The Pharma Legal Handbook

India

Regulatory, Pricing and Reimbursement Overview · Preclinical and Clinical Trial Requirements · Marketing, Manufacturing, Packaging and Labeling Advertising · Traditional Medicines and OTC Products · Product Liability · Patents and Trademarks · Regulatory Reforms · Cannabinoid Drugs, Medicinal Cannabis and Opioid Drugs · Orphan Drugs and Rare Diseases · Localization · Biosimilars and Biologics · Medical Devices · Digital Health

PHARMA BOARDROOM

India

The Pharma Legal Handbook answers essential questions about this environment for pharmaceuticals in India.
It is a must have for any company operating in the country or looking to enter the market.

Prepared in association with Nishith Desai Associates, a leading Indian law firm, it should answer any questions linked to Regulation, Pricing, Clinical and Preclinical Trials, Marketing, Manufacturing, Trademarks and Patents.

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Nishith Desai Associates
LEGAL AND TAX COUNSELING WORLDWIDE

We are an India Centric Global law firm (www.nishithdesai.com) with four offices in India and the only law firm with license to practice Indian law from our Munich, Singapore, Palo Alto and New York offices. We are a firm of specialists and the go-to firm for companies that want to conduct business in India, navigate its complex business regulations and grow. Over 70% of our clients are foreign multinationals and over 84.5% are repeat clients.

Our reputation is well regarded for handling complex high value transactions and cross border litigation; that prestige extends to engaging and mentoring the start-up community that we passionately support and encourage. We also enjoy global recognition for our research with an ability to anticipate and address challenges from a strategic, legal and tax perspective in an integrated way. In fact, the framework and standards for the Asset Management industry within India was pioneered by us in the early 1990s, and we continue remain respected industry experts.

We are a research based law firm and have just set up a first-of-its kind IOT-driven Blue Sky Thinking & Research Campus named Imaginarium AliGunjan (near Mumbai, India), dedicated to exploring the future of law & society. We are consistently ranked at the top as Asia's most innovative law practice by Financial Times. NDA is renowned for its advanced predictive legal practice and constantly conducts original research into emerging areas of the law such as Blockchain, Artificial Intelligence, Designer Babies, Flying Cars, Autonomous vehicles, IOT, AI & Robotics, Medical Devices, Genetic Engineering amongst others and enjoy high credibility in respect of our independent research and assist number of ministries in their policy and regulatory work.

The safety and security of our client's information and confidentiality is of paramount importance to us. To this end, we are hugely invested in the latest security systems and technology of military grade. We are a socially conscious law firm and do extensive pro-bono and public policy work. We have significant diversity with female employees in the range of about 49% and many in leadership positions

www.nishithdesai.com

THE AUTHORS

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Dr. Milind Antani, a renowned surgeon turned lawyer, leads the Pharma and Healthcare practice at Nishith Desai Associates where he represents high net-worth clients in matters allied to JVs, M&As, VC and Private Equity Investments, Collaborations, Regulatory advice, IP, Licensing and Commercialization.

He also leads the Social Sector Practice and represents various global and national foundations in India. He continues as an active participant in helping frame national policies on key impact areas, within the medical field. He has authored and co-authored numerous articles and prestigious publications related to the Pharma and Healthcare industry.

A regular speaker at various prominent forums on Pharma, Medical Devices, Med-Tech and eHealth, Biotech, IP, Clinical trials, Healthcare, CSR and Social Impact investments, he is also a visiting faculty at premier institutions in Mumbai and Gujarat including the Institute of Rural Management, Anand (IRMA).

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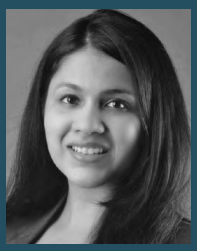

ESHIKA PHADKE

At Nishith Desai Associates Eshika is a member in the Healthcare, Pharmaceuticals & Life Sciences practice at Nishith Desai Associates. She is based out of the Mumbai office.

Eshika's practice consists of helping companies in the healthcare, pharma, medical devices, cosmetics and nutraceuticals industries navigate the myriad of legal and regulatory compliances for operating in India.

