INDIALAW

Health Care And Pharma

Leading Health Care and Pharma Law Firm in India for CDSCO Compliance

PRACTICE PROFILE • MAY 2026

Overview

Our law firm offers specialized legal services to clients in the healthcare and pharmaceutical sectors in India. We understand the critical importance of these industries and the complex regulatory environment they operate within. Our team provides comprehensive legal support to ensure compliance, protect intellectual property, manage corporate transactions, and resolve disputes efficiently, helping our clients navigate the unique challenges of the healthcare and pharma landscape.

Our Services

- **Regulatory Compliance:** Navigating the intricate web of regulations from the Central Drugs Standard Control Organization (CDSCO), Medical Council of India (MCI), and other relevant authorities.
- **Intellectual Property Protection:** Securing and defending patents, trademarks, and copyrights for pharmaceutical formulations, medical devices, and healthcare technologies.
- **Corporate and Commercial Law:** Structuring and executing mergers, acquisitions, and joint ventures; drafting and reviewing commercial agreements, including supply chain and distribution contracts.
- **Clinical Trials and Research:** Ensuring compliance with guidelines for conducting clinical trials and managing research collaborations.
- **Data Protection and Privacy:** Advising on data protection laws, particularly concerning patient data and clinical trial information.
- **Dispute Resolution:** Representing clients in litigation, arbitration, and mediation related to contract disputes, intellectual property infringements, and regulatory violations.
- **Healthcare Facility Development:** Assisting with the establishment and operation of hospitals, clinics, and other healthcare facilities, including real estate and construction law.
- **Pharmaceutical Manufacturing:** Providing legal support for manufacturing processes, including compliance with Good Manufacturing Practices (GMP) and other industry standards.
- **Medical Devices Regulation:** Ensuring compliance with regulations for the import, manufacture, and sale of medical devices.
- **Health Insurance and Reimbursement:** Advising on health insurance laws and reimbursement policies.
- **Telemedicine and Digital Health:** Navigating the legal framework for telemedicine services and digital health innovations.
- **Pharmaceutical Pricing and Distribution:** Advising on pricing strategies and distribution networks to ensure compliance with regulatory requirements.
- **Product Liability:** Managing product liability issues and recalls, ensuring compliance with consumer protection laws.
- **Corporate Governance:** Implementing robust corporate governance practices to ensure transparency and accountability in healthcare and pharma organizations.
- **Environmental Compliance:** Ensuring that pharmaceutical manufacturing processes comply with environmental regulations and standards.
- **Healthcare Fraud and Abuse:** Advising on laws related to healthcare fraud and abuse, including anti-kickback statutes and false claims acts.
- **International Trade and Export:** Providing legal support for the export of pharmaceutical products, including compliance with international trade regulations.

Key Highlights

- **Industry-Specific Expertise:** Our team has in-depth knowledge of the healthcare and pharma sectors, ensuring we provide relevant and effective legal advice.
- **Comprehensive Legal Solutions:** We offer a full suite of legal services tailored to the unique needs of healthcare and pharma clients.
- **Responsive and Client-Centric:** We prioritize personalized and responsive service, aligning our legal strategies with your business objectives.
- **Proactive Risk Management:** We proactively identify and mitigate legal risks, helping you avoid potential pitfalls.

- **Strong Industry Connections:** Our extensive network within the healthcare and pharma sectors keeps us informed and connected to the latest developments.
- **Efficient Dispute Resolution:** We handle disputes efficiently, minimizing disruption to your operations.
- **Innovation Support:** We support innovation by protecting intellectual property and navigating the legal landscape for new technologies and treatments.

Our law firm is dedicated to providing exceptional legal support to clients in the healthcare and pharma sectors. We help our clients navigate the complex legal environment, ensuring compliance, protecting intellectual property, and fostering sustainable growth. By partnering with us, you can focus on delivering high-quality healthcare and innovative pharmaceutical solutions, knowing your legal needs are in capable hands.

Key Professionals

Saswata Banerjee
Head- ESG Compliance

Frequently Asked Questions

Q1 **What does a healthcare and pharma legal practice cover in India?**

It covers regulatory compliance with CDSCO and MCI, intellectual property protection for drugs and devices, clinical trial governance, pharmaceutical manufacturing law, health insurance advisory, and dispute resolution across the healthcare value chain.

Q2 **When should a healthcare or pharma company engage a specialized lawyer?**

Ideally before launching a new drug, medical device, or clinical trial; entering a joint venture or acquisition; or setting up a manufacturing or hospital facility. Early legal involvement reduces the risk of regulatory delays, IP conflicts, and costly compliance gaps.

Q3 **Which Indian regulators and statutes govern the healthcare and pharma sector?**

Key regulators include CDSCO for drugs and clinical trials, the National Medical Commission (formerly MCI), and IRDAI for health insurance. Core statutes are the Drugs and Cosmetics Act 1940, the New Drugs and Clinical Trials Rules 2019, the Medical Devices Rules 2017, and the DPDP Act for patient data.

Q4 **What is the typical timeline for obtaining a new drug approval from CDSCO?**

Timelines vary by drug category. A new chemical entity may take 12 to 24 months after clinical trial completion, while a generic drug with established bioequivalence data can receive approval in 6 to 12 months. Incomplete filings or query responses are the most common cause of delays.

Q5 **What documents are needed to begin a pharma regulatory engagement?**

Typically, we need the drug or device dossier, existing CDSCO licenses, manufacturing site GMP certificates, clinical trial protocols if applicable, partnership or JV term sheets, and any prior correspondence with regulators. For IP matters, patent filing details and prior art searches are also required.

Q6 **What common compliance mistakes do healthcare and pharma companies make?**

Frequent pitfalls include operating without updated CDSCO manufacturing licenses, failing to report adverse events within mandatory timelines, ignoring Medical Devices Rules for software-based diagnostics, and mishandling patient data in ways that breach the DPDP Act and clinical trial consent norms.