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INDIAN PHARMACEUTICAL INDUSTRY REGULATION AND SUPERVISION: ISSUES AND PRACTICES

Asif Amin Kuchey
Al-Falah University, Faridabad, Haryana, India.
Email: aasifkuchey85@gmail.com
Dr. Anisa Jan
Sr. Assistant professor
Islamic University of Science and Technology.
Email: anisa.jan@islamicuniversity.edu.in

ABSTRACT
India is considered as one of the attractive destination for pharmaceutical market in the world. So, it is necessary to have a strict regulation and supervision of Indian pharmaceutical industry. Also, the increasing globalization of Indian pharmaceutical industries has demanded national supervisory authorities to recognize the need for regulation and supervision. This paper tries to study the role of various regulatory bodies and the practices carried out by them to ensure smooth business operations in Indian pharmaceutical industry. It also tries to identify various issues which are halting the growth of Indian pharmaceutical industry.
KEYWORDS: Merger, Acquisition, Globalization, Regulation, Takeovers, Supervision

1. INTRODUCTION

The annual estimation of Indian pharmaceutical industry is about 128044.29 crores in the year 2013-14 out of which 63293.91 crores is the share of export of drugs by Indian pharmaceutical industry. The Indian pharmaceutical industry has shown a lot of development in terms of infrastructure development, technology and in terms of wide range of products.

The Indian domestic industries have recently achieved a milestone through leadership position and global presence as a world class cost effective generic drugs manufacturer of AIDS medicine. Also, the Indian pharmaceutical firms have set high standards in terms of purity, stability and international safety, health, and environment (SHE) protection in production and supply of bulk drugs. A lot of pharmaceutical firms of India have got international regulatory approvals from agencies like USFDA, MHRA-UK, TG-Australia, MCC-SA etc. outside USA India has the highest number of USFDA approved plants for manufacturing generic drugs. A number of leading Indian Pharmaceutical companies derive 50% of their turnover from International business.

The Indian pharmaceuticals market is the third-largest in terms of volume and thirteenth largest in terms of value, as per a report by Equity Master. Branded generics dominate the pharmaceuticals market, constituting nearly 70 to 80 percent of the market. India is the largest provider of generic drugs globally with the Indian generics accounting for 20 percent of global exports in terms of volume. Of late, consolidation has become an important characteristic of the Indian pharmaceutical market as the industry is highly fragmented. India enjoys an important position in the global pharmaceuticals sector. The country also has a large pool of scientists and engineers who have the potential to steer the industry ahead to an even higher level.

The Indian pharmaceutical industry has shown a lot of development in terms of infrastructure development, technology and in terms of wide range of products. Among developing nations, India has one of the advanced and largest pharmaceutical industry. Over the years India has made an extensive investment in infrastructure development, a technological advancement which has made a significant progress in terms of manufacturing quality range of products. It is extremely important to understand the regulatory system in this sector not only due to rapid and continuous changes at international level but, also due to the responsibility on the regulatory bodies to ensure a healthy supply of quality drugs at

affordable prices to the Indian population. So, Indian pharmaceutical regulatory bodies need to match the pace of international regulatory system. In order to do so Indian pharmaceutical bodies has come up with many changes in their regulatory system. These initiatives will play a significant role to put India on the top of the pharmaceutical map.

