



A collage of images related to pharmaceutical research and development. It features scientists in lab coats, laboratory equipment like microscopes and test tubes, and a stylized molecular structure. The collage is composed of various rectangular and triangular segments, each containing a different image, all set against a light blue background with a subtle grid pattern.



Kyriakides Georgopoulos (KG) Law Firm dates back to the 1930s and is one of Greece's oldest and most reputable law firms. KG Law Firm is comprised of over 100 highly skilled professionals actively involved in the provision of legal services to high profile Greek and international clients.

The multidisciplinary teams of lawyers are efficient in working closely with clients and in ascertaining innovative and practical solutions to complex problems. The successful handling of our clients' affairs is attributed to our professionalism, efficiency and expertise, qualities that our firm constantly seeks to promote.

The life sciences sector in Greece is undergoing major restructuring and is thus becoming increasingly complex and difficult to apprehend and to codify. Industry players face growing competition - and tougher regulation.

The KG Law Firm Life Sciences & Healthcare Sector has broad experience and profound understanding of the life sciences' and pharmaceutical market, which puts us in a unique position to fluently help our clients navigate through interrelated legal risks, adhere to business requirements and realize opportunities. We provide assistance to companies in all the steps of pharma products' life cycle, from R&D to launching and marketing. Our track record includes key transactions and projects in which we have been involved in over the past few years and which are briefly described in the next pages.

KG Law Firm has been representing companies and investors in the pharmaceutical and medical device, biotechnology, vaccines and food-supplements fields. Our Life Sciences-Pharmaceutical Practice works closely with our multiple practice groups in an open, flexible manner. The team brings industry know-how, international legal experience and a thorough knowledge of local law and regulations. At the same time, our leading Tax, Employment, and Dispute Resolution practices offer to our clients integrated and cost-effective solutions on all related issues.

KG Law Firm is a founding member of **South East Europe (SEE) Legal Group**, a regional alliance of 10 leading independent law firms, covering 12 jurisdictions in South East Europe. Working together on cross-border transactions, the group is the largest legal force in South East Europe numbering over 450 lawyers, organized in cross-jurisdictional practice groups. Each of the firms has been ranked as leading firm in its jurisdiction and with a presence in capital cities and a number of satellite offices.

>LIFE SCIENCES & HEALTHCARE SECTOR OVERVIEW

The life sciences sector in Greece is undergoing major restructuring and is thus becoming increasingly complex and difficult to apprehend and to codify. Industry players face growing competition - and tougher regulation. At KG Law Firm, the broad experience and profound understanding of the life sciences and pharmaceutical market puts the Firm in a unique position to fluently help its clients navigate through interrelated legal risks, adhere to business requirements and realize opportunities. KG Law Firm retains a strong practice in the Pharmaceutical field, as reflected in the growth path of the Firm over the years. We provide assistance to companies in all the steps of pharma products' life cycle, from R & D to launching and marketing. Our track record includes key transactions and projects in which we have been involved in over the past few years and which are briefly described in the next pages.

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>How we can help

Research & Development

- Clinical trials - We provide our legal insight in navigating and overcoming legal and regulatory issues that often arise at all phases of clinical trials and observational studies.

Regulatory/Compliance

- Advertising and marketing - We help ensure compliance with advertising and promotional rules in their application to various interactions with healthcare professionals e.g. grants and donations, sponsoring et cetera.
- Compliance Programs - We provide assistance in the development, implementation, auditing and monitoring of compliance programs (e.g. FCPA review, Anti-Corruption practices) and SOPs. We are also experienced in preparing workshops on optimal internal practices to respond to dawn raids and investigations by various supervising authorities.
- Day to day Operations and Stand - Alone Projects - We advise major pharma and medical device companies on all their day to day operations such as (indicatively) commercial strategies, contractual relationships, distribution channels, pricing, IP Law, E-Commerce, Internet Policy et cetera.
- Data privacy - We develop practical and strategic privacy compliance solutions, help clients observe informed consent requirements and contractual implications of confidentiality rules. We also prepare and file the necessary notifications to, and obtain the relevant approvals from, the Data Protection Agency.
- Professional/Industry ethics - We advise on rules governing the interactions between pharmaceutical companies and healthcare professionals (article-writing and consulting services, participation in scientific events, market researches).
- Regulatory Agency strategies, processes and public policy issues - Drafting and supporting recourses, appeals and applications as well as negotiating amicable resolutions before the competent authorities (e.g. EOF, SFEE, Data Protection Authority).
- Tax - We advise our clients on a wide range of matters with tax implications.

