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INDIAN PHARMACEUTICAL INDUSTRY- GEARING FOR THE NEXT LEVEL

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ABSTRACT

This article explores the evolution of Indian Pharmaceutical Industry right from its inception and how it marked its presence in the world market with new technologies, fostering innovation through new ways of product development, customer reach, interaction and partnerships globally. Cost of production of drugs in India is nearly 33 per cent lower than that of the US because cost of labour in India is 50–55 per cent cheaper in comparison to that in the western countries. It is also seen that the skilled workforce as well as managerial & technical competence in India is much higher in comparison to its peers in Asia. In addition to these cost of setting up a production plant in India is 40 per cent lower than in western countries. This makes it cost-efficient to create opportunities in emerging markets & Africa. India has the 2nd largest number of USFDA-approved manufacturing plants outside the US and has 2,633 FDA-approved drug products. India has over 546 USFDA-approved company sites, the highest number outside the US. India's biotechnology industry which comprises of bio-pharmaceuticals, bio-industry, bio-services, bio-agriculture and bioinformatics is expected grow at an average growth rate of around 30 per cent a year and reach US$ 100 billion by 2025. However, Bio-pharma which includes vaccines, therapeutics and diagnostics, is the largest sub-sector with nearly 62 per cent of the total revenues at Rs 12,600 crore. The Indian government with the initiative to bring down health expenses has taken many steps to reduce costs by speedy introduction of generic drugs into the market. The emphasis on rural health programmes, lifesaving drugs and preventive vaccines also acts as a catalyst for the pharmaceutical companies.

Key words: Pharmaceutical industry, licensing, chronic formulation, ailments, prescriptions, drug manufacturers, symptoms, global leader.

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I. Introduction

India has an efficient pharmaceutical industry which started from a small room in Kolkata, presently accounts for 10 percent in volume terms and 2.4 percent of in value terms of the world market. The Present market size of the Indian pharmaceutical sector is USD 20 billion and expected to reach USD 55 billion by the year 2020 with a compound annual growth rate (CAGR) of 15.92 per cent between 2015 and 2020. It is projected to grow more than the annual growth rate of the world pharmaceutical sector, which is estimated about 5 per cent between same period. Joining hands the private-pharma sector and the Government will certainly take the Indian Pharmaceutical Industry to new heights with advanced technology and research providing affordable health care to all citizens of the country. The expected growth is much higher in chronic formulation segment than the traditional acute formulation segment. The increasing demand for quality health care and the size of the population are some of the other favorable domestic market conditions in India.

II. Methods & Methodology

These pages are concerned with the evolution of the Pharmaceutical Industry in India. This is a huge topic, worthy of a whole text book, and we cannot here do more than provide some basic information about its different phases of growth and problems faced by it. These pages are concerned with information provided by different journals, research paper and Indian National Bulletins. They do not pretend to be exhaustive, but aim to give broad direction and a starting point for those who want to go for detailed study and analysis of this segment.

III. Pharmaceutical Industry- Pre Liberalisation

In India the history of medicine dates back to early iron age containing prescriptions of herbs for various ailments. These traditional herbal practices to treat ailments together with a massive addition of theoretical conceptualizations later formed a large part of Ayurveda. Allopathic medication was introduced in the country during the British regime. But production of such medicines was not in the country so the allopatheic medicines were provided by the foreign country manufactures using the raw materials imported from India.

The foundation of Pharmaceutical Industry was laid by Prafulla Chandra Ray who founded Bengal Chemical Works in a rented house at, Kolkata in 1892. The company was started with a initial capital of ₹700 with the intention with fostering a spirit of entrepreneurship among the Bengali youth, and provide an alternative to jobs from the colonial British government. The company presented its herbal products in 1893 session of the Indian Medical Congress held in Kolkata. This boosted the reputation of the company and more fund were added to increase the scale of production. The business was converted into a Limited Company, and on 12 April 1901 the company was renamed Bengal Chemical and Pharmaceutical Works Ltd. (BCPW). The management of the company was taken over by the government of India on 15 December 1977 and nationalized on 15 December 1980. A new company was formed under the name "Bengal Chemicals & Pharmaceuticals Ltd." (BCPL) in 1981 and still today is one of the 5 government-owned drug manufacturers.

