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Pharmaceutical Policy in India: Evolution and Development

Dr. Pulapalli Venkataramana

Principal, GDC, Chanchalguda, Hyderabad

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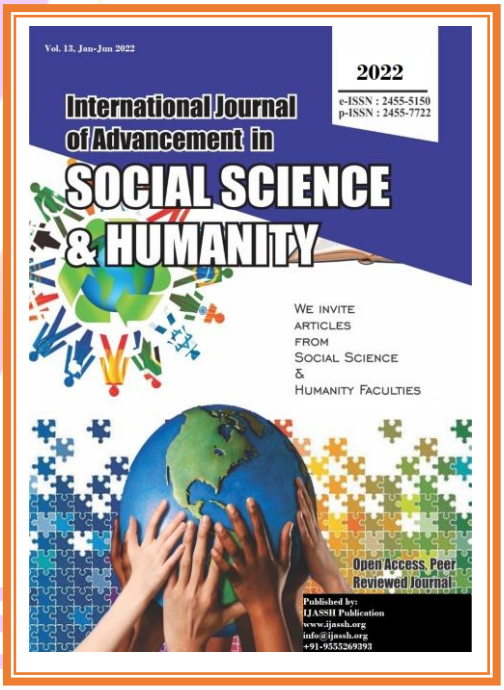

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INTRODUCTION

The pharmaceutical sector is another important sector that contributes to the macroeconomic growth in India and significantly influenced by the Trade Related Intellectual Property Rights (TRIPs) agreement of the World Trade Organization (WTO). Indian Health and Pharmaceutical Sector is a combination of public and private management. While the private sector operates many hospital services and manufacture drugs and pharmaceuticals, the public sector is mostly confined to hospital services, preventive medicine, and immunization so on. The average medical expenditure for treatment including hospitalization is many times more in the private sector than the public sector.

Indian Health and pharmaceutical industry is guided by a strict policy framework. Indian Drugs and Cosmetics Act - 1940, Indian Patents Act – 1970, National Pharmaceutical Policy 2006 and Draft Pharmaceutical Policy – 2017 are some of the major policy initiatives that influence and control the Indian Pharmaceutical Industry. These measures made adequate provisions for compulsory licensing from the government and facilitated exports to other countries. As a result of this, the size of the Indian Pharmaceutical Industry is enormously expanded only next after U.S.A. and European Countries and is emerging like Brazil, China, Mexico, Russia, South Korea and Turkey. Thus India is acknowledged as an emerging leader of the global pharmaceutical industry.

The TRIPS agreement brought changes in the Indian legal framework, pertaining to drugs and pharmaceuticals particularly in patents regime. The Indian Pharmaceutical Industry produced certain giants in the global market: It also manufactures generic medicines and exports them to various countries of the world In view of this, the government also insists on a strict regulatory framework on pharma sector in matters of quality medicines and price control. The giant multinational pharma industries are involved in Research and Development and make clinical trials as another allied sector.

THE INDIAN PHARMA INDUSTRY

The Indian Drugs and Pharmaceutical Sector is one of the most important sectors of the Indian economy in terms of meeting the health needs of the people and projected revenue growth. This sector is developed by successive governments both before and after Indian independence. The Bengal Chemical and Pharmaceutical Works (Calcutta), Kings Institute of Pharmaceuticals (Coornoor) and Central Drug Research Institute (Kasauli) were the prime institutes before independence. During the initial decades of Post Independence Period, Public Sector Companies like Hindustan Antibiotics Limited (HAnL) and Indian Drugs and Pharmaceuticals Limited (IDPL) are set up to meet the medicinal demands of people with indigenous production. Governments of post independence period have promoted the Drugs and Pharmaceutical Sector through direct investment, Intellectual property Protection, Price Regulation and Scientific Research.

The Indian Drugs and Pharmaceutical Sector provides for the growth of the Private Sector that captured a substantial

share in domestic and external markets. The public sector is gradually overtaken by private players due to so many factors such as conducive regulatory environment, low-cost innovation, access to finance from banks etc. Indian owned firms currently account for 70 percent of the domestic market. During the year 2005, nine of the 10 companies in India are domestically owned compared to just 4 in 1994[1].

