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The Indian Pharmaceutical Industry; Evolution of Regulatory System and Present Scenario

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Abstract – Indian pharmaceutical industry evolved in true sense only after independence. India is the fourth largest generic pharmaceutical market in the world. Ranking fourth in terms of volume and thirteenth in terms of value in global pharmaceutical markets and is consistently growing. Proper regulatory system ensures the quality, safety and efficacy and standard of medicinal product for sales, importing and manufacturing. India's pharmaceutical industry is one of the most highly regulated industries in the country. Understanding the regulatory scenario is extremely crucial due to the rapid and ongoing changes and due to the burden on the regulatory bodies to ensure a healthy supply of quality drugs at affordable prices to the Indian masses. India's pharmaceutical market was dominated by Western MNCs that controlled between 80 and 90 percent of the market primarily through importation. Approximately 99 percent of all pharmaceutical products under patent in India at the time were held by foreign companies and domestic Indian drug prices were among the highest in the world. According to industry estimates, a great chunk --almost 40 per cent --of machinery used in the pharmaceutical manufacturing in India. This creates a very good local and global opportunity for Gujarat in the manufacturing of pharmaceutical machinery, given its strong and well established engineering sector India. The strong growth prospects of the pharmaceutical exports segment and growing demand from the domestic market, will further fuel growth in the pharmaceutical machinery sector. However, Gujarat's engineering sector is highly fragmented, especially the Pharma-machinery manufacturing segment. Due to the highly fragmented nature, there is a dearth of pricing power and critical scale. This in turn restricts the ability to produce the technology-driven products required for operating in global markets.

Keywords: Pharmaceutical industry, Pharmaceutical Regulatory system in India, Evaluation of Pharmaceutical Industry, Pharma management, Pharma Marketing.

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INTRODUCTION

The pharmaceutical industry is the world's largest industry due to worldwide revenues of approximately US$2.8 trillion. Pharma industry has seen major changes in the recent years that place new demands on payers, providers and manufacturers. The Regulatory Affairs departments of life-science companies ensure that their companies comply with all of the regulations and laws concerning their business. The Regulatory Affairs department is an important part of the organisational structure of pharmaceutical companies. Internally it liaises at the interphase of drug development, manufacturing, marketing and clinical research. Externally it is the key interface between the company and the regulatory authorities.

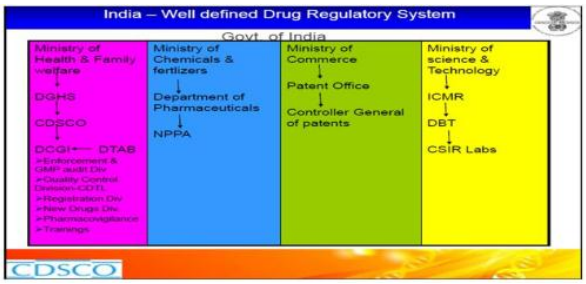
RELATIONSHIP BETWEEN PHARMACEUTICALS AND BIOTECHNOLOGY:

Unlike in other countries, the difference between biotechnology and pharmaceuticals remains fairly defined in India. Bio-tech there still plays the role of pharma's little sister, but many outsiders have high expectations for the future. India accounted for 2% of the $41 billion global biotech market and in 2003 was ranked 3rd in the Asia-Pacific region and 11th in the world in number of biotechs. In 2004-5, the Indian biotech industry saw its revenues grow 37% to $1.1 billion. The Indian biotech market is dominated by biopharmaceuticals; 75% of 2004-5 revenues came from biopharmaceuticals, which saw 30% growth last year. Of the revenues from biopharmaceuticals, vaccines led the way, comprising 47% of sales.

REGULATORY ENVIRONMENT

The principal regulatory body involved in the approval of manufacture, drug development and marketing of quality drugs in India is The Central Drug Standards and Control Organization (CDSCO) under Ministry of Health and Family Welfare which works on developing standards and measures for ensuring the safety, efficacy and quality of drugs, cosmetics, diagnostics and devices in the country. It regulates the market authorization of new drugs and clinical trials standards; supervises drug imports and approves licenses to manufacture the products. At the state level, state drug regulatory authority issues licences to manufacture approved drugs and to monitor the quality of drugs along with CDSCO.