Corporate Governance

- Corporate Governance - We observe all corporate formalities on behalf of our clients and we engage in the drafting, reviewing and commenting upon corporate documents such as Articles of Incorporation, Bylaws, Board of Directors and General Assembly Minutes, Partners' and Administrators' Resolutions, Prefecture Announcements etc.
- Dispute Resolution - We represent clients in litigation, arbitration and other administrative proceedings effectively and in ways that protect corporate reputations and brands. This includes drafting and supporting recourses, appeals and applications before the Civil and Administrative Courts and Authorities as well as negotiating amicable resolutions before the competent authorities (e.g. SFEE).

Market Access/Commercial Practices

- Commercial agreements - We negotiate, draft and review licensing, manufacturing, distribution and co-distribution, joint venture, branding, outsourcing, research, clinical trial, collaboration, co-promotion and other types of commercial agreements.
- Competition and trade - We address the antitrust implications of mergers, acquisitions and other strategic alliances, practices and policies, such as discount and credit strategies.

- Public procurement - We prepare and process files and documents for public tender procedures. We are currently representing a number of companies (both from the pharma and medical devices sector) supplying the public sector and have initiated, where needed, court proceedings on their behalf against various public legal entities.
- Reimbursement and Pricing - We advise and assist clients in gaining, keeping and defending product eligibility for reimbursement and insurance coverage. We have initiated opposition procedures against price bulletins.

>Recent work highlights

Research & Development

- Reviewing, drafting and commenting upon clinical trial and observational study agreements; drafting and reviewing patients' consent forms and accommodating relevant GDPR rules.

Regulatory/Compliance

- Acted on behalf of major pharma companies so far as the interpretation and enforcement of the provisions on rebates, claw-backs and entry fees are concerned; submission of recourses and petitions of annulment against the pertinent ministerial decisions.
 - Advice on the conduct of market research activities and preparation of the relevant agreements and questionnaires.
 - Advice on the national and EU regulatory environment concerning professional indemnity for healthcare professionals, interacting with pharma/medical devices companies.
 - Advised on local regulations governing the return of expired products and the adequacy of products' reserves in the market.
 - Assessed the eligibility of grants' and donations' recipients via the conduct of relevant due diligence reviews.
 - Assisting and educating internal auditors in conducting compliance and audit processes.
 - Conduct of internal training sessions and workshops concerning optimal internal practices to respond to dawn raids and investigations by the Competition Committee, EOF and other authorities.
 - Drafting, reviewing and adapting to local requirements the standard operating practices (SOPs) including pharmacovigilance, interactions with HCPs, anti-corruption, best market and promotional practices etc.
 - Established patient support programs intended to improve patients' disease education, lifestyle modification & adherence to medical treatment.
 - Examined the actual formulation and operation of internet sites especially as to their compliance with Greek law.
 - Advise and close collaboration with a world leading food company in the assessment, development, implementation and monitoring of a compliance program and the creation of operating policies for its Greek affiliate.
 - Represented several major pharma companies before the Supreme Court in their judicial attempts against the Greek State with regards to the annulment of payment orders that were issued and based on which the pharma industry was invited to pay rebates and clawbacks imposed by law.
- ### Regulatory Agency Processes
- Review and assessment of promotional and medical information material in adherence to SFEE's Code of Conduct and the respective Circulars of EOF.

Life Sciences & Healthcare

- Supporting cases of wrongful classification of particular products as well as the respective recourses and objections before EOF.
- Notifications and licensing proceedings before the Data Protection Authority either related to clinical trials, market research or other activities.

Corporate Governance

- Advised on the divestiture of the veterinary sector of a particular pharmaceutical company.
- Provided legal insight concerning the issue of transfer of shares as part of a major internal restructuring of a leading pharmaceutical company.
- Provided legal assistance with regard to the selling of special Greek sovereign bonds.
- Acted for a research-based biopharmaceutical company with regards to the internal audit of its local affiliate; our services consisted of advising and supporting the general counsel with regards to Greek laws governing interactions of pharmaceutical manufacturers with health care providers and other decision makers as evidenced by data and documents provided via an e-room and as more fully learned in the course of interviews with the managers of the Greek affiliate.