The Indian Pharmaceutical Industry has achieved self-sufficiency and emerged as one of the largest exporters of Drugs and Pharma products in the world. It is providing employment to millions of people and also indirectly helping thousands of ancillary enterprises in India. India is home for certain unique systems of medicines such as Ayurveda, Unani, Siddha, Naturopathy, etc. As a result, India is also emerging itself as a destination for health tourism market and has derived estimated 333 million dollars revenue in 2004.

Over the years, India has emerged as the largest exporter of quality generic medicines in the world. The issue of access to medicines is crucial not only for India but also for other developing countries. In the process of Reverse Engineering, the generic medicines are produced and this could be attributed to the exclusion of product patents in the Indian Patents Act 1970. This has resulted in the establishment of vigorous generic industry in India which could meet not only domestic demand for drugs at lower prices but could also export cheaper drugs to other countries (mostly to Third World Countries) [2].

In the Post Liberalization Period (from 1990 onwards) economic reforms facilitated the Drug and Pharmaceutical Industry to consolidate itself with 100 percent Foreign Direct Investment (FDI), the abolition of Industrial Licensing System, Liberalization of rules pertaining to foreign technology agreements and tie-ups etc. A significant step in this direction is the honoring of International Commitments through the Agreements reached in the World Trade Organization (WTO). A concrete regulatory mechanism is sought to be introduced through these agreements for the protection of product-based patents. All these developments have consolidated the position of India as a preferred global destination for pharmaceutical manufacturing and research and development. Signifying the growing importance of this sector, the government has also created a separate department of pharmaceuticals. As a result of these developments, Multinational Companies evinced keen interest in capturing the Indian market. The Multinational Companies also viewing India is an attractive destination for Research and Development, particularly for the conduct of clinical trials. Coupled with this, the medicinal needs of over one billion people, rising affluence, growing middle classes and changing lifestyles also offer huge potential for the growth of the pharmaceutical industry in India. During the year 2013-14, the size of the Indian Pharmaceutical Industry is estimated to be 14.56 billion dollars and the Pharmaceutical Export Promotion Council proposed to enhance this size to 84.9 billion dollars by 2020.

Presently, the Indian Drug and Pharmaceutical Industry has 4,655 production units employing 345 thousand workers. Indian Pharma Industry has a

good pool of Scientists and Engineers who have the potential to promote the technical know-how in realizing the targets[3]. Indian Pharma is the third largest in volume and 13th largest in value in the world and is dominated by branded generic medicines which constitute nearly 70 – 80 percent of the total market. Due to this voluminous growth, Indian Pharma is also attracting international orders for medicines. For instance, the UN backed Medicines Patents Pools has signed 6 sub-licenses with firms such as Aurobindo, Cipla, Desano, Emcure, Hetero Labs and Laurus Labs allowing them to make generic Anti-AIDS medicine Tenofovir Alafenamide (TAF) for 112 developing countries.

PHARMACEUTICAL POLICY IN INDIA: EVOLUTION AND DEVELOPMENT

The Government of India has been outlining the Drug and Pharmaceutical Policies through various legislative enactments, policy initiatives and executive orders. All these are intended to control, regulate, and make the medicines accessible to people with fair prices and strengthen the quality of medicines.

Among the policy initiatives that the Union Government undertook include a) Drugs and Cosmetics Act (1940), b) Essential Commodities Act (1955), c) National Institute of Pharmaceutical Education and Research (NIPER) Act (1998), d) Drugs (price control) Orders (1975, 1979, 2013), e) National Drug Policy (1986), f) National Pharmaceutical Policy (2002), g) National Pharmaceutical Pricing Policy (2012) and Draft Pharmaceutical Policy (2017) and so on. These are important for the promotion of pharmaceutical industry in India. More recently, the Indian Government has undertaken the Drugs and Cosmetics (Amendment) Bill, 2015. These legislative and executive initiatives have provided a comprehensive scope for the expansion of pharma sector in India.

The Drugs and Cosmetics Act 1940 and Drugs and Cosmetics Rules 1945 have clearly defined the role of the government in activities of regulation, manufacturing, distribution and sale of drugs and cosmetics in India. The Act has also provided for establishing an administrative structure with certain institutions such as a) The Drugs Technical Advisory Board; b) The Central Drugs Laboratory; c) The Drugs Consultative Committee; and d) Ayurvedic, Siddha and Unani Consultative Committee and so on.

