AN OVERVIEW OF LAWS GOVERNING PHARMACY IN INDIA

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ABSTRACT

The Indian pharmaceutical industry is one of the largest in the world both in terms of volume and value. Given its critical importance, the sector has been subject to a series of regulatory interventions, which have altered the nature of the industry quite significantly. In recent decades, many nations and international organizations have made a concentrated effort to homogenize the laws governing intellectual property. This is due to the continuing tension that exists between large, multinational pharmaceutical companies (MNCs), and developing nations that lack both the infrastructure and capital to establish their own self-subsisting pharmaceutical industries. A look through the pages of history reveals that man suffered from the so-called ‘Diseases’ in the past as he does to-day. Amongst many modes of treatment of diseases the most successful approach has been the administration of materials picked up from the environments to the sick man. Healthcare facilities in India are still below standard as compared to most developed nations. Industry today is governed by wide range of regulations and different regulatory bodies. The purpose of this article is to understand the pharmaceutical sector through the prism of competition law and regulations.

KEYWORDS: Laws, Pharmaceutical industry, Regulations, Regulatory bodies.

INTRODUCTION

A Pharmaceutical industry in most countries in the world is governed by regulations concerning ownership, staffing, medicines and prices. However, in most low and middle-
income countries regulatory enforcement of these regulations is difficult or impossible constrained by limited government capacity, and complicated by the fragmented nature of pharmaceutical markets. In most countries, pharmacy legislation and regulation is fragmented and there is sporadic and limited enforcement of regulations.\footnote{1}

The pharmaceutical companies responsible for the discovery, testing, clinical trials, production, manufacture and marketing of these products also want to ensure that they supply products that are safe and make a worthwhile contribution to public health and welfare. Regulatory affairs professionals are the link between pharmaceutical industries and worldwide regulatory agencies. They are required to be well versed in the laws, regulations, guidelines and guidance of the regulatory agencies. There is a growing need to incorporate the current requirements of pharmaceutical industries in the standard curriculum of pharmacy colleges to prepare the students with the latest developments to serve the industries.\footnote{2, 3}

With the enactment of the Indian Competition Act in 2002, India has become one of the newer countries that have a robust competition regulation. Given the unique nature of the pharmaceutical markets, it is important to understand how the different laws are applied to this division.\footnote{4, 5}

As the pharmaceutical industries throughout the world are moving ahead towards becoming more and more competitive, these are realizing that the real battle of survival lies in executing the work by understanding the guidelines related to various activities carried out to give an assurance that the process is under regulation.\footnote{6, 7}

**METHODOLOGY**

I. Healthcare Facility in India

India has been late starter specifically with reference to the Pharmacy profession. Up to the 20th Century the land had no laws to exercise any control over operation related to drugs.

- Healthcare facility in India is poor as compared to many developed countries, still various attempts made by government are found to be insufficient to ever increasing population in India.
- Healthcare industry is growing at a tremendous pace owing to its strengthening coverage, services and increasing expenditure by public as well private players.
- During 2008-20, the market is expected to record a CAGR of 16.5 per cent.
• The total industry size is expected to touch US$ 160 billion by 2017 and US$ 280 billion by 2020.

As per the Ministry of Health, development of 50 technologies has been targeted in the FY16, for the treatment of disease like Cancer and TB. Large proportion of Indian population resides in villages, which has contributed to lack of healthcare facilities to about 67% population and confinement of modern healthcare facilities to 33% population in cities and towns only.\(^8\) Figure No 1 Health Care Sector Growth Trends with Strong growth in healthcare expenditure.\(^9\)

![Healthcare sector growth trend (US$ billion)](image)

Source: Frost & Sullivan, LSI Financial Services, Deloitte, TechSci Research
Notes: E - Estimate, F - Forecast, CAGR - Compound Annual Growth Rate