Table -1-Indian Drug Regulatory System



The regulatory bodies involved in the pharmaceutical industry and their functions are as follows

- Drugs Control General of India (DCGI) – Main authority for clinical trials, ensures standards, registers all imported drugs, new drugs, biologics and medical devices.
- Indian Council of Medical Research (ICMR) – main center for biomedical research.
- Genetic Engineering Approval Committee (GEAC) – deals with genetic engineering and molecular biology, trials in which biotech products are used will be referred here by DCGI.
- Department of Biotechnology (DBT)- oversees the development of modern biology and biotechnology in India.
- Atomic Energy Review Board (AERB) – Has regulatory control over radiation equipment.
- Baba Atomic Research Centre (BARC) – approves all radiation related projects and radio pharmaceuticals in India.
- Drugs Consultative Committee (DCC) – Provides technical guidance to the CDSCO.
- Central Drugs Laboratory (CDL)-Maintains quality control of drugs
- Central License Approving Authority (CLAA)– Provides approval for manufacturing licenses'
- Drugs Technical Advisory Board (DTAB) – Provides technical guidance to the CDSCO
- National Pharmaceutical Pricing Authority (NPPA) – NPPA fixes or revises the prices of decontrolled bulk drugs and formulations and periodically updates the list under price control according to guidelines.

EVOLUTION OF PHARMACEUTICAL INDUSTRY IN INDIA

State of the economy:

Economic growth decelerated in 2008-09 to 6.7 per cent. This represented a decline of 2.1 per cent from the average growth rate of 8.8 per cent in the previous five years (2003-04 to 2007-08). The five years of high growth has raised the expectations of the people. Few remember that during slowdown from the average growth of 7.3 per cent per annum during the previous five years, it is the preceding five-year period from 1998-99 to 2002-03 average growth was only 5.4 per cent, while the highest growth rate achieved during the period was 6.7 per cent (in 1998-99). Per capita GDP growth, a proxy for per capita income, which broadly reflects the improvement in the income of the average person, grew by an estimated 4.6 per cent in 2008-09.Though this represents a substantial still significantly higher than the average 3.3 per cent per annum income growth during 1998-99 to 2002-03.

Relevance for growth:

India has the highest number of manufacturing plants approved by US FDA, which is next only to that in the US. More than 85% of the formulations produced in the country are sold in the domestic market. Over60% of India's bulk drug production is exported. India holds the lion's share of the world's contract research business as activity in the Pharmaceutical market continues to explode, over 15prominent contract research organizations (CROs) are now operating in India attracted by her ability to offer efficient R&D on a low cost basis. Thirty five per cent of business is in the field of new drug discovery and the rest 65 per cent of business is in the clinical trials arena. India offers a huge cost advantage in the clinical trials domain compared to Western countries. India got a major boost with the signing of Trade Related Intellectual Property Rights (TRIPS) under the General Agreement on Tariffs and Trade (GATT) in January 2005 with which it began recognizing global patents.

REGULATORY FUNCTIONS

- Regulatory Affairs is actively involved in every stage of development of a new medicine and in the post-marketing activities with authorized medicinal products.
- Regulatory Affairs professionals can play a key role in guiding drug development strategy in an increasingly global environment.
- Regulatory professionals ensure that the information and data to be conveyed and discussed with the regulatory bodies are presented in the right way and form.
- They develop the regulatory strategy, arrange agency meetings, prepare and compile the questions and briefing documents; they attend the meetings and manage all communication with the agencies.
- Since the regulatory environment is constantly changing the regulatory team provides advice on necessary adaptations to development plans and target product profiles.
- Many aspects in India are not regulatory intensive, these may lead to supply of poor quality pharmaceutical agents to the patients. There is no way to check the quality of drugs after 4 years from the date of first introduction in India.
- During this 4-year period the drugs will be under ―new drug‖ category and they require bioequivalence and if necessary clinical studies are conducted.
- Those drugs which are called ―old drugs‖ after this 4-year period, need not be subjected to bioequivalence studies and they can be permitted to market without these stringent requirements as compared to new drugs.
- Evolution of regulatory system changes the industry in any country and encourages people to do more to discover and invent new drugs for emerging diseases. India is rich in biodiversity and plants with high medicinal values.
- The USFDA is responsible for giving rise to the most competitive pharmaceutical industry in the world. They set standards so that doctors and patients are not afraid of using new drugs.

Regulatory Approval in India

The drug approval process in India has faced challenges in recent years, some around compulsory licensing of patents, government price control and narrow standards for patentability. Other issues have also occurred in the clinical trials area, which, despite India's high treatment-naïve population and emerging economy, have reduced pharmaceutical sponsors' interest in India as a priority area in which to conduct clinical studies. The international regulatory organizations play essential role in all aspects of pharmaceutical regulations related to drug product registration, manufacturing, distribution, price control, marketing, research and development, and intellectual property protection.