She has extensive experience advising multinational companies and start-ups on regulatory issues, compliances, marketing and promotional activities, product labelling and claims, anti-trust risks, public procurement, and commercial documentation. She also has experience working with hospitals and doctors to defend medical negligence suits.

Eshika has authored articles on a range of topics relevant to the healthcare and pharmaceutical industry, and has contributed to publications such as Express Healthcare, the Economic Times, and the Telemedicine Society of India's newsletter.

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VARSHA RAJESH

Varsha is a core member of the Pharma, Healthcare, Medical Device and Digital Health Team at Nishith Desai Associates. She has advised numerous multinational pharmaceutical and medical device companies on the regulatory aspects of clinical trials, licensing, digital health, ongoing compliances, price regulation, intellectual property and health data privacy. In addition to advisory, she has experience in corporate transactions, commercial documentation and litigation matters involving pharmaceutical and medical device clients. Varsha also advises clients on matters relating to data privacy, advertising and technology laws.

Varsha has been a speaker at various webinars and events including events hosted by industry associations such as OPPI, USISPF and USIBC discussing contemporary issues in pharma, life sciences and medical device industry.

Varsha regularly contributes to national and international publications including Thomson Reuters and Data Guidance, writing on various topics on pharmaceutical, medical devices, healthcare regulations, data privacy, digital health and emerging technologies.

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TANYA KUKADE

Tanya is a core member of the Pharmaceutical, Healthcare, Medical Device and Digital Health Team at Nishith Desai Associates. Tanya's practice primarily focuses on advising clients in the pharmaceutical, med-tech and life sciences industry. She has advised numerous multinational pharmaceutical and medical device companies on regulatory aspects oof licensing, price regulation, import, compliances, as well as intellectual property matters. In addition to general advisory, she also has experience in commercial documentation and litigation matters for pharmaceutical companies. Tanya also advises clients on matters relating to technology and media laws, and public procurement.

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Tanya contributes to national and international publications including Thomson Reuters and Data Guidance, writing on various topics on pharmaceutical, medical devices, digital health, data privacy, disruptive technology and intellectual property laws.

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LEGAL AND TAX COUNSELING WORLDWIDE

PHARMAECUTICALS, LIFESCIENCES, MEDICAL DEVICES AND DIGITAL HEALTH PRACTICE STATEMENT

THE PRACTICE

We have represented various pharmaceutical, life sciences, medical devices, med-tech and digital health companies on regulatory issues as well as transactions that have included PE and VC investments, M&A, joint ventures, co-development, multi-level collaborations and IP driven deals.

On the pharmaceutical, healthcare and medical device front- NDA has advised various companies on legal and regulatory issues as well as on documentation. This includes providing advice licensing and compliance, intellectual property, digital health applications, marketing, clinical trials and investigations and negotiation of commercial agreements for the manufacture, import, supply, and distribution of products.

Dr. Milind Antani, a successful surgeon turned lawyer lead our practice team consisting of legal experts with unparalleled domain knowledge in law and economics. The Team brings an acute understanding of the economics of the business led by key industry insights substantiated by Dr Antani's vast experience in the field.

SERVICES WE OFFER

Strategy

We offer expert opinion, based on our years of experience as a leader in this sector, to business entities at every phase of their growth cycle, including - entity formation, early stage financing, technology and licensing, research and development, intellectual property portfolios, initial public offerings and follow-on securities offerings, protection and litigation of intellectual property, development and financing of manufacturing facilities as well tax structuring. We are especially well-equipped to service the legal and tax complexities involved for multinational clients setting up operations in India. We also represent clients across a wide range of services including the drafting and negotiation of research and collaboration agreements, intellectual property protection and litigation and numerous public finance, Joint Venture, M&A, private equity and venture capital transactions.

Regulatory Issues

We advise on various regulatory issues and compliances related to licensing, pricing, clinical trials, research and development, etc. We also counsel pharmaceutical, life sciences and medical device

companies on regulations related to collaborative activities in India such as joint ventures and partnerships.

