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.

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www.nishithdesai.com

THE AUTHORS

DARREN PUNNEN

Darren Punnen is a senior member of the Pharmaceutical, Medical Device and Healthcare team, and leads the Technology in Healthcare Practice at Nishith Desai Associates. His practice particularly focuses on advising several foreign and domestic clients in the pharmaceutical, med-tech and life sciences industry on commercial, regulatory, litigation, investment, white collar and intellectual property matters. He has also been part of multiple pharmaceutical and healthcare transactions, providing investors with essential inputs that are unique to this industry. He also advises several clients on matters in the food and beverage industry, and handles matters relating to technology, media and telecom laws as well.
Darren regularly contributes to national and international publications, writing on various topics including pharmaceutical, medical device and healthcare regulations, med-tech and digital health. He is a monthly contributor for Thomson Reuters and has also prepared various guidebooks ranging from medicinal product regulations to pharmaceutical and medical device regulatory, intellectual property and competition law framework.

darren.punnen@nishithdesai.com

DR. MILIND ANTANI

Dr. Milind Antani, a renowned surgeon turned lawyer, leads the Pharma & Healthcare practice at multi-skilled, research-based international law firm, 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. Dr Antani 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 and is a regular speaker at various prominent forums on Pharma, Medical Devices, Med-Tech & 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). He is also the member of task for of National Accreditation Board for Hospitals & Healthcare Providers (NABH) to formalize reforms for Digital Health.

Dr. Antani has also successfully completed a certificate course in professional services marketing from Harvard and is also a certified Soft Skills trainer.

milind.antani@nishithdesai.com

SHREYA SHENOLIKAR

Shreya Shenolikar is a member of the Pharmaceutical, Medical Device, Healthcare and Med-Tech team at Nishith Desai Associates. Her practice particularly focuses on advising several multi-national pharmaceuticals, medical device and healthcare companies on complex regulatory and investment matters. She has also been part of prominent civil and criminal litigation involving pharmaceutical companies.

Shreya regularly contributes to national and international publications, writing on various topics including pharmaceutical, medical device and healthcare regulations, med-tech and digital health. She is a regular contributor for Thomson Reuters and takes a keen interest in the development of healthcare policy both in India and internationally.

shreya.shenolikar@nishithdesai.com

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01 REGULATORY, PRICING, AND REIMBURSEMENT OVERVIEW

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

The following authorities are responsible for the regulation drugs, biologics and medical devices in India:

(i) Central Drugs Standard Control Organization **("CDSCO")**, headed by Drugs Controller General of India **("DCGI")** under the Ministry of Health and Family Welfare

The CDSCO regulates import, manufacture, marketing and clinical trials of drugs, biologics and medical devices for the entire territory of India.

(ii) State-level licensing authority **("SLA")**

Each State, through SLAs (who are the state-level Food and Drug Administration), independently regulates manufacture and sale of drugs, biologics and medical devices within the territory of that State.

In certain cases, there is an overlap of function between DCGI and SLAs. In such cases, SLAs operate under the direction of DCGI.

(iii) National Pharmaceutical Pricing Authority **("NPPA")** under the Department of Pharmaceuticals

NPPA fixes prices of certain essential drugs, biologicals and medical devices for entire territory of India. It monitors price movements other drugs, biologicals and medical devices to ensure that the prices do not increase more than 10% year on year. NPPA also monitors the availability of drugs and takes remedial steps to prevent shortage.

(iv) Controller of Legal Metrology

Each State, through its Controller of Legal Metrology, regulates packaging and labelling of medical devices. The Controller of Legal Metrology does not have jurisdiction over drugs and biologicals.

(v) Review Committee on Genetic Manipulation **("RCGM")** under the Department of Biotechnology **("DBT")**

The RCGM, under the Ministry of Science and Technology to evaluate safety related aspects of on-going research involving Genetically Modified Organisms.

(vi) Genetic Engineering Approval Committee **("GEAC")**

The GEAC, under the Ministry of Environment, Forests and Climate Change regulates research, testing, safe use and handling of Genetically Modified Organisms and their products from an environment safety perspective.