A cursory overview of the Indian drug regulatory process is as follows

Currently, the Drug Controller General of India (DCGI) requires a confirmatory Phase III study that includes a proportion of local patients, although if Indians are included in multinational trials this can be avoided and decided on a case-by-case basis. The Central Drug Standard Control Organization (CDSCO) handles the approval process. Apart from the CDSCO approval, DCGI has given rights to each state's drug control authority to regulate the manufacture, sale and distribution of drugs. The states include North India: Jammu and Kashmir, Himachal Pradesh, Uttaranchal, Haryana, Panjab; South India: Kerala, Tamilnadu, Karnataka, Andhrapradesh; East India: West Bengal, Assam, Arunachal Pradesh, Nagaland, Manipur, Mizoram, Tripura, Jharkhand, Bihar, Orrisa; West India: Gujarat, Rajasthan, Maharashtra; and Middle India: Madhya Pradesh, Chhattisgarh. However, final authority does rest with DCGI. The first occurred when a principal investigator was found to have generated fraudulent data and referring patients from a government hospital where he was working, to his private clinic to gain more income. Meanwhile, amendments to clinical trial regulations under the Drugs and Cosmetics Rules (Third Amendment) were introduced in February 2013. The objective was to improve patient safety, reporting timeliness of serious adverse events including deaths during clinical trials, and the payment of compensation to patients. The amendment resulted in several concerns for researchers and research organizations around the areas of financial compensation and liability of the trial researchers. Because of these changes to the regulatory framework, many multinationals withdrew their clinical studies from India. This resulted in a standstill for the entire clinical research industry in India. Regulatory authorities act as a guardian that ensures the safety, efficacy and quality of drugs available to the public, to identify the strengths and weaknesses of drug

regulation and to propose strategies to improve drug regulations.

INDIAN PHARMACEUTICAL INDUSTRY:

It is often said that the pharma sector has no cyclical factor attached to it. Irrespective of whether the economy is in a downturn or in an upturn, the general belief is that demand for drugs is likely to grow steadily over the long-term. The Indian pharmaceutical sector has come a long way, being almost non-existent before 1970 to a prominent provider of healthcare products, meeting almost 95 per cent of the Country's pharmaceuticals needs. The Industry today is in the front rank of India's science-based industries with wide ranging Capabilities in the complex field of drug manufacture and technology. It ranks very high in the third world, in terms of technology, quality and range of medicines manufactured. The Indian pharmaceutical industry is the world's fourth-largest by volume and is likely to lead the manufacturing sector of India. The number of purely Indian pharma companies is fairly low. Indian pharma industry is mainly operated as well as controlled by dominant foreign companies having subsidiaries in India due to availability of cheap labour in India at lowest cost. In 2002, over 20,000 registered drug manufacturers in India sold $9 billion worth of formulations and bulk drugs. 85% of these formulations were sold in India while over 60% of the bulk drugs were exported, mostly to the United States and Russia. Most of the players in the market are small-to-medium enterprises; 250 of the largest companies control 70% of the Indian market. The government started to encourage the growth of drug manufacturing by Indian companies in the early 1960s and with the Patents Act in 1970.

Functions of Pharmaceutical Management

Figure- 1 Function of Pharma Management

Types of Pharmaceutical Management

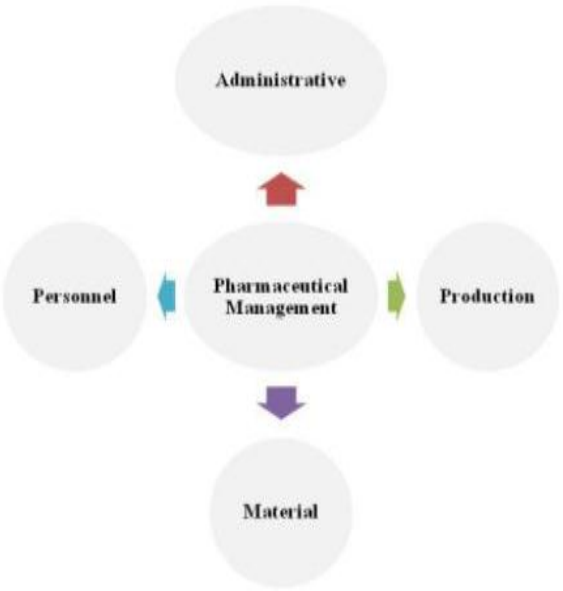


Figure- 2 Pharma Management

CONCLUSION

This integration is opening up tremendous new opportunities for Indian Pharma across all segments including generics, research and development of New Chemical Entities (NCE) & New Biological Entities (NBE) and Contract Research and Manufacturing Services (CRAMS). Indian companies are now well positioned to explore these opportunities as they adopt effective and efficient business models that are spread across one or more of each of these segments. Regulatory agencies and organizations around the world need to ensure the safety, quality and efficacy of medicines and medical devices, harmonization of legal procedures related to drug development, monitoring and ensuring compliance with statutory obligations. The major challenges of these regulatory bodies are to promote public health and protect the public from harmful and dubious drugs. To establish proper legalization covering all products with a medicinal claim and all relevant pharmaceutical activities, whether carried out by the public or the private sector. To increase worldwide regulatory growth to ensure safety of people.

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