This venture opened the door for many Indian entrepreneurs to start pharma companies in India, the segment which was left untapped by the entrepreneurs. The Alembic Chemical Works in Baroda started in 1907, followed by Bengal Immunity in 1919. These ventures paved the path for many more in upcoming years making a promising foundation for Indian pharmaceutical industries. This initial achievement of Indian Pharma companies could meet only 13% of local demand. Rest of the medical demand was to be met by the supplies from the foreign companies.The foreign supply of medicines later on got disrupted due to the break of the World War II (1939-1945) which led to rise of number of pharmaceutical companies in the country. To cater the local demand companies like Unichem, Chemo Pharmaceuticals, Zandu Pharmaceutical work, Calcutta Chemicals, Standard Chemicals, Chemical Industrial and Pharmaceutical Laboratories (Cipla), East India Pharmaceutical Works etc came into existence. These companies were able to achieve the 70% of the countries drug requirement before independence.

With the thrust in the area of research and development, the pharmaceutical sector observed a tremendous growth world wide after 1950s. The entry of first oral contraceptive, "The Pill", tranquilizers, Cortisone, blood-pressure drugs and other heart medications in the market created more opportunities for the pharmaceutical companies globally. The new research of drugs led to the systematic approach in medicine that included treating the symptoms to treat for the diseases

itself. The major contributions was made by countries like Germany, Switzerland, UK and to some extent US which focused on research and development rather than in building more and more production units. The Indian Pharma sector was far behind their western counterparts as their were lack of adequate capital and new technologies.

The Indian Pharma sector was far behind their western counterparts as their were dearth of capital and new technologies. The rapid industrialization of the country along with the liberalizations in the government policies encouraged many foreign companies to invest in Indian sector. With the government interventions and foreign investors in the Indian economy, Indian pharmaceutical sector could grow from Rs 10 crore in 1947 to Rs 35 crore in 1952.

The Government of India observed that in the Pharma sector the Multinational Companies (MNCs) are only marketing in India and are not helpful in building domestic competencies. A new strategy was formulated giving the public sector firms leading role for building up the pharmaceutical industry. The Industrial Policy Resolution of 1956 classified industries into three categories based on their priorities. The public sector industries were exclusively kept in"Schedule A" whereas "Schedule B" consisted of industries of private sector along with public sector playing a lead role to supplement the efforts of the State. Rest of the industries were left in "Schedule C" who were dependent on private initiatives. The pharmaceutical industry fell under Schedule B and was strictly regulated through industrial licensing.

Government of India to promote research tried to attract multinational companies to invest in India acknowledging the dearth of capital and modern technology. The rapid industrialization of the country along with the liberalizations in government policies, many foreign companies came forward to invest in Indian Pharma sector. Industry observed, invention of new drugs and commercialization of these newly invented drugs like Penicillin and other synthetic drugs opened new doors. Further in the licensing policy, it was mandatory for the MNC's to produce the final drug in the local units keeping into an account of the medicinal need of the country. This resulted in the emergence of new units as well as expansion of existing ones leading to growth up to Rs 100 crore in 1962.