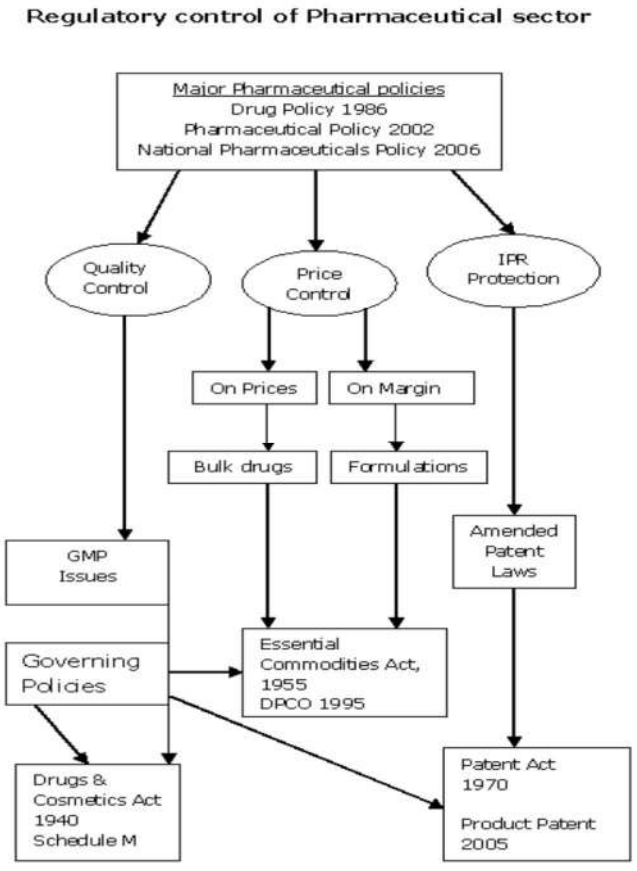
1.2. Objectives of the study

- To study the role of various regulatory bodies and the practices carried out by them to ensure smooth business operations in Indian pharmaceutical industry.
- To identify the various issues that halts the growth of Indian pharmaceutical sector.

1.3. Regulatory Bodies and Policy Environment for Indian Pharmaceutical Industry

The central drugs standard control organization (CDSCO) started in 1940, is the primary regulatory body for Indian pharmaceutical industry. Besides CDSCO, the department of chemicals and petrochemicals which started in 1991 is responsible for handling the policy and planning aspects of chemical, petrochemical, and pharmaceutical industry. Also in order to fix and revise the prices of controlled bulk drugs, National Pharmaceutical Pricing Authority (NPPA) was established in 1994. In addition to these regulatory bodies, following regulatory bodies play a crucial role in regulating the Indian pharmaceutical industry:

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



Source: Adapted from Dun & Bradstreet (D&B) 2007

1.3.1. The Patent Act, 1970

The Act's stated objective was to foster the development of an indigenous Indian pharmaceutical industry and to guarantee that the Indian public had access to low-cost drugs. The Act replaced intellectual property rights laws left over from the British colonial era and ended India's recognition of Western-style "product" patent protection for pharmaceuticals, agricultural products, and atomic energy. Product-specific patents were disregarded in favor of manufacturing "process" patents that allowed Indian companies' to reverse engineer or copy foreign patented drugs without paying a licensing fee. This allowed the domestic industry build up considerable competencies and offers a large number of cheaper "copycat" generic versions legally in India at a fraction of the cost of the drug in the West, as long as they employed a production process that differed from that used by the patent owner. The Act protected process patents for 7 years instead of the usual 15 years needed to develop and test new drugs.

The outline of regulation and policy environment of Indian Pharmaceutical Industry is shown in a table below

CDSCO	Central Drugs Standard Control Organization (CDSCO), Ministry of Health & Family Welfare, Government of India provides general information about drug regulatory requirements in India.
NPPA	Drugs (Price Control) Order 1995 and other orders enforced by National Pharmaceutical Pricing Authority (NPPA), Government of India.
D & C Act, 1940	The Drugs & Cosmetics Act, 1940 regulates the import, manufacture, distribution and sale of drugs in India.
Schedule M	Schedule M of the D&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.
Schedule T	Schedule T of the D&C Act prescribes GMP specifications for the manufacture of Ayurvedic, Siddha and Unani medicines.
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.

Data Protection	TRIPS provides protection for undisclosed information under Intellectual Property Rights (IPR)

1.4. Practices carried out by Indian pharmaceutical industry

The value of Indian pharmaceutical market is valued at Rs. 72069 crores in 2013 as compared to Rs. 65654 crores in 2012. It has experienced a halt with its growth going down to 9.8 % from 16.6 % in 2012 due to new policies formulated by the government of India. The implementation of NPPP National Pharmaceutical Pricing policy 2012 has resulted in profit reduction of retailers from 20 % and 10 % to 16 % and 8 %. This decrease in profit margin has created a substantial uncertainty among many retailers regarding the probability of staying in the business. Also, the pharmaceutical industry is struggling with the issues like delays in clinical trials, FDI policy, and the new pharmaceutical pricing policy, a uniform code for sales and marketing practicing and compulsory licensing.

1.4.1. Clinical Trials

Clinical trials are the standard processes which decide the safety and effectiveness of the drugs. Clinical trials are also required for the Indian pharmaceutical industry to develop cost-effective drugs for diseases like TB, malaria, etc. it also helps the aspiration of developing a sound R&D center.

The delays and regulatory uncertainties have disrupted the innovation curve and the growth of the clinical trial industry. In order to become a major contributor in the global pharmaceutical industry, India needs to speed up clinical trials as well as address other issues which disrupt the growth of Indian pharmaceutical industry.

