthcare establishments, institutions and products



Construction & Public Works



Urban planning, development and environmental law



Insurance law



Company law / mergers & acquisitions



Economic law



Tax law



Business criminal law



Public business law



Employment law



Restructuring



Immigration / International Mobility



Intellectual Property Law



Computer and Information Technology



Franchising



Competition law



Telecommunications

## OUR TRAINING COURSES

- "Health litigation: the do's and don'ts", LexCase Morning
- "Early access reform: temporary use authorisations (cohort/individual), temporary use recommendation (off-label), expanded access/compassionate use, early access", Lunchwork
- "Launching an e-health project with regard to legal and privacy issues", IFIS
- "Designing an e-health project: integrating "privacy by design" and "by default"", IFIS
- "Digital promotion and communication of medical devices: mastering and applying the regulations of digital communication", IFIS
- "Clinical validation of an e-health project: managing personal health data", IFIS
- "Medical device assistants and managers: update and improve your processes with regard to the anti-gift law and transparency under the reform", IFIS,

We also teach health law in the specialized courses of several higher education institutions (Université Catholique de Lille, University of Lille, Leonardo da Vinci University, Law Faculty of Tours), and with our organization LexFormation.

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