TozziniFreire.

PHARMACEUTICAL INDUSTRY

Strategic legal expertise for national and international pharmaceutical companies



We strive to have a comprehensive and strategic vision of our clients so we can act with precision and interdisciplinary expertise, offering assertive, up-to-date solutions.

Our committed and experienced team is ready to offer efficient, close, and personalized advice, aiming to optimize results and build long-term relationships.



Legal advice on:

- Antitrust;
- · Transactional operations;
- Impacts related to drug legislation and contractual aspects;
- · Clinical research and issues involving health data;
- Labor issues;
- · Compliance;
- · Biodiversity and ABS;
- · Government projects;
- · Consumer law and traceability aspects;
- Tax issues, including import and export.

For more information about the area, <u>click here</u> or scan the QR code.



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Assistance in notifying the Brazilian Administrative Council for Economic Defense (CADE) of mergers and partnership agreements. Review of commercial policies (including pricing and discounts) and distribution policies from a competition perspective. Defense in cartel and unilateral conduct proceedings and investigations conducted by CADE.

Legal assistance in various mergers, acquisitions, and projects involving pharmaceutical companies, with multidisciplinary analysis and work, including the creation of timelines and specific stages based on regulatory restrictions and conditions, aligned with contractual, business, and corporate aspects.

Comprehensive advisory services on matters involving health and health surveillance. Because medicines are subject to health surveillance, the multidisciplinary team is accustomed to responding to complex legal and regulatory issues involving the market and the pharmaceutical industry, preparing memoranda, opinions, and responses to legal inquiries.

Assistance with clinical research, in accordance with regulations of the National Health Council (CNS) and ANVISA, among others.

Interpretation and implementation of rules for conducting clinical trials, as well as expanded access and compassionate use programs in Brazil and their respective contracts, among other regulatory and contractual issues.

Assistance with implementation and consulting on various matters involving patient data protection and industry interaction with healthcare professionals, in line with best practices.

Planning labor issues, both operationally and in terms of activity costs, in the pharmaceutical industry across a wide range of functions, from manufacturing to drugstores. Acting in cases involving professional councils and requirements for the operation of establishments belonging to the pharmaceutical sector.

Advising companies, boards of directors, and independent committees on the prevention, identification, and remediation of potential violations of anti-corruption legislation, fraud, and other compliance-related matters.

Strategic and litigation legal advice related to biodiversity and ABS (Access and Benefit Sharing). The pharmaceutical industry is known to be at the forefront of Research and Development (R&D) activities, and when such initiatives, whether domestically or abroad, involve Brazilian biodiversity assets, specific environmental legislation applies from the initial research phases through the development, registration, and commercialization of new products.

We advise clients on highly complex projects involving supply to public agencies, either through traditional bidding processes or through arrangements involving offset mechanisms such as technology transfer (PDPs, technology orders) and local content commitments.

Comprehensive assistance on consumer issues, as well as medication recalls, with joint efforts with the National Health Surveillance Agency (ANVISA) and the National Consumer Affairs Secretariat (SENACON). This assistance also includes issues related to pharmacovigilance and medication traceability, including all regulations involving drug distribution and adverse event reporting.

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