



/85

Partners

/500+

Lawyers

/30

Practice Areas

/25

Industry Groups

/6

Offices

PHARMACEUTICAL INDUSTRY

Advising the pharmaceutical industry requires interdisciplinary legal work. This sector of the industry can cover different and diverse areas of Law, which requires a complete understanding of the client's business. TozziniFreire is a full-service law firm and is therefore ready to assist national or international pharmaceutical companies with all legal matters. Here are some examples of the services offered by our team, consisting of partners from different areas.

SERVICES

- **Antitrust:** advising on merger notifications and association agreements before the Brazilian Antitrust Authority (CADE); reviewing commercial and distribution policies from a competition perspective. Defense in cartel and unilateral conduct investigations and proceedings conducted by CADE.
- **Transactional matters:** legal advice on mergers, consolidations, acquisitions, and projects involving pharmaceutical companies, with analyses and multidisciplinary work, including the creation of schedules and specific stages based on regulatory conditions and constraints, aligned with contractual, business, and corporate aspects.
- **Medicine legislation and contractual aspects:** advice in matters involving health surveillance and health, such as complex legal and regulatory issues involving the pharmaceutical industry and market, by drafting memoranda, opinions, and responses to legal inquiries. We also assist companies in matters involving contractual and business aspects.
- **Clinical research and issues involving health data:** the advisory service provided includes the interpretation and implementation of rules for conducting clinical trials, as well as expanded access and compassionate use programs in Brazil and their respective contracts. We also assist with implementation and advice on topics related to patient data protection and the industry interaction with healthcare professionals.
- **Labor:** we handle cases involving professional councils and requirements for the operation of establishments within the pharmaceutical industry.
- **Compliance:** we have experience in advising companies, boards of directors and independent committees on the prevention, detection, and remediation of potential violations of anti-corruption legislation, fraud, and other compliance-related matters, with a personalized approach for pharmaceutical companies.
- **Biodiversity and ABS:** for Research & Development (R&D) activities, and when such initiatives involve assets from Brazilian biodiversity, specific environmental legislation applies from the early stages of research to the development, registration, and marketing of new products. We have extensive knowledge of the topic and practical experience in providing strategic advisory and litigation legal services.

- **Government Projects:** we assist clients in highly complex projects involving the supply of these products to government agencies, through traditional bidding processes or arrangements involving offset mechanisms, such as technology transfer and local content commitments.
- **Consumer law aspects and traceability:** we have experience in consumer matters and in medicine recalls, with combined actions before the Brazilian Health Surveillance Agency (ANVISA) and the National Consumer Secretariat (SENACON). Our practice also encompasses issues relating to pharmacovigilance aspects and medicine traceability, including regulations involving the distribution of medicines and notification of adverse events.
- **Tax, imports, and exports:** analysis of specific operations and structures of the medicine sector, including tax classification and Health Surveillance Inspection Fee. We also have experience in matters involving the import and export of medicines, pharmaceutical ingredients, and other products of interest to the pharmaceutical industry. We also have experience in tax litigation.
- **General inquiries, civil litigation, and arbitration:** we work on advisory and litigation issues involving many topics, such as trademarks and patents, agency and distribution (sales channels), as well as commercial arbitration and/or arbitration involving the government.

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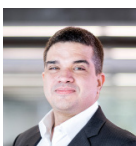
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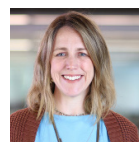
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