

Elisabethann Wright

Partner

Brussels

Biography

Elisabethann has been practising in the Life Sciences sector for over 30 years in both private practice and international institutions. She is among a handful of lawyers specialized in EU law and regulation of pharmaceuticals and medical devices who have consistently drawn praise from market sources for her knowledge of the legislation, technical competence, and commercial acumen. She helps clients place and keep their products on the European Union market through strategic advice, advocacy before institutions and agencies, and litigation before EU courts.

Her experience covers the full regulatory life cycle of products: classification of their products, establishment of a pathway to authorisation and marketing of their products in the EU (including related regulatory obligations), pharmacovigilance obligations, conformity assessment of medical devices, promotion and marketing of products, sales agreements, clinical trial agreements, adverse event reporting, product withdrawals, data privacy obligations, and conduct of compliance and anti-bribery investigations. In recent years she has advised clients and published extensively on digital health issues, such as their implications for CE marking obligations for medical devices, and obligations for life sciences companies related to collecting and processing personal health data under



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Languages

English
Dutch
French

Practices

Pharmaceuticals and Biotechnology
Regulatory

Medical Device and Technology
Regulatory

Health Law

Administrative and Public Law

the GDPR.

Elisabethann has substantial experience in litigation before the European Court of Justice, the European Court of First Instance, and the European Free Trade Agreement (EFTA) Court, including challenges, on behalf of industry clients, to decisions of EU institutions and the validity of EU legislation. Elisabethann was a *Référénaire* (Law Clerk) at the Court of Justice of the European Communities for several years.

Elisabethann is recognized as a leading practitioner in the field by *Chambers Europe, Legal 500, Best Lawyers in Belgium, Who's Who Legal, and Acritas Stars*.

Awards and rankings

- Recommended, Life Sciences – Regulatory, *Who's Who Legal, 2020*
- Recommended, Product Liability, *Who's Who Legal, 2020*
- Biotechnology and Life Sciences Practice, *Best Lawyers in Belgium, 2020*
- Acritas Star, *Acritas Stars Independently Rated Lawyers, 2018-2020*
- EU Regulatory: Pharma, Medical Devices and Biotech, Leading Individual, *Legal 500 EMEA, 2018-2020*
- EU Regulatory: Food, *Legal 500 EMEA, 2018-2020*
- Elisabethann Wright is ranked Band 1 for Life Sciences in Belgium and Band 2 for Regulatory: Life Sciences / Pharma Europe-wide, *Chambers Europe, 2017-2020*
- Listed as expert in regulatory issues on EU Life Sciences law, *Who's Who Legal: Life Sciences 2017, 2017*
- Brussels Life Sciences practices awarded Finance Monthly – Law Award 2015 in the category of Life Sciences Law Firm of the Year – Belgium, 2015

Industries

Life Sciences and Health Care

Areas of focus

Pharmaceuticals and Biotechnology
Digital Health
Medical Devices
Regulatory Exclusivities, Hatch-Waxman, and Similar Statutes
Cell, Tissue, and Gene Therapies
International Programs
Premarket Review
Unique Device Identifiers
Product Development and Approval
Clinical Trials
Controlled Substances and DEA
Public International Law
Judicial Review
Consumer Product Safety Regulation
Medical Foods and Dietary Supplements
International Regulatory Compliance
Postmarket Compliance and Enforcement Actions
Advertising and Promotion Compliance
Combination Products

- Listed as 'leading authority' on EU Life Sciences law, *Who's Who Legal: Life Sciences*, 2015
- Recognised as one of the five "most highly regarded individuals" worldwide, *Who's Who Legal: Life Sciences 2014 edition*, 2014

Latest thinking and events

- News
 - COVID-19 Report for Life Sciences and Health Care Companies
- News
 - COVID-19 Report for Life Sciences and Health Care Companies (12 - 15 October 2020)
- News
 - Genetically modified soybean authorised by the European Commission for food and feed use
- News
 - COVID-19 Report for Life Sciences and Health Care Companies (5 - 9 October 2020)
- News
 - The EMA plans to grant early access to a test version of the CTIS
- News
 - COVID-19 Report for Life Sciences and Health Care Companies (28 September - 1 October 2020)

Education and admissions

Education

Postgraduate Diploma in EC Competition Law, King's College London, 2004

B.L., The Institute of Professional Legal Studies, Belfast, 1985

LL.B., The Queen's University of Belfast, 1984

Bar admissions and qualifications

Brussels

Barrister, Republic of Ireland

Barrister, England and Wales

Accolades

Listed as an expert in regulatory issues on EU Life Sciences law.

Who's Who Legal: Life Sciences
2017
