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Pharmaceutical Regulatory Policies in India in The Post-Liberalization Period: A Brief Overview

KEYWORDS: Pharmaceutical regulation, policy studies, liberalization

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ABSTRACT *The present paper attempts to provide a brief temporal and socio-historical account of the shift in pharmaceutical regulatory policies in India during the period after liberalization of the economy. The paper also attempts to demonstrate how post 1986, the government reversed its earlier policies, reduced the span of price control, allowed scope for more profits to firms, approved the liberalization of imports and scrapped various production control measures and that in this context, Drug Price Control Order of 1987 marked the increasing tilt of the government towards liberalization in the industry.*

The present paper attempts to provide a brief temporal and socio-historical account of the shift in pharmaceutical regulatory policies in India during the period after liberalization of the economy.

The pharmaceutical industry in India is a fragmented and heterogeneous sector consisting of nearly three hundred large and medium scale firms and over ten thousand registered small scale firms, (Gehl, Sampath 2008: 14) with varying capabilities in terms of research and development and manufacturing activities. The proliferation of these firms, with their varying levels of expertise, occurred during the eighties, in the context of the Patent Act of 1970 and associated industrial policies, which recognized only process patents and permitted firms to come up with generic versions of the original drug with alternate processes. (Abrol 2004:273). Other factors, which have contributed to the present levels of technological capability in the industry include the emphasis on process technology by domestic firms and the interaction between firms and government laboratories, particularly the laboratories of the Council of Scientific and Industrial Research (CSIR). (Chaudhuri 2005:20).

The allopathic system of medicine came to India with the arrival of the Britishers. However, though the British government initiated the production of modern drugs in India, the development of the Indian pharmaceutical industry has largely been due to indigenous efforts. Some of these important indigenous initiatives, in the period between the late nineteenth century and the early twentieth century, include the setting up of the Bengal Chemical and Pharmaceutical Works (BCPW) in 1892 and firms like Zandu Pharmaceutical Works, Calcutta Chemicals and Standard Pharmaceuticals during the period before the Second World War. These firms were already engaged in the production of synthetic drugs, drugs of plant and animal origin and sera and vaccines. The production of antibiotics in India was initiated in the 1940s. By the 1950s, the indigenous sector dominated the pharmaceutical industry in India and accounted for nearly 62% of the market. The sector soon engaged in the production of a wide range of bulk drugs and formulations.

However, during this period, due to the introduction of new drugs by multinational firms, the role of patents became very important and the indigenous sector operated under the restrictions imposed by the prevailing patent related legislations. Moreover the liberal licensing regime in this period ensured that a host of multinational companies such as Burroughs Welcome, Cynamide, Glaxo etc. were permitted to set up formulation units inspite of well-established indigenous capabilities in this area. By 1970, due to the dominance of the multinational companies, the market share of indigenous firms had dwindled to about 32 percent. (Chaudhuri 2005:22).

In India, drug manufacturing, testing and marketing is regulated in accordance with the Drugs and Cosmetics Act of 1940. This act has witnessed several amendments over the last few decades. The Drugs Controller General of India (DCGI), who heads the Central Drugs Standards Control Organization (CDSCO), assumes responsibility for the amendments to the Acts and Rules. Other major related Acts and Rules include the Pharmacy Act of 1948, The Drugs and Magic Remedies Act of 1954 and Drug Prices Control Order (DPCO) 1995 and various other policies instituted by the Department of Chemicals and Petrochemicals.

Some of the important schedules of the Drugs and Cosmetic Acts include: Schedule D: dealing with exemption in drug imports, Schedule M: which, deals with Good Manufacturing Practices involving premises and plants and Schedule Y: which, specifies guidelines for clinical trials, import and manufacture of new drugs.

There are several regulatory bodies entrusted with the responsibility of ensuring the approval, production and marketing of drugs in India. The Central Standards Drug Control Organization (CDSCO), located under the aegis of the Ministry of Health and Family Welfare, prescribes standards and measures for drugs, cosmetics, diagnostics and devices in the country; regulates the market authorization of new drugs and clinical trials standards; supervises drug imports and approves licences to manufacture the above-mentioned products.

In accordance with the Act of 1940, there exists a system of dual regulatory control or control at both Central and State government levels. The central regulatory authority undertakes approval of new drugs, clinical trials, standards

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setting, control over imported drugs and coordination of state bodies' activities. State authorities assume responsibility for issuing licenses and monitoring manufacture, distribution and sale of drugs and other related products.[1]

The Patent Act of 1970, which recognized only process patents, provided a much-needed impetus to the growth of the indigenous industry. In practical terms, this meant that Indian firms could copy new drugs using a different process and market them in India at low prices, a mere three years after they were introduced in the global market, rather than wait for the patents to expire over a period of ten to twelve years. This trend was also significant in the context of affordability of drugs since the latest therapeutic products were now available in the Indian market at a fraction of the price in which they were sold in their country of origin. The Patents Act of 1970, together with the Drug Price Control Order of 1970 and Foreign Exchange Regulation Act of 1973 also played a significant role in curbing the dominance of multinational companies and encouraging the building of indigenous capabilities with regard to the production of bulk drugs and formulations.