Figure No 1 Health Care Sector Growth Trends

II. History of Pharmaceutical Industry in India

The Indian pharmaceutical industry has come a long way since the time of independence when multinational corporations dominated the industry. Over the years, under a favourable policy regime, the industry has grown phenomenally and has established itself as a major supplier of not only generic products but also new formulations. The history of the evolution of the Indian pharmaceutical industry can be divided into four principal epochs. The first epoch is from 1850 to 1945. The second epoch spans from 1945 to the late 1970s. The third epoch for development is from the early 1980s to the early 1990s, and the fourth epoch spans from the early 1990s to the present time. Precisely the history of the Indian pharmaceutical industry can be divided into three distinct phases. In the first phase, immediately after independence, the Indian pharmaceutical industry was dominated by global multinational manufacturers. The current Pharmaceutical Industry is well organized, systematic and compliant to international regulatory standards for manufacturing of Chemical and Biological
drugs for human and veterinary consumption as well as medical devices, traditional herbal products and cosmetics. Stringent GMPs are being followed for blood and its derivative as well as controlled manufacturing for Traditional Herbal Medicines, Cosmetics, Food and Dietary products which was otherwise differently a century before. Each regulatory system had faced certain circumstances which led to current well-defined controlled regulatory framework.\textsuperscript{10, 11, 12}

Patent Procurement in India (Evolution of the Indian Patent Act and the present position), the details are shown in the Table No-1.\textsuperscript{13, 14}

**Table No-1 Indian Patent Laws prior to and post Independence**

<table>
<thead>
<tr>
<th>Year</th>
<th>Act/ Amendment in Patent System</th>
</tr>
</thead>
<tbody>
<tr>
<td>1856</td>
<td>Protection of inventions based on the British patent law of 1852. Certain exclusive privileges granted to inventors of new manufacturers for a period of 14 years.</td>
</tr>
<tr>
<td>1859</td>
<td>Patent monopolies called exclusive privileges (making-selling and using interventions in India and authorizing others to do so for 14 years from date of filling specifications).</td>
</tr>
<tr>
<td>1872</td>
<td>The patents &amp; designs protection act</td>
</tr>
<tr>
<td>1883</td>
<td>The protection of inventions act</td>
</tr>
<tr>
<td>1888</td>
<td>Consolidated as the inventions &amp; designs act</td>
</tr>
<tr>
<td>1911</td>
<td>The Indian patents and designs act</td>
</tr>
<tr>
<td>1972</td>
<td>The patents act (act 39 of 1970) came into fore on 20\textsuperscript{th} April 1972</td>
</tr>
<tr>
<td>1999</td>
<td>On March 26, 1999 patents (amendment) act came into force</td>
</tr>
<tr>
<td>2002</td>
<td>The patents (amendment) act 2002 came into force</td>
</tr>
</tbody>
</table>

**III. Pharmaceutical Industry competition**

Competition law and policy is central to managing healthcare markets in many nations. This report addresses, from the perspective of competition law and policy, issues concerning anticompetitive practices prevailing in the pharmaceutical industry in India and its competitiveness as a provider of safe and affordable drugs. The pharmaceutical sector is among the highly regulated sectors across the globe. Yet, it is often noted that the required degree of competition is often missing from these markets.

Pharma industry is one of the most competitive industries in the country with as many as 10,000 different players fighting for the same pie. Another major factor that adds to the industry rivalry is the fact that the entry barriers to pharma industry are very low. The fixed cost requirement is low but the need for working capital is high.\textsuperscript{15, 16}
IV. Scenario of Pharmaceutical Industry

The annual turnover of the Indian pharmaceutical industry is over 11 billion USD. Globally it ranks 4th in terms of volume with a share of 8% in the world pharmaceutical market. In terms of value, it ranks 14th. The flexible provisions of the Patent Act of 1970 and other supportive policies of the Government of India played an instrumental role in the growth and development of this industry. Given the importance of public policies in influencing the present structure of the industry this chapter, reviews in brief the important policy changes that have taken place in this sector and also examines the current changes in the structure of the industry and the changing behavior of firms in responding to policy changes.\textsuperscript{[17, 18]}