Hindustan Antibiotics Ltd. (HAL) and Indian Drugs and Pharmaceuticals Ltd (IDPL) are among the five public sector companies established with foreign technical assistance like USSR, WHO & UNICEF to provide affordable drugs throughout the country. It focused on bulk production of drugs like Penicillin, Streptomycin sulphate, Penicillin-G, 6-APA and Ampicillin. Discovery of two new molecules namely Hamycin and Aurofungin were another feather in its cap. The public pharma companies played a pioneering infrastructural role in the growth of Indian drug industry. A number of research bodies aiming to provide a research base in the region was formed by the Indian government. ICMR, one of the oldest medical research bodies in the world for formulation, coordination and promotion of biomedical research in India was established. This was followed by Council of Scientific and Industrial research, established in 1942 with the mission to provide scientific industrial research and development that maximizes the economic, environmental and societal benefits for the people of India. These two institutes acted as guide to number of research organisation like Central Drug Research Institute (CDRI), Indian Institute of Chemical Technology (IICT) and National Chemical Laboratory (NCL) are among the few. To accelerate the research process, number of products were transferred to private units. The effort of these research institutes benefited the pharmaceutical Industries and its growth sore to Rs 72 crore for bulk drug and Rs 370 crore for formulation in 1972. Inspite of several efforts, the pharmaceutical companies in the region lagged behind MNC's in the profit share as MNC's were more with high value products taking advantage of Product Patent. To overcome these differences in profit share government of India changed the policy and process of patent and reduced the life of the patent. To have control over the drug, the innovator companies patent a large number of processes so as to prevent others from manufacturing the product, so the Indian pharmaceutical companies started developing new process to produce the drug in India. Eli Lilly protected its anti-infective drug, Cefaclor through 32 processes, still Ranbaxy managed to develop a new process which gained Ranbaxy international fame. This helped the Indian pharma companies break the control of the MNC's over the Indian sector and move on for a vast expansion. This was further catalysed by the subsidies and facilities provided by the government to spread it to other states also. This was welcomed by new products in different segments of ailment and by the heavy export demand the sector got huge boost. The government further revised the policy in 1980's to increase the number of private players. Due to its low cost products and bulk manufacturing, the sector emerged as global leader.

IV. Growth of Pharma Sector- Post Liberalisation

The Indian pharmaceutical sector saw many changes due to the liberalization of market. It paved way for the Indian companies to start operating in foreign countries. The liberalisation measures of July 1991 were implemented in the pharmaceutical sector in 1994 with the modification in Drug Policy 1986. The new features adopted were abolition of industrial licensing for all bulk drugs and their intermediaries and for all formulations except specific cell/ tissue-targeted ones, promotion of indigenous bulk drugs, abolition of restrictions on import of drugs and pharmaceuticals, reduction in tariffs for the import of pharmaceuticals, automatic approval of foreign direct investment (FDI) up to 100%; and relaxation of the drug price control mechanism. The industry became export-oriented and the share of exports in sales steadily grew from 15% in 1993-94 to 41% in 2009-10

It was observed that exports of bulk drugs and formulations were growing at higher rates after 2005 than in the years between 1994-2005 which was due to the outsourcing of API production by MNC's. Foreign Pharma companies were keen to outsource their production for cost consideration. India become a favourable destination as it had the largest number of FDA-approved plants outside the US. According to reports, in 2005, India had 60 FDA-approved plants whereas its competitor China had only 22.

For the Indian Pharma companies, US became the most desired export destination for both bulk drugs and formulations due to Hatch-Waxman Act. According to this Act, in US, to market a generic drug, a company is required to file ANDA (an abbreviated new drug application) to certify that its product is not infringing any patent rights or that a patent is invalid. If the country is the first to get approval for the generic version, it gets exclusive market for 180 days during which no other generic company is permitted to enter the market which brought immense profits to a company. Ranbaxy was the first Indian Pharma company to obtain 180 days exclusive right for the fluoxetine 40 mg. But it could not launch the product on time. Dr Reddy launched this drug in August 2001 due to which Dr Reddy slated rise in sales of generics drugs from Rs 304 million in 2000-01 to Rs 4,066 million in 2001-02.

