Pharma & Healthcare

Sector & Laws in India

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INTRODUCTION

Pharma and Healthcare Sector is a dynamic area in India. The industry ranks 3rd in terms of volume and is 14th in terms of value globally. It has shown tremendous progress as far as infrastructure development, technology base creation and a wide range of products are concerned. It has established its presence and determination to flourish in the changing environment.

The industry now produces bulk drugs belonging to all major therapeutic groups requiring complicated manufacturing technologies. Formulations in various dosage forms are being produced in GMP compliant facilities. Strong scientific and technical manpower and pioneering work done in process development have made this possible.

Globally, it ranks 4th in terms of generics production and 17th in terms of export value of bulk actives and dosage forms. Indian exports are destined to more than 200 countries around the globe including highly regulated markets of US, West Europe, Japan and Australia

The pharmaceutical sector is growing consistently and this reflects the inherent strengths of the industry and improving healthcare standards in the country. The industry meets the country's demand for bulk drugs, pharmaceutical formulations, chemicals, tablets, capsules, orals, and injectables.

The Indian healthcare sector constitutes of the following:

- Medical care providers: physicians, specialist clinics, nursing homes and hospitals;
- Diagnostic service centers and pathology laboratories;
- Medical equipment manufacturers and suppliers - includes establishments primarily engaged in medical equipment and supplies, such as surgical, dental and laboratory instruments, etc.
- Medical Insurance – includes health insurance and covers an individual's hospitalisation expenses and medical reimbursement facility incurred due to sickness.
- Pharmaceuticals – includes the manufacture, extraction, processing, purification and packaging of chemical materials to be used as medications for humans or animals.

Market Drivers of this sector

- Increasing government expenditure on health care sector;
- Rising Health awareness;
- Rise in Health insurance sector
- Private sector companies are growing fast in terms of owning and managing hospitals;

REGULARTORY FRAMEWORK

The prominent laws, which govern the pharmaceutical and health sector, are as under:

A. The Drugs and Cosmetics Act, 1940 ("Drugs Act") & corresponding Rules, 1945 ("Drugs Rules")

The manufacture, import, distribution and sale of drugs and cosmetics in India are regulated by the Drugs and Cosmetics Act of 1940 and the Drugs and Cosmetics Rules of 1945.

- Schedule M of the Drugs and Cosmetics Act specifies the general and specific requirements for factory premises and materials, plant and equipment and minimum recommended areas for basic installation for certain categories of drugs.

- Schedule T of the Drugs and Cosmetics Act prescribes Good Manufacturing Practices (GMP) specifications for manufacture of Ayurvedic, Siddha and Unani medicines.

- Schedule Y of the Drugs and Cosmetics Act governs the clinical trials legislative requirements of the Drugs and Cosmetics Act.

The Drugs Act and the Drug Rules provides procedure for obtaining approvals for the following activities.

Manufacturing a Drug in India

Under the Drugs Act "Manufacturing" includes any process (or part) for making, altering, ornamenting, finishing, packing, labelling, breaking up or otherwise treating or adopting any drug with a view to its sale or distribution. However, "manufacturing" does not include dispensing or the packing of any drug at the retail sale level.

All manufacturing of drugs in India requires a license. The license shall be valid for a period of five years on and from the date on which it is granted .It is also possible to obtain a license to manufacture a product in the factory premises owned by another party, through a practice called "loan licensing".

The good manufacturing practices (GMP) and requirements of premises, plant & machinery are provided in the Schedule M.

The items covered are: locations and surroundings, buildings, water supply, disposal of waste, working space and storage areas, health, clothing and sanitation of workers, medical services and equipment standards.

The Drug & Cosmetics Act also specifies other conditions for grant of license, competent technical staff and qualification with experience in drug manufacture.

Registration for Importing a Drug into India

All drugs to be imported require import registration. An application for issue of a Registration Certificate shall be made to the licensing authority either by the manufacturer himself, having a valid license or valid wholesale license for sale or distribution of drugs specified under the Drugs & Cosmetics Rules, 1945 and information and undertakings specified in Schedule D (I) and D (II) should duly signed by the manufacturer.

Schedule D(I) and D(II) should comprise actual plant and drug data, such as the plant master file ; the manufacturing license in country of origin; a GMP Certificate; a Certificate of Pharmaceutical Products(CPP); drug substance information; finished formulation information; clinical documentation and packaging and labelling information.

License for Importing a Drug into India

An application for import license shall be made to the licensing authority for drugs excluding those specified in Schedule X either by the manufacturer himself or by the manufacturer's agent in India having a valid wholesale license for sale or distribution of drugs under these rules A license is valid for a year, up to December 31st of the year following the year in which the license was granted and has to renewed thereafter.

New Drugs

No new drug can be imported without the permission of the Licensing Authority. Approval to manufacture a new drug should be obtained from the Licensing Authority. Permission should be obtained from the Licensing Authority to conduct clinical trials for New Drug.

"New Drugs" shall mean and include –

- Drugs not previously available in Indian market.