![Figure No-2 Regulatory Control of Pharmaceutical Sector](image)

A regulatory affair (RA) also has a very specific meaning within the healthcare industries (pharmaceuticals, medical devices, Biologics and functional foods). Most companies, whether they are major multinational pharmaceutical corporations or small, innovative biotechnology companies, have specialist departments of regulatory affairs (RA) professionals. Figure 3 shows the various role of DRA department and Figure 4 shows the various major regulatory authorities of different country.\textsuperscript{[19]}

![Figure No-3 Various role of DRA Department](image)
Most of the Pharmacies are showing rapid and consistent growth with their impact worldwide. India is also turning out to be a prime destination for clinical trials. Industry today is governed by wide range of regulations and different regulatory bodies. Different Bodies like CDSCO, NPPA, D & C Act, 1940, Schedule M, Schedule T, Schedule Y, GCP guidelines, The Pharmacy Act, 1948, The Drugs and Magic Remedies (Objectionable Advertisement) Act, 1954, The Narcotic Drugs and Psychotropic Substances Act, 1985 etc are in the limelight.\[20\]

In order to understand the problems faced by pharma professionals in accessing requisite information in order to comply with the regulatory requirements at home and in the regulated foreign markets below mentioned Table no-2 shows the Indian and international guidelines and regulations.\[21\]

**Table No-2 Indian Regulations & Guidelines**

<table>
<thead>
<tr>
<th>CDSCO</th>
<th>Central Drugs Standard Control Organization (CDSCO), Ministry of Health &amp; Family Welfare, Government of India provides general information about drug regulatory requirements in India.</th>
</tr>
</thead>
<tbody>
<tr>
<td>NPPA</td>
<td>Drugs (Price Control) Order 1995 and other orders enforced by National Pharmaceutical Pricing Authority (NPPA), Government of India. View the list of drugs under price control.</td>
</tr>
<tr>
<td>D &amp; C Act, 1940</td>
<td>The Drugs &amp; Cosmetics Act, 1940 regulates the import, manufacture, distribution and sale of drugs in India.</td>
</tr>
<tr>
<td>Schedule M</td>
<td>Schedule M of the D&amp;C 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.</td>
</tr>
</tbody>
</table>

Schedule Y
The clinical trials legislative requirements are guided by specifications of Schedule Y of The D&C Act.

GCP guidelines
The Ministry of Health, along with Drugs Controller General of India (DCGI) and Indian Council for Medical Research (ICMR) has come out with draft guidelines for research in human subjects. These GCP guidelines are essentially based on Declaration of Helsinki, WHO guidelines and ICH requirements for good clinical practice.

The Pharmacy Act, 1948
The Pharmacy Act, 1948 is meant to regulate the profession of Pharmacy in India.

The Drugs and Magic Remedies (Objectionable Advertisement) Act, 1954
The Drugs and Magic Remedies (Objectionable Advertisement) Act, 1954 provides to control the advertisements regarding drugs; it prohibits the advertising of remedies alleged to possess magic qualities.

The Narcotic Drugs and Psychotropic Substances Act, 1985
The Narcotic Drugs and Psychotropic Substances Act, 1985 is an act concerned with control and regulation of operations relating to Narcotic Drugs and Psychotropic Substances.

Details about Indian Regulations and Guidelines
Indian pharmaceutical sector is rising very rapidly and there is a want of regulatory affairs professionals to provide the current needs of industries for the global competition. It is therefore important to know the following regulations in detail as mentioned below.

1. CDSCO
The Central Drugs Standard Control Organization (CDSCO) is the Central Drug Authority for discharging functions assigned to the Central Government under the Drugs and Cosmetics Act. CDSCO has six zonal offices, four sub-zonal offices, 13 port offices and seven laboratories under its control. Regulatory control over the import of drugs, approval of new drugs and clinical trials, meetings of Drugs Consultative Committee (DCC) and Drugs Technical Advisory Board (DTAB), approval of certain licences as Central Licence Approving Authority is exercised by the CDSCO hqrs.