1.4.2. National Pharmaceutical Pricing Policy

The recommendations made by Dr. Pronab Sen have been considered which resulted in the formation of NPPP. The government has implemented the NPPP to control the pricing of essential drugs. With the help of NPPP government has increased the scope of Drug price control order (DPCO). The NPPP included all the drugs in the National List of Essential Medicine (NLEM) 2011. The purpose of drafting NPPP was to promote research and development of new drugs along with the availability and affordability of new patent medicine for effective treatment of the masses in case of diseases like Cancer and HIV.

1.4.3. FDI Policy

FDI, up to 100 percent, under the automatic route, is allowed for greenfield investments in the pharmaceuticals sector. FDI, up to 100 percent, is permitted for brownfield investment (i.e. investments in existing companies), in the pharmaceutical sector, under the government approval route. The approval for brownfield investment comes under Foreign Investment Promotion Board (FIPB). The conditions laid by FIPB for 100 % brownfield investment are as follows:

- To maintain the production level of National List of Essential Medicine (NLEM) at the highest level for three years preceding the FDI.
- To maintain the R&D expenses at the highest level for three years preceding FDI.
- To share the information regarding the need for transfer of technology to the administrative ministers and FIPB.

1.4.4. Uniform Codes for Sales and Marketing

To prevent the unethical practices and corruption in the pharmaceutical sector the Department of Pharma (DoP) has issued certain guidelines on uniform sales and marketing for pharmaceutical companies which are different from MCI guidelines. Tax authorities use the information given by Central Board of Direct taxes which follow the rules laid by MCI. To remove corruption and unethical practices there is a need for clarity in terms of guidelines issued by both DoP and MCI.

1.4.5. Compulsory Licensing

Compulsory licensing is an important tool in the hands of government to control the price hikes of patent drugs. The objective of compulsory licensing is to ensure the availability and affordability of patent drugs at reasonable prices. The compulsory licensing allows third parties to produce and market patented drugs without the consent of the patent holder. The compulsory licensing can be revoked in India due to non-affordability and unavailability of patent drugs in masses. This will help in the protection of public health especially in the case of chronic diseases like Cancer and AIDS.

Also, India has adopted it on the following grounds under section 84 of the patent act:

- The drug did not meet reasonable requirements of citizens.
- The drug was not reasonably priced, and
- The patent was not locally manufactured.

However, due to these restrictions, there is a derailed growth in the pharmaceutical sector. The government needs to find a right balance between the need for affordability and protection of intellectual property rights.

1.4.6. Quality by Design (QbD) Principle

Quality by Design (QbD) has become a thrust area for the regulatory authority and the pharmaceutical industry for the development of pharmaceutical products. It started in 2004 when FDA released its final report "Pharmaceutical Current Good Manufacturing Practices (CGMPs) for 21st Century: A risk-Based Approach." The purpose of this step was to encourage innovation and implementation of new manufacturing technologies, focus the agency's resources on those areas of pharmaceutical manufacturing considered to pose the most risk, and improve on the consistency and predictability of the agency's work in ensuring drug quality and safety.

QbD principles, when implemented, lead to a successful product development, subsequent prompt regulatory approval, reduce exhaustive validation burden, and significantly reduce post-approval changes. QbD has become a principle in the pharma sector. USFDA has made use of QbD mandatory for generic manufacturing from January, 2013. The regulatory agencies are making it mandatory to build quality into the products during the product development stage itself. The Indian pharmaceutical industry is working hard to adhere to QbD principle as many regulatory agencies across the globe like US FDA, Health Canada, WHO, EMEA, TGA, MHA etc. has already adopted these ICH guidelines. The key elements of QbD include the QTPP, CQAs, QRM, design space, control strategy and continuous improvement, as enumerated in the ICH guidelines, Q8, Q9, Q10 and Q11.

1.5. Issues Related To The Supervision And Regulation

- Price controls
- Delay in approvals for clinical trials
- Counterfeiting
- Post-Marketing Surveillance
- Intellectual property

1.5.1. Price control

As Indian is the price controlled market, the primary issue that many companies face in Indian pharmaceutical market is Price Control. Price controlled drugs are essential medicines, such as antibiotics and painkillers, and drugs used for the treatment of cancer and Asthma. Such medicines contain raw materials whose prices are controlled by NPPA; therefore manufacturer cannot hike prices on their own. While consumers demand that the government should expand the umbrella DPCO, but the industry believes that there is cut throat competition for the prices to be modulated by the market itself. They also believe that the price caps would inhibit the development of R&D in the country as companies would be less inclined to invest in R&D without the possibility of high returns.

1.5.2. Infrastructure

Infrastructure is an important parameter for the growth of any industry all over the world. In Indian pharmaceutical industry, the infrastructure has always been considered as a barrier to growth.

