

LIFE SCIENCES

Regulatory Framework

Our team has a detailed understanding of the Belgian and EU regulatory framework relating to the life sciences and biotechnology sectors. We advise and litigate on all regulatory issues, including marketing authorizations, pricing and reimbursement decisions, legislative reforms, off-label use questions, parallel import, etc. We also advise clients on the marketing and advertising of medicinal products, including compliance with the applicable rules and codes of conduct, restrictions regarding promotional offers and hospitality towards health care providers, internal audits and drafting of company guidelines.

Our clients are increasingly confronted with public procurement and competitive tendering procedures when contracting with public authorities or with private entities. We regularly advise and litigate both in relation to the generally applicable rules and with respect to particular tenders.

We have represented clients in regulatory matters before the Belgian administrative and civil courts and assisted clients in procedures before the European Medicines Agency (EMA), the Ethical Health platform Mdeon, the Deontological and Pharmaceutical Ethics Committee and other regulatory and legislative bodies.

Our colleagues at C&M International, many of whom have extensive prior experience as trade negotiators, help us to guide our clients in matters involving public policy and international trade, and allow us to reach key decision-makers within the European institutions.

Intellectual Property Law

We provide creative advice on all aspects of IP law and have particular experience with regards to medicinal products and medical services. Our team has developed a reputation for representing clients in launching strategies and in litigation relating to the validity and infringement of patents and supplementary protection certificates and on

trademark issues relating to parallel imports. We are also one of Belgium's leading practices when it comes to pre-trial discovery and preliminary injunction proceedings ('saisie-contrefaçon').

Corporate Commercial Employment

We advise our life sciences clients on the full range of corporate and commercial issues affecting their businesses. We have specific experience in drafting and negotiating complex commercial agreements, for example between pharmaceutical companies and (IT) suppliers, or licensing and development agreements. We also provide advice on joint venture arrangements, commercial contracts, employment matters, corporate governance, etc. Our corporate and employment team has led the legal due diligence for several acquisitions in the life sciences sector, where the typical target companies are small to medium sized Belgian start-ups and University spin-offs.

Competition Law

We were involved in the European Commission's pharmaceutical sector inquiry report, and we regularly advise pharmaceutical companies on matters related to their settlement, distribution and cooperation agreements, and on parallel imports. We also advise on a wide range of transactional activity and represent clients in merger control proceedings. We counsel on compliance with competition law and offer related training specifically tailored to individual companies or associations.

Litigation Proficiency

We are trial lawyers first and foremost. When it comes to regulatory, IP or commercial disputes, our lawyers have extensive courtroom experience and understand how to present complex ideas in straightforward terms. Our first goal as litigators is to work with our clients to prevent disputes arising. Should it become necessary to take further action, our aim is to help businesses resolve disputes quickly and favorably. Our broad litigation experience allows us to

provide our clients with clear, concise advice on all relevant issues, including ‘freedom to operate’, cross-border and UPC litigation strategies, nullity arguments, infringement questions and advice on the applicability of the “Bolar” or research exemptions. Our track record is impressive and makes us one of the ‘go-to’ litigation firms.

Our Team

A multi-disciplinary approach is required to meet the specialist needs of life sciences and biotechnology companies. A number of our lawyers have a technical background in biotechnology or biomedical sciences, enabling us to quickly grasp the technical issues involved. We have been recommended and are recognized as one of Belgium’s leading firms in this area by legal publications such as Chambers Europe and Legal 500 EMEA.

“The firm, considered by one prominent peer as “a main competitor and op-ponent in pharmaceutical patent litigation,” is particularly well known for representing generic drug manufacturers.” LMG Life Sciences, 2015

“Sharp-shooting litigator Kristof Roox is “a very tough opponent – efficient, tenacious and incredibly focused on achieving results. He stands out, even within the gold category.” IAM Patent 1000, 2014

Representative Matters

- Represented several companies in litigation concerning generic versions of medicinal products, vaccines, genetically modified bacterial strains, etc.
- Advised pharmaceutical companies on orphan drug designations, data exclusivity, the scope of the Bolar and research exemptions, Article 10 of the Belgian Medicines Act, clinical trials, privacy, etc.
- Advised on state aid in the biosimilars sector.
- Provided regulatory advice in the animal health sector on the mutual recognition procedure required to obtain an EU marketing authorization for vaccines, including assisting in arbitration proceedings before the CVMP.
- Represented a trade association before Belgium’s highest administrative court challenging Government reforms to the healthcare system.
- Assisted clients in resolving an IP dispute concerning the ownership of a joint research project regarding cancer therapy.
- Assisted in the negotiation of pricing and reimbursement decisions for medicinal products.

CONTACTS



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