Functions: Under the Drug and Cosmetics Act, the regulation of manufacture, sale and distribution of Drugs is primarily the concern of the State authorities while the Central Authorities are responsible for approval of New Drugs, Clinical Trials in the country, laying down the standards for Drugs, control over the quality of imported Drugs, coordination of the activities of State Drug Control Organisations and providing expert advice with a view of bring about the uniformity in the enforcement of the Drugs and Cosmetics Act. Drug Controller General of India is responsible for approval of licenses of specified categories of Drugs such as blood and blood products, I. V. Fluids, Vaccine and Sera.\[22\]
2. NPPA

NPPA is an organization of the Government of India which was established, inter alia, to fix/revise the prices of controlled bulk drugs and formulations and to enforce prices and availability of the medicines in the country, under the Drugs (Prices Control) Order, 1995. The organization is also entrusted with the task of recovering amounts overcharged by manufacturers for the controlled drugs from the consumers. It also monitors the prices of decontrolled drugs in order to keep them at reasonable levels.

**Functions**

- To implement and enforce the provisions of the Drugs (Prices Control) Order in accordance with the powers delegated to it.
- To deal with all legal matters arising out of the decisions of the Authority;
- To monitor the availability of drugs, identify shortages, if any, and to take remedial steps;
- To collect/ maintain data on production, exports and imports, market share of individual companies, profitability of companies etc, for bulk drugs and formulations;
- To undertake and/ or sponsor relevant studies in respect of pricing of drugs/pharmaceuticals;
- To recruit/ appoint the officers and other staff members of the Authority, as per rules and procedures laid down by the Government;
- To render advice to the Central Government on changes/ revisions in the drug policy;
- To render assistance to the Central Government in the parliamentary matters relating to the drug pricing.[23]

3. D&C Act 1940

The Drugs and Cosmetics Act, 1940 is an Act of the Parliament of India which regulates the import, manufacture and distribution of drugs in India. The primary objective of the act is to ensure that the drugs and cosmetics sold in India are safe, effective and conform to state quality standards. The related Drugs and Cosmetics Rules, 1945 contains provisions for classification of drugs under given schedules and there are guidelines for the storage, sale, display and prescription of each schedule.[24, 25]

4. Schedule M

Good manufacturing practices and requirements of premises, Plant and equipment for pharmaceutical products. Schedule M is a part of Drug and Cosmetic act 1940. It is GMP for
pharmaceuticals that should be followed by pharmaceutical manufacturing units in India. Schedule M is having the details about company premises, quality control system, quality control laboratories, GMP in production, cleaning of equipments, housekeeping, cross-contamination and other related topics.\[26\]

<table>
<thead>
<tr>
<th>Part-I Good Manufacturing Practices for Premises and Materials</th>
</tr>
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<tbody>
<tr>
<td>General Requirements</td>
</tr>
<tr>
<td>Production Area (New concept)</td>
</tr>
<tr>
<td>Quality Control Area (New concept)</td>
</tr>
<tr>
<td>Health, clothing &amp; sanitation of workers</td>
</tr>
<tr>
<td>Sanitation in the manufacturing Premises</td>
</tr>
<tr>
<td>Equipment</td>
</tr>
<tr>
<td>Labels &amp; other Printed Materials</td>
</tr>
<tr>
<td>Self inspection &amp; internal Quality Audit (New concept)</td>
</tr>
<tr>
<td>Specifications (New concept)</td>
</tr>
<tr>
<td>Batch Processing Record</td>
</tr>
<tr>
<td>SOPs (New concept)</td>
</tr>
<tr>
<td>Reprocessing &amp; Recovery</td>
</tr>
<tr>
<td>Validation &amp; Process Validation (New concept)</td>
</tr>
<tr>
<td>Market Complaints &amp; Adverse Reaction</td>
</tr>
<tr>
<td>PART-IA- Requirements for Manufacture of Parenteral &amp; Ophthalmic Preparations</td>
</tr>
<tr>
<td>PART-IC- Specific Requirements for Manufacture of Oral Liquids</td>
</tr>
<tr>
<td>PART-ID- Specific Requirements for Manufacture of External Preparations</td>
</tr>
<tr>
<td>Part-II Requirements of Plant and Equipments</td>
</tr>
</tbody>
</table>