Subsequently, the New Drug Policy of 1978, based on the recommendations of the Hathi Committee, which was constituted in 1974, provided an added thrust to the development of indigenous self-reliance and availability of therapeutically effective drugs at low prices. Some of these recommendations included according priority to public sector companies engaged in the manufacture of drugs, the reservation of certain medicines for production by the public sector companies, setting up a fixed ratio of the production of bulk drugs to formulations to compel multinational companies to produce more bulk drugs, the use of medicines in generic names, tax exemption of certain kinds for small scale producers, the strengthening of the licensing system to restrict the activities of the multinational companies to the preparation of simple formulations and the directive to multinational companies to whittle down their foreign share holdings to below forty percent. These directives stimulated the growth of Indian drug companies during this period. (Jan Swasthya Abhiyan 2007:30).

This was succeeded by the Drug Prices Control Order (DPCO) of 1979, which brought nearly 378 medicines under price control. However, in 1986, in a reversal of its earlier policies, the government reduced the span of price control, allowed scope for more profits to firms, approved the liberalization of imports and scrapped various production control measures. In this context, DPCO 1987 marked the increasing tilt of the government towards liberalization in the industry. One of the important features of this act was the reduction in the number of drugs under price control to 143 drugs.[2]

The subsequent policies of the government were in accordance with this trend of liberalization. The major objective of DPCO 1995 was to decrease monopoly in any given market segment, further decrease the number of drugs under price control to 74 drugs and the inclusion of products manufactured by small scale producers under price control list. In 1997, the National Pharmaceutical Pricing Authority (NPPA) was constituted in order to administer DPCO and deal with issues related to price revision.[3]

The NPPA, which was instituted in 1997 under the Department of Chemicals and Petrochemicals, also fixes or revises the prices of decontrolled bulk drugs and formulations at judicious intervals; periodically updates the list under price control through inclusion and exclusion of drugs in accordance with established guidelines; maintains data on production, exports and imports and market share of pharmaceutical firms and enforces and monitors the availability of medicines in addition to imparting inputs to Parliament on issues pertaining to drug pricing.

Additionally, the Department of Chemicals and Petrochemicals also oversees policy, planning, development and regulatory activities pertaining to the chemicals, petrochemicals and pharmaceutical sector. The responsibilities assumed by this body are relatively broader and varied in comparison to the other two bodies. The main aspects of pharmaceutical regulation are thus divided between the above two ministries. The Ministry of Health and Family Welfare examines pharmaceutical issues within the larger context of public health while the focus of the Ministry of Chemicals and Fertilizers is on industrial policy. However, other ministries also play a role in the regulation process. These include the Ministry of Environment and Forests, Ministry of Finance, Ministry of Commerce and Industry and the Ministry of Science and Technology. The process for drug approval entails the coordination of different departments, in addition to the DCGI, depending on whether the application in question is for a biological drug or one based on recombinant DNA technology. Issues related to industrial policy such as the regulation of patents, drug exports and government support to the industry are governed by the Department of Industrial Policy and Promotion and Directorate General of Foreign Trade, both under the aegis of Ministry of Commerce and Industry and the Ministry of Chemicals and Fertilizers. With respect to licencing and quality control issues, market authorization is regulated by the Central Drug Controller, Ministry of Health and Family Welfare, Department of Biotechnology, Ministry of Science and Technology and Department of Environment, Ministry of Environment and Forests. State drug controllers have the authority to issue licences for the manufacture of approved drugs and monitor quality control, along with the Central Drug Standards Control Organization (CDSCO). (Srivastava 2008, Iyer 2009).

The Pharmaceutical Policy of 2002 furthered the shift towards liberalization in terms of permitting hundred percent share in foreign investment and doubling the excise duty from sixteen to eighteen percent for medicines trade barriers. Concurrently, it also liberalized imports and sanctioned a cut in import duties. This period witnessed the decline of public sector companies like the Indian Drugs and Pharmaceuticals Limited (IDPL) and Hindustan Antibiotics Limited (HAL) and also saw a rise in prices of drugs. (Lalitha 2002, Jan Swasthya Abhiyan 2007).

In 2003, the Mashelkar Committee[4] undertook a comprehensive examination of the problem of spurious and substandard drugs in the country and recommended a series of stringent measures at Central and state levels. The central regulatory body came in for censure for inadequate monitoring of such drugs, with the committee noting that there were only 17 drug testing laboratories in the country, of which only seven laboratories were fully functional.

The National Pharmaceuticals Policy 2006, among other initiatives, has proposed a slew of measures such as increasing the number of bulk drugs under regulation from 74 to 354, regulating trade margins and instituting a new framework for drug price negotiations in a move to make drugs more affordable for the Indian masses. (Jan Swasthya Abhi-

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