



# HEALTHCARE PRODUCTS AND INDUSTRIES

## Cross-disciplinary expertise

**The firm advises and assists its French and international healthcare industry customers** throughout the life cycle of their products: from clinical trials to post-marketing litigation, including product liability disputes and disputes with health authorities, thanks to the joint work of lawyers with complementary expertise.

We have been *in-house lawyers* in your industry, and interact on a daily basis with the authorities and courts in charge of healthcare cases. We are therefore familiar with internal procedures and can provide you with effective support in managing your legal issues.

Our team's expertise covers all types of healthcare and other regulated products:

- Drugs and vaccines
- DM and DMDIV
- Cosmetics
- Food supplements
- Frontier products
- ADDFMS
- Biocides
- Connected healthcare solutions

## AREAS OF EXPERTISE

- R&D and pharmaceutical patents / Clinical trials
- Marketing: MA, CE marking (new DM regulation), qualification of borderline products
- Market access: pricing & reimbursement, early access mechanisms
- Anti-corruption, legislation on benefits & transparency
- Structuring activities, projects or companies
- E-health: telemedicine, software, websites, data (RGPD), *quantified self*
- Contracts with partners: distribution, subcontracting, national & international marketing
- Hospital procurement and summary procedures
- Promotion and medical information
- Assistance with inspections
- Vigilance: drafting appropriate tools / assistance in determining and defining processes
- Health product liability, grouped actions, image risk management
- Negotiations with authorities, administrative decisions and health and safety regulations
- Commercial and competition law disputes between industry operators

## OUR STRENGTHS

We are referenced with industry unions (SNITEM, FEBEA, COMIDENT) and actively collaborate with associations in the healthcare field. We have a wide network of partners abroad, experts in healthcare law and business law as French representatives of the Conférence Bleue and Legus International, and are listed in leading rankings (Chambers&Partners, LEGAL500, BestLawyers and Décideurs).

### WHAT WE DO

- Structuring the regulated activities of international groups (notably multi-product) and assisting in the creation of new activities in France and Europe
- Negotiations with the authorities and appeals against ANSM decisions (suspension of marketing authorizations in the event of a health crisis, modification and withdrawal of marketing authorizations, obsolescence, suspension of marking) or against administrative decisions refusing reimbursement or withdrawing reimbursement for healthcare products.
- Implementation of operational tools to manage regulatory constraints linked to the law on the supervision of benefits and transparency of links of interest.
- Defending manufacturers of drugs, DM, cosmetics and borderline products in individual or grouped actions, notably on the basis of product liability.
- Advice on digital communications, in particular by validating content according to distribution media and target audience, or developing operational decision-making tools.
- Litigation between operators in the sector (AMM challenges, unfair competition, illegal comparative advertising, breach of established commercial relations, etc.).
- Advice and support on market access strategy (including early access, pricing and reimbursement).

### WHAT WE PUBLISH

- "Panorama de droit pharmaceutique 2022", LEH Edition, February 2023
- "Panorama 2022 de jurisprudence en matière de responsabilité du fait des produits de santé", JCP Entreprise et Affaire n°51-52, LexisNexis, December 2022
- "Healthcare Enforcement & Litigation 2023", France Chapter, Lexology GTDT, August 2022
- "L'usage des réseaux sociaux pour les DM", DeviceMed Magazine, April 2022
- "Lutte contre les pénuries de produits de santé : état des lieux d'une réglementation en mutation dans un contexte de crise sanitaire", Revue générale de droit médical n°29, January 2021
- Lancer un projet de e-santé - Acquérir les réflexes juridiques, Éditions législatives, December 2019
- LexCase Flash on current topics of interest to the healthcare sector

# PRESENTATION OF LEXCASE

LexCase was born of an entrepreneurial project: to set up a multi-disciplinary law firm with offices in Paris, Lyon and Marseille, developing close partnerships with a number of international law firms.

LexCase has over 60 lawyers, including 15 partners specialized in the various disciplines of corporate law.

  
Associations  
and  
foundations

  
Commercial  
litigation

  
Personal data

  
Insurance  
law

  
Constructio  
n law

  
Competitio  
n law

  
Cyber-  
risk law

  
Health law

  
Environmental and  
energy law

  
Urban planning  
and  
development law

  
Corporate law /  
Mergers &  
acquisitions

  
Economic law

  
Tax law

  
Real estate law

  
Business  
criminal  
law

  
Public business  
law

  
Mediation  
and  
arbitration

  
Employe  
nt law

  
Companies in  
difficulty

  
Immigration

  
Intellectual  
property

  
Information  
technology

## OUR TRAININGS

- "Health Litigation: the do's and don'ts", LexCase Matinale
- "Early access reform: ATU, RTU, compassionate access, 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 DM: mastering and applying digital communication regulations", IFIS
- "Clinical validation of an e-health project: managing personal health data", IFIS
- "DM assistants and managers: update and improve your anti-gift law and transparency processes in the light of the reform", IFIS

We also teach health law in the specialized curricula of several establishments de de l'enseignement supérieur (Université Catholique de Lille, Université Léonard de Vinci, Faculté de droit de Tours), and as part of our LexFormation organization.

## TEAM &amp; CONTACTS



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