5. Schedule T

Good manufacturing practices for Ayurvedic, Siddha and Unani Medicines. The Good Manufacturing Practices (GMP) are prescribed as follows

Part I - Good Manufacturing practices

Part II - Requirement of list of machinery, equipment and minimum manufacturing space (A) for Ayurvedic & Siddha system of medicines (B) for Unani system of medicines. (B) for Unani system of medicines.\[27\]

6. GCP guidelines

Good Clinical Practice (GCP) is an international ethical and scientific quality standard for designing, conducting, recording and reporting trials that involve the participation of human subjects. Compliance with this standard provides public assurance that the rights, safety and well-being of trial subjects are protected; consistent with the principles that have their origin in the Declaration of Helsinki, and that the clinical trial data are credible.
The objective of this ICH GCP Guideline is to provide a unified standard for the European Union (EU), Japan and the United States to facilitate the mutual acceptance of clinical data by the regulatory authorities in these jurisdictions. The guideline was developed with consideration of the current good clinical practices of the European Union, Japan, and the United States, as well as those of Australia, Canada, the Nordic countries and the World Health Organization (WHO). This guideline should be followed when generating clinical trial data that are intended to be submitted to regulatory authorities. The principles established in this guideline may also be applied to other clinical investigations that may have an impact on the safety and well-being of human subjects.[28]

7. The Pharmacy Act, 1948
An Act to regulate the profession of pharmacy. Whereas it is expedient to make better provision for the regulation of the profession and practice of pharmacy and for that purpose to constitute Pharmacy Councils.[29]

8. The Drugs and Magic Remedies (Objectionable Advertisement) Act, 1954
An Act to control the advertisement of drugs in certain cases, to prohibit the advertisement for certain purposes of remedies alleged to possess magic qualities and to provide for matters connected therewith. The Drugs and Magic Remedies (Objectionable Advertisements) Act, 1954 is an Act of the Parliament of India which controls advertising of drugs in India. It prohibits advertisements of drugs and remedies that claim to have magical properties, and makes doing so a cognizable offence.[30]

9. The Narcotic Drugs and Psychotropic Substances Act, 1985
An Act to consolidate and amend the law relating to narcotic drugs, to make stringent provisions for the control and regulation of operations relating to narcotic drugs and psychotropic substances 1[, to provide for the forfeiture of property derived from, or used in, illicit traffic in narcotic drugs and psychotropic substances, to implement the provisions of the International Convention on Narcotic Drugs and Psychotropic Substances and for matters connected therewith.[31]

The Narcotic Drugs and Psychotropic Substances Act, commonly referred to as the NDPS Act, is an Act of the Parliament of India that was assented to by President Giani Zail Singh on 16 September 1985, and came into force on 14 November 1985. Under the NDPS Act, it is illegal for a person to produce/manufacture/cultivate, possess, sell, purchase, transport, store,
and/or consume any narcotic drug or psychotropic substance. The Act has been amended thrice - in 1988, 2001 and 2014. The Act extends to the whole of India and it applies also to all Indian citizens outside India and to all persons on ships and aircraft registered in India.[32]

10. The Medicinal and Toilet Preparations Act 1955
An Act to provide for the levy and collection of duties of excise on medicinal and toilet preparations containing alcohol. It also specifies the manufacturing conditions to be maintained for such products.[33]