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

AUTHORIZATION/LICENSING

The Drugs and Cosmetics Act, 1940 ("**D&C Act**") along with the Drugs and Cosmetics Rules, 1945 ("D&C Rules") and The Medical Device Rules, 2017 ("**MDR**") governs the authorization, import, manufacture, distribution and sale of drugs, biologicals of medical devices.

The MDR regulates only certain categories of medical devices specifically notified for regulation by the Ministry of Health and Family Welfare. Medical devices are categorised into one of four classes under the MDR on the basis of increasing risk, from Class A to Class D.

At the time of enactment of the MDR, only 15 categories of medical devices were regulated under the rules. 14 additional medical devices were notified and included within the regulatory framework in 2018 and 2019 with effect from different points of time in 2019, 2020 and 2021.

Subsequently, on 11 February 2020, the Ministry of Health and Family Welfare published a notification (which came into force on 1 April 2020) effectively bringing all medical devices under the ambit of the MDR. The notification notified an expansive and catch-all definition of medical devices (rather than notifying an individual or category of medical devices), so that all medical devices were notified and consequently brought under the ambit of the MDR.

To provide a transition period for the medical device industry to undertake the compliance requirements under the MDR, the Ministry of Health and Family Welfare has also provided a temporary exemption from adhering to the compliance requirements for a period of 30 months for Class A and B devices and 42 months for Class C and D devices. The exemption commenced on February 11, 2020 and is conditional on the manufacturer/importer of the medical device registering their device on the Online System for Medical Devices established by the CDSCO for this purpose.

PRICING

The Drugs (Price Control) Order, 2013 **("DPCO")** under the Essential Commodities Act 1954 **("ECA")** regulates the pricing of drugs, biologicals and notified medical devices in India.

REIMBURSEMENT

India currently does not have a mechanism for reimbursement of drugs, biologics and medical devices. Out-of-pocket expenditure by patients is the primary means of financing of drugs, biologicals and medical devices. For more details on India's healthcare system, please refer to **Chapter 1 Question 7.**

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

DEVELOPMENT

There is no authorization required to develop a product in India. However, once a product starts showing properties that qualify it to be called as drug, then a license is required to import or manufacture it.

A product in development becomes a drug when it starts satisfying the criteria for what is considered a drug for the purposes of the D&C Act, which includes:

i) "all medicines for internal or external use of human beings or animals and all substances intended to be used for or in the diagnosis, treatment, mitigation or prevention of any disease or disorder in human beings or animals, including preparations applied on human body for the purpose of repelling insects like mosquitoes;

ii) such substances (other than food) intended to affect the structure or any function of the human body or intended to be used for the destruction of vermin or insects which cause disease in human beings or animals, as may be specified from time to time by the Central Government by notification in the Official Gazette;

iii) all substances intended for use as components of a drug including empty gelatine capsules; and

iv) such devices* intended for internal or external use in the diagnosis, treatment, mitigation or prevention of disease or disorder in human beings or animals, as may be specified from time to time by the Central Government by notification in the Official Gazette, after consultation with the Board"

TESTING

Any processing activity carried out on a drug, biological or medical devices requires a manufacturing license from the CDSCO or SLA, as the case may be. Testing of product amounts to processing. Therefore, a manufacturing license for the purpose of examination, test or analysis is required to be obtained from the SLA. If a product on which testing is to be carried out is to be imported, then a separate import license for the purposes of test and analysis is required from CDSCO. Please note that the import license is to be obtained in addition to the manufacturing license.

MARKETING

If the drug or biological qualifies as a "new drug" or if a notified medical device qualifies as an "investigational medical device" or "new In Vitro Diagnostic Device", then a marketing permission from the CDSCO is required to be obtained in respect of such drug, biological or medical device before its manufacture or import, respectively.

The definition of investigational new drug is as follows:

"*investigational new drug" means a new chemical or biological entity or substance that has not been approved for marketing as a drug in any country*"

The definition of new drug is as follows:

"new drug" means, -

(i) a drug, including active pharmaceutical ingredient or phytopharmaceutical drug, which has not been used in India to any significant extent, except in accordance with the provisions of the D&C Act and the rules, as