Documentation and Advisory Services

The team's expertise is well established when it comes to providing strategic guidance on structuring, drafting and negotiation of various contracts including outsourcing contracts, clinical trial agreements, contract research, service agreements, IP assignment and license agreements, master service agreement, non-disclosure agreement, sponsored research agreement, material transfer agreement and confidentiality disclosure agreements, informed consent forms and other relevant documents.

Investments

Our knowledge and proficiency, when it comes to the healthcare industry in India as well as globally, has been the main stimulus in the growth of our funds and private equity practice. We guide overseas private equity investors and venture capital funds on their investments in the healthcare industry through term sheet, due diligence, documentation and negotiations.

Corporate Transactions

Our team provides advice and assistance across various corporate transactions, including Mergers & Acquisitions, Joint Ventures and various collaborations in the healthcare, pharmaceutical and biotechnology sectors.

IP Advisory

We assist in the drafting, filing and prosecution of intellectual property applications. We routinely handle the drafting of complex patent specifications for a wide array of technologies in addition to filing domestic, PCT and National Phase patent applications and assisting in the filing of foreign patent applications and freedom to operate opinions. We assist clients in identifying their intellectual property in order to formulate comprehensive strategies to help clients protect and leverage such intellectual property. We also assist companies managing patent compliance, patent landscape study as well as trademark portfolio management with uniquely designed software. Our team also assists clients in conducting detailed IP audit of the portfolio of a company.

Patent Litigation

We have an extensive litigation practice that focuses on the protection of patents and other intellectual property. As mentioned earlier, the presence of a surgeon, chemical and biomedical engineers, Indian patent agents and a U.S. Patent Attorney helps us to understand the underlying science and technology at great speed and provide focused solutions.

Funds

Our funds team is expert in structuring and positioning healthcare focused funds in India. We guide our clients in tax and legal issues in their investment decisions as well as service them on new issues arising in their investments.

Due Diligence

We undertake comprehensive legal and regulatory due diligence of healthcare businesses using our industry insights. Our expertise in the healthcare sector enables us to identify critical issues that a financial or strategic investor in healthcare should carefully understand and address.

Structuring

We routinely advice in structuring transactions from a tax, legal and regulatory perspective. On the tax side, we advise on tax favourable jurisdictions for investment purposes, permanent establishment, and transfer pricing instruments. We also facilitate the establishment of business in India, including the incorporation of companies and logistical operations of setting up branches and liaison offices.

Litigation

Our team assists and advices on pre-litigation strategies based on the current IP and regulatory landscape in India. We have represented international and domestic clients in IP litigation and alternate dispute resolutions. We have extensive experience representing clients at every level of the judicial system and in all types of disputes, from relatively simple matters to highly complex cases of product liability, patent infringement, antitrust and securities.

Training

We conduct workshops for employees of healthcare companies on Indian legal and regulatory compliance requirements encapsulating the current healthcare and IP landscape at national and international seminars.

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REGULATORY, PRICING, AND REIMBURSEMENT OVERVIEW

1. What are the regulatory authorities with jurisdiction over drugs, biologicals, and medical devices in your country?

2. What is the regulatory framework for the authorization, pricing, and reimbursement of drugs, biologicals, and medical devices?

3. What are the steps to obtaining authorization to develop, test, and market a product?

4. What are the approximate fees for each authorization?

5. For how long are marketing authorizations/registrations valid? How are marketing authorizations/registrations renewed?

6. How does the authorization process differ between brand-name products and generic products? Are there differences for local manufacturers versus foreign-owned manufacturers?

7. How are combination products (drug + drug, drug + biologic, drug + device, biologic + device, drug + biologic + device) regulated?

8. How is compliance with regulation monitored and evaluated? Is the regulatory regime comparable with the U.S. Food and Drug Administration or the European Medicines Agency expectations and requirements?

9. What is the potential range of penalties for noncompliance?

10. Is there a national healthcare system? If so, how is it administered and funded?

11. How does the government (or public) healthcare system function with private sector healthcare?

12. Are prices of drugs and devices regulated and, if so, how?

13. How are drugs and devices used by patients paid for? What roles do public and private payers play?

14. Who dispenses drugs and devices to patients and how are those dispensers compensated?

15. What are the professional and legal responsibilities of those who dispense drugs and devices? What role do they play in providing patient care, information, and safety?