

HEALTHCARE, PHARMACEUTICALS AND LIFE SCIENCES | FRANCE

Gide has a long tradition of excellence in advising and defending companies active in the health sector. Throughout our offices worldwide, we have been assisting pharmaceutical companies, biotechnology companies, cosmetics and healthcare product manufacturers, healthcare facilities and public or private institutions implementing healthcare policies on a daily basis. Our dedicated team provides legal representation and assistance when disputes arise in relation to these activities and in particular during investigations carried out by national and/or European authorities.

Our Healthcare, Pharmaceuticals & Life Sciences team keeps a close eye on all developments relating to medicines policies, legislative reforms, biotechnology or control of medical risks, all the while assessing the practical impact of these changes from the point of view of substantive law.

Main Areas of Expertise

• **Transactional & Venture Capital** | Gide is called upon for its comprehensive expertise by pharmaceutical clients in their M&A transactions, ranging from simple portfolio disposals/acquisitions (including obtaining regulatory authorisations) to more complex asset combinations, outsourcing of manufacturing, restructurings and disposals/acquisitions of subsidiaries. We help established and emerging life science companies negotiate and structure deals that will help foster their growth and reach their goals. More specifically, our services dedicated to leading and emerging life science companies include:

- Corporate Structuring
- Tax Structuring
- Financing Arrangements
- Equity Investments
- Venture Capital
- Private Investments
- Public Offerings
- Royalty Monetisations

Our team is a key player in representing emerging life science companies and venture funds and is very active in private investments and IPOs.

• **Intellectual Property** | The scope of Gide's work in life sciences and healthcare covers all aspects of intellectual property, particularly patents and Supplementary Protection Certificates (SPCs), but also trademarks. As regards patents and SPCs, we provide both advisory services, particularly on freedom to operate issues, and dispute resolution services, often in relation to pan-European patents and SPCs.

Our team also has experience in advising on issues surrounding employee inventions, including government officials.

Gide's expertise in litigation of pharmaceutical and life-science patents is widely recognized. With one of the largest specialist IP teams in France, Gide has acted successfully in the biggest cases of the past twenty years, and was at the centre of recent battles on the interpretation of the European Regulation on SPCs.

Gide advises on regulatory healthcare issues and has unique expertise advising on matters with high technological content, whether contracts relating to IP rights and know-how (assignments, licenses, R&D agreements, partnerships between manufacturers and universities, etc.) or intra-group restructuring. These activities are further enhanced by Gide's comprehensive experience in dispute resolution. Our firm also advises clients on matters relating to trademarks and unfair competition / free riding in relation to medicines, medical devices and cosmetic products.

ALGIERS

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ISTANBUL

LONDON

MOSCOW

NEW YORK

PARIS <

SHANGHAI

TEHRAN

TUNIS

WARSAW

- **Personal Health Data** | Gide advises clients on rules applicable to personal health data, whether issued in the context of Directive 95/46 (including the MR 001 Reference Methodology on clinical trials), or related to health data providers. We assist clients in ensuring the compliance of their data processing and activities, as well as in preparing the relevant filing formalities. On these sometimes sensitive issues, we assist clients in their contact with Data Protection Authorities, including in case of investigation/audit. Gide also advises clients on international health data transfers, including outside the EU, when these are required by the client's activities.
- **Distribution & Marketing** | Gide provides its clients with advice regarding the distribution and marketing of pharmaceutical products, medical devices, chemical products, food, food supplements and cosmetics, with particular expertise in:
 - setting up, implementing and monitoring different types of distribution networks (commercial agency agreements, medical representatives agreements, commissionaire and depository agreements, exclusive distribution agreements, etc.);
 - drafting general terms and conditions for the supply of drugs and medical devices, cooperation agreements with chemists, medical practitioners, clinics etc.
- **Regulatory & Licensing** | Gide has gained extensive experience in guiding and assisting clients on regulatory issues regarding medicinal products, medical devices, biocide products, human cells/tissues, cosmetics and food, including:
 - analysing health products and their qualification under the applicable regulations as well as liaising with administrative authorities;
 - ensuring compliance with regulations as regards pricing, labelling, advertising and promotion of medicines and health products.

The team is experienced in risk management strategies and compliance with requirements in the case of adverse events (including pharmacovigilance and materiovigilance obligations). Gide also assists companies in obtaining the licenses and registrations necessary for the operation or manufacturing, distribution or promotion of medicinal products and/or services, the practice of medicine or the operation of healthcare facilities and public or private institutions.
- **Ethics & Compliance** | Gide has solid experience in analysing the relationships of health sector companies with medical practitioners and chemists. We regularly review commercial practices for compliance with rules on medical ethics (namely rules against gifts to medical practitioners) and acts before professional associations for the clearance of cooperation agreements with medical practitioners (clinical trials, R&D, etc.). We are also highly experienced in preparing codes of conduct and compliance programmes and procedures. On an international level, Gide provides its clients with advice on compliance and prevention of risks related to their presence in various countries.
- **Product Liability** | Gide is a recognised practitioner in the field of medical liability and health products safety and represents its clients on product liability issues, through expert procedures and court actions, including negotiating settlement agreements with patients. We assist in implementing recall procedures with public authorities, preventing and coordinating civil, criminal and disciplinary litigation at both national and international levels. We are currently acting in several proceedings before French courts for major product liability issues and monitor several significant expert proceedings.
- **Antitrust & Competition** | Our lawyers are frequently instructed to assess the compliance with competition law of commercial and cooperation agreements (R&D agreements, joint ventures, licensing agreements, parallel imports, etc.) in the pharmaceutical industry. Gide represents its clients before the European Commission and the national competition authorities in merger control clearance and/or antitrust proceedings.
- **Advertising & Unfair Competition** | Our team handles all aspects relating to the advertising of medical products (comparative advertising, misleading advertising, prohibition of advertising prescription medicine) and of medical practitioners.

Gide Loyrette Nouel A.A.R.P.I.'s healthcare and life sciences group has strong intellectual property, corporate and competition law expertise and is led by Grégoire Triet, Anne Tolila and Dimitri Dimitrov, respectively. Jean-Hyacinthe de Mitry advised biopharmaceutical company Annapurna Therapeutics on its merger with Avalanche Biotechnologies, and Raphaëlle Dequiré-Portier teamed up with Emmanuel Larere to represent Ono and Bristol-Myers Squibb in a multijurisdictional patent litigation pertaining to an innovative cancer treatment. In other recent highlight work, Arnaud Michel represented Merck and five of its subsidiaries in trade mark infringement and unfair competition proceedings regarding the use of the name 'Merck' in France, and Dimitrov assisted a manufacturer of medical devices with the review of its contracts in light of French distribution law provisions. Other notable clients include Johnson & Johnson, Shionogi and Guerbet. Market-leading practice offering a full service in the area, from IP prosecution to infringement proceedings. Advises French and multinational clients in various industries including engineering, life sciences, fashion and retail. »

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