# LIFE SCIENCES AND HEALTHCARE

Our firm works to facilitate new business. We specialize in regulatory, contractual, and litigation matters in the sector. Our expertise involves:

- Wide range of regulated products such as medicines, vaccines, biotechnology, medical devices (including software), cosmetics, hygiene products, medical cannabis, food and beverages, veterinary products, agrochemicals, sanitizers, chemicals, seeds, and genetically modified organisms.
- The entire health services sector, including hospitals (for-profit and not-for-profit), clinics, diagnostic medicine laboratories, pharmacies and drugstores, administrators, insurance and health plans, telehealth companies, and clinical research organizations.
- Extensive experience in digital health with healthtechs, medtechs, biotechs, agrotechs, and foodtechs.

OUR EXPERIENCE IN THE SECTOR INCLUDES SERVICES IN THE FOLLOWING AREAS:

- **Pre- and post-market regulatory:** advisory services and litigation in matters involving regulations of the Ministry of Health (MS), National Health Surveillance Agency (Anvisa), National Supplementary Health Agency (ANS), Drug Market Regulation Chamber (CMED), National Commission for the Incorporation of Technologies in the SUS (Conitec), professional health boards (medicine, pharmacy, nutrition, psychology, nursing, physiotherapy, veterinary medicine, etc.), National Technical Biosafety Commission (CTNBio), Ministry of Agriculture and Livestock (Mapa), and others.
- **Contracts:** drafting and negotiation of contracts typical of the sector, such as manufacturing and supply, distribution, research and development, licensing and technology transfer, productive development partnerships (PDPs), technological health orders (ETECs), strategic alliances and cooperation projects, risk sharing agreements, management of Health Organizations (OSS).
- **Licensing and incorporation strategies:** strategies for incorporation of technologies into SUS and ANS, as well as regulated entities, pricing of medicines, and support for obtaining permits, operating authorizations, certificates of good practices and operating licenses, registration and post-registration of regulated products.
- **Clinical research:** assistance on ethical approvals and protocols, contracts, consents, and waivers for clinical research.
- **Compliance:** corporate investigations related to allegations or reports of violations involving industry regulations.
- **M&A:** practice in mergers and acquisitions, investment rounds (private equity, venture capital, and corporate venture capital), data-driven health transactions, purchase and sale of health insurance portfolios, licensing of regulated assets, joint ventures, and foreign investments in the sector.

**Digital health:** advisory services on the development of innovative legal models involving investments in or structuring of healthtechs, medtechs, and biotechs, including telemedicine, software as a medical device (SaMD), artificial intelligence (AI), remote sale of medicines, blockchain, big data and analytics, wearable devices, 3D printing, electronic health records, Internet of Things (IoT), medical cannabis, discount programs, and new payment models.

**Health data:** support in demands involving adaptation to ethical, sanitary, supplementary health, and health data protection regulations, enabling data-driven businesses, preventing and managing security incidents, interacting with supervisory authorities.

**Supplementary health:** drafting and negotiating contracts for the provision of insurance or health plan benefits and/or medical-hospital and/or dental care, including via benefit administrators and policyholders. In addition, we advise on price setting processes, structuring of resizing of healthcare networks, fiscal and technical interventions, out-of-court liquidation, and compulsory sale or transfer of health insurance portfolios. We also practice in economic and financial suitability and in ANS regulatory approval processes for transfer of control or portfolio.

**Institutional and governmental relations:** legal consulting to identify prospective procurement opportunities with federal, state, and/or local public entities and associations.

**Recalls:** support in procedures involving evaluation and strategies for recall of products regulated by Anvisa or Mapa.

**Plants, seeds, and GMOs:** consulting services for access to Brazilian genetic heritage and associated traditional knowledge with sharing of benefits, in addition to representation before the Genetic Heritage Management Council (CGEN) and advising on the protection and exploitation of cultivars and new plant varieties.

**Intellectual property:** protection, registration, and maintenance of assets, including trademarks, patents, industrial designs, domain names, software, and plant varieties (cultivars), among others. Drafting and reviewing intellectual property policies. Advice on creations and inventions by employees and contractors.

**Labor, tax, and litigation advisory services.**

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