Market Access/Commercial Practices

- Acted as legal advisors to a plethora of pharma and medical devices companies so far as the establishment of their supply chain and allocation system is concerned, giving due consideration to the recent pricing policy evolutions in Greece.
- Acting for major pharma companies, on an on-going basis, in relation to the regulatory and competition law parameters of discount policies.
- Addressed the issue of importation of pharmaceutical products in case of urgency and shortages, as to their prerequisites and particulars.
- Advised on commercial strategies in the pharma sector and access to medicines policies via pertinent workshops.
- Advised on the modification/termination of crucial distribution agreements.
- Evaluated critical regulatory aspects of on-line OTC pharmaceuticals' sales.
- Examined the -crucial for the industry- EU Internal Market and Competition Law parameters of Parallel Import/Export activities.
- Preparation and review of the documentation for public tenders.
- Represented a major pharmaceutical company on the prospective insolvency of one of its distributors. Successfully established a new corporate entity to take over the distribution of products in case the insolvency scenario materializes.
- Reshaped and restructured the relationship of a leading pharma company with its local distributor.
- Reviewing, drafting and commenting upon toll manufacturing, labeling, packaging, co-promotion and license agreements.

- Acted for a global healthcare company in relation to the sale of its local vaccines and OTC (Over-the-Counter)/consumer healthcare businesses to another pharma company and the purchase by the former of the latter's local oncology business.
- Acted for a global leader in the manufacture of musculoskeletal medical products, with regards to the Greek part of the acquisition of the worldwide trauma business of an Orthopedics company.
- Acted for a medical devices company with regards to the global acquisition of the electrophysiology business of another medical devices company in what regarded the Greek part of the transaction.
- Advise and close collaboration with a world leading pharmaceutical company who decided to take the first step and pioneer in restructuring its wholesale network, by reducing its members and enhancing the use of digital means in supplying its products to the market. We rendered legal advice with regards to the design, development and implementation of the re-mapping of the distribution network and successfully represented our client before the Greek courts against several wholesalers who raised claims both with lawsuits, requesting compensation, and petitions for injunction, seeking the continuation of the terminated distributorships.

>LATEST CONTRIBUTIONS/PUBLICATIONS

KG Law Firm's Life Sciences & Healthcare sector has contributed to accredited publications such as:

- Lexology, Clinical Trials in Greece and Life Sciences: Product Regulation and Liability, 2018
- ICLG - International Comparative Legal Guides, Pharmaceutical Advertising, 2017
- Lexology, Pharmacovigilance in Greece, 2017
- Greek Law Digest, The Official Guide to Greek Law, Production, Circulation and Pricing of Drugs-Brand Name and Generic and Life Sciences, 2016

At the same time, our lawyers are closely monitoring the ongoing Economic Adjustment Programs for Greece and the respective -critical for the pharma industry - Governmental measures aiming at the containment of pharmaceutical cost and are constantly reflecting the said developments via regular newsletters.

>OUR PEOPLE

KG Law Firm's Life Sciences & Healthcare sector consists mainly of five (5) lawyers, three of which are dedicated in working exclusively on life sciences-related projects and who are able to cover the entire spectrum of these projects.

Irene C. Kyriakides is the Head Partner of KG Law Firm's Life Sciences & Healthcare sector and is assisted by a number of other lawyers depending on the specialisation required to address particular matters.

Contact

Irene C. Kyriakides
Partner
E-mail: i.kyriakides@kglawfirm.gr
Tel.: +30 210 81 71 500

Victoria Mertikopoulou
Partner
E-mail: v.mertikopoulou@kglawfirm.gr
Tel.: +30 210 8171545

Athens Office: 28, Dimitriou Soutsou Str., 115 21, Tel.: +30 210 817 1500, Fax: +30 210 685 6657
Thessaloniki Office: 17, Ethnikis Antistasseos Str., 551 34, Tel.: +30 2310 441 552
www.kglawfirm.gr