



# 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 unions (SNITEM, FEBEA, COMIDENT) and actively collaborate with associations in the health sector. We have a large network of partners abroad, experts in health law and business law as French representatives of the Blue Conference and Legus International, and are listed in the main rankings (Chambers&Partners, LEGAL500, BestLawyers and Décideurs).

## 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 (challenge to marketing authorization, 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

- "Panorama of pharmaceutical law 2022", LEH Edition, February 2023
- "Panorama of case law on health product liability 2022", JCP Entreprise et Affaire n°51-52, LexisNexis, December 2022
- "Healthcare Enforcement & Litigation 2023", France Chapter, Lexology GTDT, August 2022
- "The use of social networks for MD", DeviceMed Magazine, April 2022
- "Combatting health product shortages : a changing regulatory environment in the context of a health crisis", Panorama of pharmaceutical law 2020, Revue générale de droit médical n°29, January 2021
- Launching an e-health project - Acquiring the legal reflexes, Editions Législatives, December 2019
- Health Industries and Products monitoring and legal update service

# PRESENTATION OF LEXCASE

LexCase has been founded as an entrepreneurial project: to establish a multidisciplinary law firm, present in Paris, Lyon and Marseille and having close links with foreign law firms.

Regional, national and international, LexCase relies on the proximity with its clients with a view to excellence.

LexCase has more than 70 lawyers, including 13 partners specialized in the various disciplines of business law.



Commercial litigation



Business law



Competition law



Corporate criminal law



Construction law



Corporate law / mergers & acquisitions



Corporate restructuring and insolvency



Cyber-security



Environmental & energy law



Employment law



Immigration



Insurance law



Intellectual property



Internet & new technology



Land use planning and development & environmental law



Lifesciences



Mediation and arbitration



Non-profit associations & foundations



Personal data



Public business law



Real estate law



Tax law

## 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 (University of Lille, Leonardo da Vinci University, Law Faculty of Tours), and with our organization LexFormation.

## TEAM & CONTACTS



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