Pharmaceuticals, Healthcare and Life Sciences

Turkey's large population, research hospitals, low investment cost, as well as its geographic proximity to fast-developing markets all combine to mean the country is well placed to emerge as a global hub for pharmaceuticals, healthcare and life sciences. Moro?lu Arseven provides clients at all stages of the production and supply chain with clear advice on the legal aspects of these complex industries.

The unique nature of clients and transactions becomes particularly pronounced in the medical sector, where clients and their products are often innovative and ground-breaking, yet simultaneously subject to close regulatory scrutiny. Moro?lu Arseven is well connected with regulatory, entrepreneurial, scientific, medical and financial communities, supporting the firm to understand clients' business goals, as well as how to best achieve them.

Our clients are active in all stages of research, development, production, toll manufacturing and distribution for a wide range of medical products and services, each being subject to specific and highly detailed regulatory compliance, disclosure and pricing rules. In the pharmaceutical context, we support companies involved in original, generic, biosimilar, as well as orphan drugs, with close collaboration with the firm's strong intellectual property team. Our clients also include cosmetics and food supplement companies, which are also subject to tight regulatory rules.

The Turkish government acknowledges the importance of supporting and encouraging the development of life sciences, as can be seen by legislation providing incentives for R&D projects in the life sciences industry. The rate of technology adoption and the country's unmet medical needs further drive growth in the healthcare market.

Turkey has many prominent generic-drug manufacturers, pharmaceutical companies, and medical device producers which contribute to an active and expanding healthcare market. These domestic manufacturing capabilities for generic and name-brand drugs are a powerful incentive for foreign companies to move production to Turkey, while domestic brands are also increasing production.

Private service providers are a key part of the local medical sector. Medical tourism has also steadily increased over recent years, for cosmetic as well as medically necessary procedures.

Moro?lu Arseven supports a broad client base in this area, ranging from emerging medical start-ups through to established multi-nationals. We also advise venture capital and private equity clients who invest in pharmaceutical, healthcare and life sciences companies. These include original, generic and orphan pharmaceuticals, medical devices, implants and diagnostics, as well as baby-care and telemedicine services. We also advise clients involved in developing raw chemicals, as well as cosmetics, food supplements, biotechnological (such as plant seed), biocidal and veterinary products.

The firm guides clients through negotiating all types of agreements in this area, including toll manufacturing, supply, license, co-marketing, and joint development agreements. We also provide clients with a full range of corporate advisory services, including advice on daily matters, competition, human resources, tax and customs issues.

Moro?lu Arseven's strong intellectual property team helps pharmaceuticals, healthcare and life sciences clients to proactively protect their intellectual property in Turkey. The firm supports with a full range of issues, including litigation, enforcement, counselling, prosecution and transactions. Intellectual property advice is tightly integrated with other practice areas, assisting clients to establish, protect and commercialise their intellectual property assets from the earliest possible stage. For instance, advising on trademarks, patents, trade secrets, data exclusivity and R&D or refurbishment schemes. We have significant experience assisting client to deal with the marketing authorization

process for possibly infringing pharmaceuticals, obtaining marketing licenses, as well as understanding complicated pricing rules.

Moro?lu Arseven advises clients at all stages of regulatory approval, including risk assessments, import/export rules, packaging and advertising limitations, reference pricing, reimbursement, as well as other aspects of product development. We support clients to negotiate and draft all types of agreements in this area, with close attention to ensuring regulatory compliance and enforceability. These include toll manufacturing, supply, license, technology transfer, co-marketing, and joint development agreements.

Moro?lu Arseven has a strong track record supporting clients to plan and conduct regulatory compliance audits, develop tailored compliance programs, as well as implement risk-mitigation strategies and deal with sensitive regulatory investigations. The firm is very familiar with local procedures and requirements, assisting our clients to mitigate costly penalties and delays which can stem from regulatory non-compliance.

Moro?lu Arseven regularly advises on processes and requirements for Turkey's Ministry of Health, Medicines and Medical Devices Agency, the Social Security Institution, as well as other relevant regulatory bodies. We strategically support and represent clients during all aspects of their interactions with these bodies, assisting clients to obtain a wide range of routine and exceptional approvals, exemptions or licenses. Our support includes dealing with day-to-day regulatory relations, as well as high-stakes regulatory investigations or enforcement proceedings. For instance, we regularly advise local and multinational clients about rules for conducting clinical trials, technical product regulations, as well as represent them during the Ministry of Health's technical approval process. We also advise clients about Turkish import regulations, issues impacting contract research organisations, marketing authorisation and pricing issues, as well as rules for sponsorship and promotional activities.

The firm's dispute resolution team provides full-scope and integrated support to pharmaceuticals, healthcare and life sciences clients, meaning conflict specialists are involved from the early stages of emerging issues. We support clients with all aspects and perspectives on disputes, along with regulatory investigations. Support includes representing clients in a full spectrum of forums and related processes, including civil and administrative litigation, arbitration and alternative dispute resolution methods, strategic negotiation and settlement processes, as well as injunctions and enforcement actions. For instance, representing clients involved in disputes about licenses, product and advertising liability, as well as contractual issues.

Moro?lu Arseven assists pharmaceuticals, healthcare and life sciences clients with all types of major corporate transactions, including mergers, acquisitions, joint ventures, strategic partnerships, spin-offs, divestitures and group restructures. The firm has significant expertise assisting during complex, inter-jurisdictional transactions, where strategic guidance is required to deal with the legal, commercial and operational factors simultaneously. These projects often involve high values, or complicated leveraging and equity structures. We work closely with companies, shareholders, investors and financiers on both buy and sell-side, assisting through all stages of these projects. Moro?lu Arseven places a strong focus on ensuring we consider each client's business objectives and the dynamics of the pharmaceuticals, healthcare and life sciences industries, then reflect these factors into the transaction's structure, risk allocation, or asset transfers.

Related Practices

- R&D, Licensing and Technology Transactions
- Patents and Utility Models
- IP Licensing
- Privacy and Data Protection
- Product Liability and Consumer Protection
- Trademarks
- Public Procurement and Government Contracts
- Consulting, Services and Outsourcing Agreements
- Real Estate and Construction

- Commercial Contracts
- Corporate
- Mergers and Acquisitions
- Foreign Investment and Business Set-up
- Antitrust and Competition
- Employment and Labor
- Tax, Fiscal and Public Debts
- Directors' and Officers' Liability
- Corporate and Commercial Litigation
- Investigations
- Business Crimes
- Anti-Counterfeiting