- Drugs with new therapeutic indications or dosages that have not been marketed in India.
- New fixed -dose combinations of two or more drugs.
- Any drug which was first approved in India less than four years ago, unless it is included in the Indian pharmacopoeia.
- All vaccines are treated as new drug, unless notified otherwise by DCGI.

B. The Pharmacy Act, 1948

In India there was no restriction to practise the profession of pharmacy. One could practise this profession as any other profession. It was found necessary to enact a law for the regulation of the profession and practice of pharmacy. Under the provisions of this act the Central Government constitutes a Central Pharmacy Council of India and the State Governments constitute State Pharmacy Councils.

C. The Drugs and Magic Remedies (Objectionable Advertisement) Act, 1954

The Drug & Magic Remedies (Objectionable Advertisement) Act & Rules mentions a list of ailments for which no advertising is permitted. It also prohibits false or misleading advertisements which, directly or indirectly, give false impressions regarding the true character of the drug, make false claims, or are otherwise false or misleading in any particular respect.

D. The Narcotic Drugs and Psychotropic Substances Act, 1985

This is an act concerned with control and regulation of operations relating to Narcotic Drugs and Psychotropic Substances.

E. The Medicinal and Toilet Preparations (Excise Duties) Act, 1956

An Act to provide for the levy and collection of duties of excise on medicinal and toilet preparations containing alcohol, narcotic drug or narcotic.

F. The Drugs Price Control Order (DPCO), 2013

DPCO controls the domestic prices of major bulk drugs and their formulations with an aim to provide patients with medicines at affordable prices.

- This is an order issued by the Government of India under the Essential Commodities Act, 1955 to regulate the prices of drugs.
- The Order provides the list of price controlled drugs, procedures for fixation of prices of drugs, method of implementation of prices fixed by Government and penalties for contravention of provisions among other things.

- India's Department of Pharmaceuticals on 15 May published the Drug (Price Control) Order (DPCO) 2013, authorising the National Pharmaceutical Pricing Authority (NPPA) to regulate prices of drugs on India's National List of Essential Medicines (NLEM) 2011 using new market-based rules. This will see the number of drugs under government price controls increased to 652, including combination products, from just 74 bulk drugs previously.

<u>Non Applicability of Drug Pricing Control Order 2013</u>

- a manufacturer producing a new drug patented under the Indian Patent Act, 1970 (product patent) and not produced elsewhere, if developed through indigenous Research and Development, for a period of five years from the date of

commencement of its commercial production in the country.

- a manufacturer producing a new drug in the country by a new process developed through indigenous Research and Development and patented under the Indian Patent Act, 1970 (process patent) for a period of five years from the date of the commencement of its commercial production in the country.

- a manufacturer producing a new drug involving a new delivery system developed through indigenous Research and Development for a period of five years from the date of its market approval in India:

Provided that the provision of this paragraph shall apply only when a document showing approval of such new drugs from Drugs Controller General (India) is produced before the Government.

REGULATORY BODIES

The Ministry of Health & Family Welfare (MoHFW) and the Ministry of Chemicals and Fertilisers (MoC&F) of the Government of India play a major role in regulating the healthcare & pharmaceutical sector in the country.

1. Ministry of Health & Family Welfare (MoHFW)

The Ministry of Health & Family Welfare regulate the Pharmaceutical & healthcare sector in the country through the deparment of health

Department of Health

The following are the main agencies of the department which deal with key issues including drug approvals:

a) Central Drugs Standard Control Organisation (CDSCO)

As an agency of the Department of Health, the CDSCO works both at the Central and the State level and is responsible for ensuring safety, efficacy and quality of drugs supplied to the public.

b) Drugs Controller General of India (DCGI)

The DCGI is an apex body in the pharmaceutical industry governing issues such as product approval and standards, clinical trials, introduction of new drugs, import licences for new drugs and enforcing new drug legislation.

2. Ministry of Chemicals and Fertilizers (MoC&F)

The Ministry of Chemicals & Fertilisers constitutes bodies such as the Department of Chemicals & Petrochemicals and the National Pharmaceutical Pricing Authority (NPPA). These departments are entrusted with the responsibility of policy making, planning, development and regulations relating to Chemicals, Petrochemicals and Pharmaceuticals.

a) Department of Chemicals & Petro-Chemicals

This department is the concerned authority for formulating and implementing policies and programmes for achieving growth and development of pharmaceuticals in the country. In order to attract investment into the sector, the Department has undertaken several initiatives, the major being the Pharmaceutical Policy with the objective to strengthen the production, export & R&D.

The National Pharmaceutical Pricing Policy-2012 has been notified on 07.12.2012. The objective of National Pharmaceutical Pricing Policy-2012 is to put in place a regulatory framework for pricing of drugs so as to ensure availability of required medicines – "essential medicines" – at reasonable prices even while providing sufficient opportunity for innovation and competition to support the growth of industry, thereby meeting the goals of employment and shared economic well-being for all.

