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

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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01

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?

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**"), The Medical Device Rules, 2017 ("MDR") and the New Drugs and Clinical Trial Rules, 2019 ("New Drugs &

CT Rules") governs the authorization, import, manufacture, distribution and sale of drugs, biologicals and following categories of medical devices in India:

1. Disposable hypodermic syringes.
2. Disposable hypodermic needles.
3. Disposable perfusions.
4. In vitro diagnostic devices for HIV, HBsAg and HCV.
5. Cardiac stents.
6. Drug eluting stents.
7. Catheters.
8. Intra ocular lenses.
9. Cannulas.
10. Bone cements.
11. Heart valves.
12. Scalp vein sets.
13. Orthopaedic implants.
14. Internal prosthetic replacements.
15. Ablation devices.
16. Organ Preservation Solution

14 additional categories of medical devices will be brought under the regulation of the MDR in 2020 ("Additional Medical Devices"). The Additional Medical Devices are:

1. All implantable medical devices
2. CT scan equipment.
3. MRI equipment
4. Defibrillators
5. Dialysis machine
6. PET equipment
7. X-ray machine
8. Bone marrow cell separator
9. Nebulizer
10. Blood pressure monitoring devices
11. Digital thermometer
12. Glucometer
13. Ultrasound equipment

Nebulizers, blood pressure monitoring devices, digital thermometers and glucometers will be regulated as medical devices from January 01, 2020 while ultrasound equipment will be brought under regulation from November 01, 2020. The remaining Additional Medical Devices will be regulated as medical devices from April 01, 2020. Medical devices that fall under the above categories are referred to as notified medical devices. Medical devices that do not fall within the above categories are, as such, outside the purview of regulation of sale, pricing and reimbursement.

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 intendedto 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 gelatin 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.