Lured by Dr Reddy's profit, Cipla also followed the same foot steps. By 2003, 161 ANDAs were filed by only four companies – Ranbaxy, Dr Reddy's, Wockhardt and Lupin. This number went up to 701 ANDAs which was filed by 17 companies in the second quarter of 2007. ANDA approvals held by Indian firms as a percentage of total approvals went up sharply from 7% in 2001 to 21% in 2006 and 30% in 2008, and to 1000 approvals in 2018

Department of Pharmaceuticals was framed under the Ministry of Chemicals & Fertilizers which came into being w.e.f. 1st July 2008 with the objective to regulate various complex issues related to pricing and availability of medicines at affordable prices, to give greater focus and thrust on the development of pharmaceutical sector in the country and for protection of intellectual property rights and number of issues related to pharmaceutical sector. The Department got divided into three Divisions viz. Pharmaceuticals Industry Division, Public Sector Undertakings Division and R& D Division constituting National Institute of Pharmaceutical Education & Research (NIPER) and Research & Development. Pharma exports rose to record CAGR of 11.9% for year ending 2015-16 and this is expected to be of worth Re 105.7 billion during 2016-19. The Annual turnover of the Indian Pharma Industry was 1,85,388 crores during 2015-16. It represented a decline of 7.4% over the year for 2014-15 i.e. 2,00,151 crores. The CAGR for last 5 financial years was 8.88%.

The government effort to bring medicines affordable for common man and the increasing operating expenses has impacted negatively on the profit margin of the pharma companies during last couple of financial years. There has been observed a slow growth of only 2.9 per cent in the September 2016 quarter. Owing to the downward pricing pressure and escalating manufacturing cost in pharma sector prevailing world wide, the industry is facing challenges and is forced to adopt new methods of research, technology, manufacture, marketing etc. The environmental concern is also putting pressure on this sector due to factors like pollution, scarce resource and disposal of waste materials etc.

Opposite to domestic market, the pharma export grew at a CAGR of 11.9 per cent during the Financial year 2015-16 owing to the change in patent policy, rise in the number of drug approvals and access to new foreign markets. But the following years, the drug exports started

declining and fell by one per cent due to price erosion in the US market and stiffening of the regulatory mechanism in the foreign market. The export market of the pharma companies, further got shadowed due to the emerging markets economic crisis. The preceding years saw a decline in drug imports on account of withdrawal of customs duty exemption on a total of 71 drugs by the government. This was to back the local production, and reduce the dependence on drug imports. During the year 2016-17, drug imports declined by 9.3 %.

An important factor contributing to the growth in exports of bulk drugs in the last few years has been the outsourcing of API production by MNCs. The Pharma industry expanded its capacity to manufacture active pharmaceuticals ingredients (API) or bulk drugs manufacturing to become self-sufficient with respect to API requirements. The industry commissioned 11 projects in 2016 involving an investment outlay of Rs.11.6 billion. Glaxosmithkline Pharmaceuticals, Shantha Biotechnics, Cipla Biotec and Aurobindo Pharma are some of the companies which completed their projects during the period. It completed projects worth Rs.17.5 billion by March 2017 and projects worth Rs.45.1 billion completed in 2017-18, followed by projects worth Rs.31.5 billion to come up in 2018-19.

V. Future Prospects of Indian Pharma Companies

Indian Pharma sector has faced various challenges and amidst number of turbulence in the global as well as domestic front making it stronger with each passing year. Currently the Pharma companies are facing tough time due to the recent pricing regimes by the Indian Government. The Department of Pharmaceuticals had notified the National Pharmaceutical Pricing Policy-2012 (NPPP-2012) to regulate pricing of drugs to ensure availability of required medicines i.e. essential medicines at reasonable prices bringing 348 drugs into India's National List of Essential Medicines. The government aims to fulfill this by meeting the goals of employment and shared economic well being for all.

The growth challenges of the pharmaceutical industry is also grappling with number of issues like delays in clinical trial approvals, FDI policy, pricing policy, a uniform code for sales and marketing practices and compulsory licensing. The industry is also facing stricter regulations on manufacturing and quality practices in the domestic as well as the international markets. The

pharma sector also got tainted by the reports of quality of medicines and production of fake drugs. Indian government amended the drug policy to maintain good quality manufacturing processes and to produce products as per the WHO standards. Inspite of these hurdles a PriceWaterhouseCooper's (PWC) report stated the value of the sector would reach US $ 74 billion by 2020.