1.5.3. Delay in approvals for clinical trials

Indian is the second largest country in terms of population and nearly 20 percent of the population is burden with global diseases. However, very few clinical trials take place in India. The reason behind it is the regulatory uncertainty with respect to the conduct of clinical trials in the country, which is affecting the growth of the clinical research organization (CRO) industry. As per the report of Drug Controller General of India (DCGI), new drug approvals dropped by 56.25% during 2011 to 98 from 224 in 2010. Also, the DCGI has withdrawn from its role of approving drug trials in the country and has handed over the responsibility to a 10-member new Drug Advisory Committee (NDAC).

1.5.4. Counterfeiting

The counterfeiting of drugs is a major challenge to the regulatory body of Indian pharmaceutical industry. Recently, 294 fixed dose combinations were withdrawn by central drug control authority on the grounds of sub-standard drugs. According to the Mashelkar Committee report which is based on the WHO study, nearly 30% of the Indian market is loaded with superiors/substandard/counterfeited drugs. The main reason behind this is due to lack of transparency in licensing procedures.

1.5.5. Post-Marketing Surveillance/ Pharmacovigilance

According to World Health Organization (WHO), "Pharmacovigilance is defined as the science and activities relating to the detection, assessment, understanding and prevention of adverse effects or any other drug-related problems." Even though in India this system is functional but it ceases to function smoothly. This is because it has limited outreach among patients and medical professionals. The lack of integration between the state and CDSCO makes it difficult for the patients as well as medical practitioners regarding the measures taken after the adverse drug report (ADR) is reported.

1.5.6. Intellectual Property Rights (IPR)

India became obliged to intellectual property rights by signing the WTO accord and hence incorporated necessary provisions to provide product patents since January 1, 2005, after making amendments in the Patent Act of 1970. As per the provisions of TRIPS Agreement, all the member countries have to provide protection to regulatory data submitted for market approval of pharmaceutical products under specific circumstances. The government of India constituted an expert committee under the chairmanship of Mr. Satwant Reddy to formulate adequate steps to deal with the issue of data protection. The Reddy Committee report brought out in 2007, stated that in the context of pharmaceuticals, the present legal regime was inadequate to address the issues related to data protection with respect to Article 39(3) provisions. It also underscored the need for more clear and stringent mechanisms within the Drugs and Cosmetics Act to ensure that undisclosed test data was not put to unfair commercial use in India.

2. METHODOLOGY

The research is of descriptive in nature based on the review of leading studies in the area exploring the issues and practices carried out by Indian pharmaceutical supervising and regulatory body. Secondary data is used for this study. The data was obtained from annual reports, Articles, government reports. The literature was analyzed for the content related to Indian pharmaceutical industry regulation and supervision, their issues and practices.

3. FINDINGS

- The regulatory body of Indian pharmaceutical sector is working hard to protect the interest of common people.
- The anti-counterfeiting program is designed to prevent the counterfeiting of drugs
- The present legal regime is inadequate to prevent Intellectual property
- Lack of infrastructure for conducting Clinical Trials.
- The delay in approval of Clinical trials is also hindering the growth of Indian pharmaceutical industry.
- The Indian regulatory authority works towards the prevention of unethical practices and corruption in the industry.
- The Foreign investment through Greenfield investment is made easy as compared to Brownfield investment.

4. CONCLUSION

The Indian pharmaceutical industry needs strict, efficient and transparent regulatory body for its survival and growth. The Indian state and central government are regulating the pharmaceutical industry. The state government is responsible for regulating manufacturing, sales, and distribution of drugs and on the other hand, the central government is responsible for approvals of a new drug and clinical trials. The central government is also responsible for controlling the import of drugs and coordinating with the state government bodies. Even though Indian has a well structured regulatory body for ensuring the smooth growth of the pharmaceutical industry, still there are certain areas that need to be addressed like Clinical Trials, IPR, counterfeiting of drugs.

India needs strong and transparent regulatory system in the context of patent regime. Presently there is a need to simplify procedures for approvals of new drugs and also fastening of clinical trials. Counterfeiting of drugs is another challenge to the Indian regulatory system. Even though it seems hard to overcome this issue, but it can be minimized by a collaboration of regulatory authorities at international, national and regional level. The issues need to be addressed and necessary steps should be taken to ensure smooth growth of the industry.

Further, the Indian pharmaceutical sector demands harmonization of legal procedures related to drug development, supervision, monitoring and ensuring compliance with statutory obligations. The current scenario demands:

- More centralized drug regulatory system.
- Empowering the regulatory authority
- More infrastructural investment to boost the clinical trials.
- Transparent system
- More liberal policy towards the protection of intellectual property.

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