The key principles for regulation of prices in the National Pharmaceuticals Pricing Policy (NPPP) 2012 are:

(1) Essentiality of Drugs

- This is to be met by considering the List of medicines specified under National List of Essential Medicines (NLEM)-2011 as revised from time to time and most recently declared by the Ministry of Health and Family Welfare, Government of India.
- The NLEM contains such medicines that satisfy the priority health needs of the country's population.

(2) Control of Formulations prices only

The regulation of prices of drugs in the National Pharmaceuticals Pricing Policy 2012 would be on the basis of regulating the prices of formulations only.

"**formulation**" means a medicine processed out of or containing one or more drugs with or without use of any pharmaceutical aids, for internal or external use for or in the diagnosis, treatment, mitigation or prevention of disease and, but shall not include –

(i) Any medicine included in any bonafide Ayurvedic (including Sidha) or Unani (Tibb) systems of medicines;

(ii) Any medicine included in the Homeopathic system of medicine; and

(iii) Any substance to which the provisions of the Drugs and Cosmetics Act, 1940 (23 of 1940) do not apply;

(3) Market Based Pricing

- The methodology of fixing a ceiling price of NLEM medicines, by adopting the Average price of all the brands having market share (on the basis of moving annual turnover) more than and equal to 1% of the total market turnover of that medicine, will be as per the formula below:

  (Sum of prices of all the brands of the medicine having market share more than and equal to 1% of the total market turnover of that medicine) / (Total number of manufacturers producing such brands of that medicine)

- The formulations will be priced only by fixing a **Ceiling Price (CP).** Manufacturers would be free to fix any price for their products equal to or below the CP.

- The Ceiling Price will be fixed on the basis of readily monitorable Market Based Data (MBD). The Basis for this readily monitorable market data would be the data available with the pharmaceuticals market data specializing company – IMS Health (IMS).

- The IMS data gives price figures for stockist level prices hence in order to arrive at ceiling price (which will be the maximum retail price), the IMS price will be further increased by 16% as margin to the retailer so as to arrive at a reasonable ceiling price chargeable from the consumers.

- The CP for a drug listed in NLEM would be the Average of Prices as calculated on the basis of IMS date six months prior to the

date of receipt of application for fixing the price of the new drug.

b) National Pharmaceutical Pricing Authority (NPPA)

The National Pharmaceutical Pricing Authority (NPPA) monitors and controls pricing in the Indian market for essential medicines, through the Drug Price Control Order (DPCO).

3. Patent Act, 1970

Product patent in pharmaceuticals has been introduced in the country with effect from 1st January, 2005 by amending the Patents Act, 1970 in conformity with the TRIPS agreement. Under this Act both product as well as process patents can now be granted for pharmaceuticals.

India's first compulsory license has been granted by the Controller General of Patents, Designs and Trade Marks to Natco for Bayer's kidney-cancer drug Nexavar in March 2012. The compulsory licensing (CL) provision arms the government with the power to ensure that medicines are available to patients at affordable rates.

Compulsory licensing has been granted on the following grounds under Section 84 of the Indian Patent Act.

- the drug did not meet the reasonable requirements of the public;
- the drug was not reasonably affordable;
- the patent was not being sufficiently worked in India because it was not locally manufactured.

FDI IN PHARMA & HEALTHCARE SECTOR

Currently, India permits 100 per cent FDI in pharma sector through automatic approval route in the new projects but the foreign investment in the existing pharma companies are allowed only after FIPB's approval.

India's foreign investment policy is very liberal for hospitals. FDI is permitted up to 100% under the automatic route for the healthcare sector in India.

PACKAGING AND LABELLING OF DRUGS

The Drugs and Cosmetics Rules, 1945 have laid the requirements for packaging and labelling of drugs which must be mandatorily followed while packaging & labelling such commodities.

No Drugs can be sold or distributed or manufactured in India unless it is labelled in a manner provided by the Drug Rules. The Drug Rules Lay down different labelling standards for non- homeopathic drugs (Part IX), homeopathic drugs (Part IX-A), biological & other special Products (Part X).

HOW INDIA JURIS CAN ASSIST

India Juris can provide legal, regulatory and business advisory assistance to Indian and foreign private sector companies and independent businessmen. Our Services in Pharma and Healthcare Sector include following:

- Developing structure and roadmap for entry into the Pharma & Healthcare business in India.
- FDA registration / approvals & LiaIsoning with FDA departments in India.
- Assistance and advisory on Pharma & Healthcare business and other assistance.
- Setting up of the Companies, Subsidiary, Liaison/ Branch Office in India for foreign companies.

- Joint Ventures, M&A, Collaboration, MoUs, Strategic acquisitions in Pharma & Healthcare business such as assistance in acquisitions of labs, etc.
- Legal assistance and services with respect to Drugs and Cosmetics Laws, Good Manufacturing Practice requirements.
- Taxation
- Repatriation and remittance of money and other legal services not included here.
- Legal advisory on foreign exchange laws and corporate compliances.
- Dispute resolution legal services including litigation & arbitration in Pharma & Healthcare business.

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