Goods and Services Tax of the country benefited most of the sectors and make the taxation process easier as it replaces a number of different taxes and duties. The Indian Healthcare Industry is now among of the major sectors with respect to revenue and employment. As the expenditure on the Healthcare increases, so do revenues from taxes. Recently, the Government of India decided for the implementation of GST, which would merge various taxes of the complex tax system in the country into one uniform tax system. GST has a constructive effect on the Pharma sector by streamlining the taxation structure as 8 different types of taxes imposed on the Pharmaceutical Industry amalgamated into one uniform tax providing ease way of doing business in the country. GST also help the Pharmaceutical companies in rationalising their supply chain. The biggest advantage for the companies is the reduction in the overall transaction costs with the withdrawal of CST (Central Sales Tax). It is also expected that GST will lower the manufacturing cost. Currently, the technical machinery and equipment which are imported into the country by the healthcare sector are very costly, however, with GST duty charged on the import of such equipment and machinery is allowed as a credit.

Indian Pharma companies have built their fortunes by exporting to US markets. Currently, over 40% of the four top Indian drugmakers' revenues comes from the US market. However, In the international front, the Trump effect has started putting restrictions for the pharma growth. India exports generic drugs worth $12.5 billion annually through out the world and the U.S is a big market of it. President Donald Trump emphasis on manufacturing drugs locally in America could be a target in the border adjustment tax that Republican lawmakers are trying to impose on imports. This "Buy American" move could affect the largest market for Indian pharmaceutical companies. But the strong political support and stable economic growth is creating enormous opportunities for the Indian pharma especially opportunities for Generics as bulk drug exports and for off patent products will increase tremendously.

VI. Conclusion

Indian pharmaceutical industry is the third largest, in terms of volume and it is number thirteen in terms of value in the world market. It is dominated by branded generic drugs contributing 70 percent of market share in terms of revenue. The over the counter (OTC) drug market contribute 9 percent where as patented drug market contribute 21 percent of total USD 20 billion revenue. Indian Pharmaceutical export market is thriving due to the strong presence in the generic market, which supplies about 20 percent of the global market in terms of volume.

The government has launched a flagship National Health Protection Scheme to cover over 10 crore poor and vulnerable families, benefiting approximately 50 crore people, providing coverage up to Rs 5 lakh per family per year. This health insurance scheme will introduce innovative methods in marketing and sales of the drugs and the distribution, to penetrate into the rural area of India. It will further improve the market share of Indian pharmaceutical companies and the availability of the needed medicines to the rural population. Rashtriya Swasthya Bima Yojana (RSBY) a Health Insurance Scheme for the below poverty line families with the objectives to increase access to health care by providing financial protection against costs for hospitalization and other vulnerable groups. India also perceives itself as becoming a knowledge hub for Pharma. R&D and clinical trials in particular are important pillars for this ambition. India as a diverse country and vulnerable to varied disease, comparative cost advantage, is also a favourable destination for conducting clinical trials. However, the regulatory policies and the delays in approvals regarding clinical trials are adversely affecting this possibility.

'Pharma Vision 2020', is the Indian Government policy for growth of pharma industries which aims to make India a global leader in drug manufacturing for domestic as well as global market. It is going to be proved as the most prosperous sector. Foreign Direct Investment (FDI) Policy amended in 2016 allows Pharmaceutical Companies for Greenfield Pharma Projects to invest 100% FDI through automatic route and for Brownfield Pharma Projects foreign investment upto 74% under automatic route and beyond that the companies have to come through government route. Along with this the ease of doing business with an upward trend in Government expenditure are few positive fundamentals which are favoring growth in the industry.

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