The Essential Commodities Act 1955 also provides for controlling the pharma sector by the government. It provides a list of 15 items on which the government has control on production, supply, distribution etc., of essential commodities for maintaining or increasing supplies and for securing equitable distribution and availability of these listed commodities at fair prices. Using this Act, the Ministry of Health and Family Welfare (Director General of Health Services) and Ministry of Chemicals and Fertilizers (Department of Pharmaceuticals) issue control orders pertaining to regulating the production, distribution, quality management etc., with regard to drugs and pharmaceuticals. The Amended Act 1980 also prevent unethical practices like hoarding and black marketing of drugs and pharma products which are declared as essential commodities for people.

The Indian Patents Act of 1970 and the National Drug Policy of 1978 (first comprehensive policy) paved the way for the progress of Indigenous Research and Development (R & D) in the pharma sector in India. This has enhanced its ability to develop generic drugs during 1970-1990. Particularly the Indian Patents Act of 1970, which recognized process patents, but not product patents has paved the way for such progress. In fact, the patent regime during these decades had encouraged reverse engineering and the development of alternative processes for products patented in other countries[4].

POLICY FRAMEWORK – CONSEQUENT CHANGES

Indian Patents Act (1970) was amended in 1999, 2002 and 2005 to comply with the provisions of Trade Related Intellectual Property Rights (TRIPs) agreement of WTO. India notified an amendment to the Indian Patents Act by incorporating Exclusive Marketing Rights (EMR) provision from January 1, 1995. These EMR provisions are related to the filing process of patents based on process and product inventions after January 1, 1995. The amendment came into force in 1999 with retrospective effect from 1995. As a result, all the product based and process-based applications for new patents filed from 1995 to 1999 become 'mailbox' and India had to register these patents, after due verification from retrospective effect, which is entitled to receive exclusive marketing rights. Accordingly, around 8,500 applications were filed in mailbox category. However, many of these applications are rejected for non-fulfillment of criteria in the later years[5].

In the year 2002, India has to amend the Patents Act, to meet other requirements and obligations of the TRIPs Agreement. This Amendment brought two major policy changes. First, it had provided for a 20 year term for each patent and secondly, it reversed the provisions relating to the burden of proof. To protect the generic medicines industry, Section 107 A stated that any act of making, constructing, using, selling or importing a patented invention for uses related to the development and submission of information does not amount to infringement. The provisions on Exclusive Marketing Rights (EMRs) and others with their exemptions to research are specifically useful for generic manufacturers to manufacture generic version in advance of the patent expiry. These provisions are also useful for research purposes in the pharmaceutical sector[6].

The last amendment to the Indian Patents Act (1970) came into force on January 1, 2005, incorporated the provisions for granting product patent in all fields of technology including chemicals, food, drugs and Agrochemicals. The Act also provided for the grant of compulsory licensing by the government for the production of medicines within the country as well as for exporting to other countries in certain circumstances. The Act introduced Section 92 (A) which deals with compulsory licensing of pharmaceuticals for export purposes. This is meant to facilitate the Indian industry to continue supplying cheaper generic versions of patented drugs to Less Developed Countries (LCDs) that do not have adequate domestic manufacturing capabilities.

There were also many apprehensions expressed both by the pharmaceutical companies and civil society groups on these amendments to the Indian Patents Act. The Confederation of Indian Industry (CII) sensed that multinational companies may express fears that provisions of compulsory licensing may lead to the emergence of License Raj. Further, the words like "extreme urgency"[7] or "national emergency" may be misused for establishing a complex License Raj.

In accordance with the provisions of the TRIPs Agreement, New Drug Policy was adopted in 2002. This policy has certain important provisions on price control. Firstly, the policy suggested that price control will apply to bulk drugs with annual sales exceeding 25 crores where a single brand has more than 50 percent market share. Besides this, in cases where a single branded has more than 90 percent market share and the turn over the limit for the category of drugs is lower than 10-20 crores, these will have controlled prices under a competitiveness clause. Thus, the new policy stated that for drugs of mass consumption where there is inadequate competition, there is a need for price control[8].

Thus, there are divergent views on the impact of TRIPs agreement on the Indian policy framework. While the government claims to have struck a balance between public interests and TRIPs agreement provisions, certain civil society groups and experts believe that compliance with TRIPs will have negative effects. Further, the pharma industry led by Multinational Companies is also not satisfied with provisions relating to compulsory licensing.

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