11. GLP Guidelines
The OECD Principles of Good Laboratory Practice (GLP) ensure the generation of high quality and reliable test data related to the safety of industrial chemical substances and preparations. The principles have been created in the context of harmonizing testing procedures for the Mutual Acceptance of Data (MAD). In the experimental (non-clinical) research arena, the phrase good laboratory practice or GLP specifically refers to a quality system of management controls for research laboratories and organizations to try to ensure the uniformity, consistency, reliability, reproducibility, quality, and integrity of chemical (including pharmaceuticals) non-clinical safety tests; from physio-chemical properties through acute to chronic toxicity tests.

Good Laboratory Practice (GLP) embodies a set of principles that provides a framework within which laboratory studies are planned, performed, monitored, recorded, reported and archived. These studies are undertaken to generate data by which the hazards and risks to users, consumers and third parties, including the environment, can be assessed for pharmaceuticals (only preclinical studies), agrochemicals, cosmetics, food additives, feed additives and contaminants, novel foods, biocides, detergents etc. GLP helps assure regulatory authorities that the data submitted are a true reflection of the results obtained during the study and can therefore be relied upon when making risk/safety assessments.[34]

DISCUSSION
India has become one of the newer countries that have a robust competition regulation. Given the unique nature of the pharmaceutical markets, it is important to understand how competition law applies to this sector. Effective pharmaceutical policy is an essential piece of any country’s legislation, particularly given the increasingly widespread availability of inexpensive prescription medicines. In many low-income countries, formulating policies to legislate and regulate the production, approval and sales of drugs remains challenging.
Differences in legislation between neighboring countries, inadequate administration and enforcement, and a lack of qualified personnel, make this a particularly difficult area for many governments.

The most important aspect of the pharmaceutical industry is that it affects every human’s life and well-being, and therefore ensuring access to end-users is of critical importance.

Deficiencies and Limitations of the current regulatory regime

- Proliferation of spurious and substandard drugs in the Indian market
- Dual licensing mechanism acts as a deterrent to uniform implementation of regulatory procedures
- Lack of transparency in licensing procedures
- Inadequate regulatory expertise and testing facilities to implement uniform standards
- Need for greater thrust on institutional support to small scale firms to enable speedy implementation of Schedule M upgradation and standardization of drug quality.
- Need for greater clarity on patentability of pharmaceutical substances and conditions under which firms can apply for compulsory licenses to prevent legal battles between local firms, MNCs and civil rights groups.
- Need for greater coordination, accountability and transparency in functioning among different ministries concerned with drug regulation.

The Indian pharmaceutical industry is one of the major pharmaceutical industries in the world, both in terms of volume of consumption and value of production. Further, given its critical importance, this industry has attracted significant policy attention. Given the ever changing policy environment, it is only appropriate to assume that the firms also adapt their strategies as per the policy environment, thereby altering the industry dynamics itself.

Recent and Future regulatory initiatives

- Move to establish an integrated regulatory system through the constitution of a National Drug Authority so that quality regulation and price control is performed by the same agency.
- Establishment of pharmacovigilance centers at national, zonal and regional levels to monitor adverse drug reactions.
- Move to bring nearly 374 bulk drugs under price control and regulate trade margins.
- Capability strengthening to monitor clinical trials, including the setting up of the Clinical Trials Registry of India (CTRI).
CONCLUSION

The Indian Pharmaceutical Industry has shown great potential and continues to grow consistently. The Indian generic drug sector is robust and is establishing its presence in foreign markets too. Regulatory Affairs Profession believe the new approach to regulation will eventually be adopted for all healthcare products as it represents the best model for delivering new healthcare advances to market in a reasonable time with acceptable safety. Two main factors determine the extent to which consolidation occurs in the pharmacy sector:

1. Legislation on ownership,
2. Regulation, licensing and registration of pharmacies.

The proper conduct of its Regulatory Affairs activities is therefore of considerable economic importance for the company.

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