

Economic Reforms and Health Sector: Implications for Indian Pharmaceutical Industry

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Abstract

One of the important achievements of economic development in post-independent period in India has been our ability to ensure availability of life saving drugs at affordable prices. This was a result of various policies followed since late 1960s with the objective of providing affordable drugs. These strategic initiatives involved various incentives for development of domestic healthcare industry. It also included building a national innovation system for developing process innovation capability in the country and providing an intellectual property protection (IPR) framework designed to facilitate indigenous process development of known compounds.

The paper highlights the difference between product and process patents. Over the past two decades, there have been a number of changes in the policy framework developed since the late 1960s. The paper highlights the various changes that took place from time to time since independence to strengthen the Indian healthcare industry. The IPR framework has undergone important changes as per India's obligations under the TRIPs Agreement of WTO. In this context this paper briefly reviews different elements of economic reforms in the Indian healthcare sector. It highlights the important implications for the healthcare industry in light of economic reforms in our country. It also highlights trends taking place since 1991 that tend to alter the policy framework evolved thus far that are likely to affect the availability of drugs and their prices in the coming years. It also discusses issues such as liberalization of trade, investment and pricing policies and strengthening IPR regime under TRIPs Agreement, among other policies.

Key Words: Economic Reforms, Healthcare Industry, Intellectual Property Rights, WTO

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Introduction

One of the important successes of economic development in post-Independent period has been ability to ensure availability of life saving drugs at affordable prices. Since many life saving and other drugs are available in India at a fraction of prices prevailing internationally, it has attracted widespread attention from other countries. Competitive prices have also resulted in rising exports of pharmaceuticals from India. This success is a result of a combination of policies consciously followed since late 1960s with the specific objective of providing affordable drugs for the masses. These strategic interventions included incentives for development of indigenous pharmaceutical industry, giving incentives for localization of production right from bulk drugs and intermediates and not just formulations, encouraging generics over branded products, and regulation of prices through the Drug Prices Control Order (DPCO).

Finally and more importantly, it included building a national innovation system for developing process innovation capability in the country, through incentives for R&D activity to enterprises and providing an intellectual property protection (IPR) framework designed to facilitate indigenous process development of known compounds. This integrated framework has led to the development of a strong indigenous pharmaceutical industry which presently produces bulk of the country's requirement right from the raw material stage using indigenous and cost effective processes.

Over the past decade, however, there have been a number of changes in the policy framework developed since the late 1960s. Besides import liberalization and removal of restrictions on foreign firms, DPCO has been diluted as a part of economic reforms. The IPR framework is undergoing important changes as per India's obligations under the TRIPs Agreement of WTO covering adoption of product patents by 2005 and provision of pipeline protection through EMRs (exclusive marketing rights) in the transition period. All these trends of the past decade viz. liberalization of trade, investment and price regulations, and emerging changes in the IPRs are likely to have implications for the availability and prices of pharmaceutical products in India.

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In this context, this paper briefly reviews different elements of integrated drug policy framework as evolved between 1960s and 1990 and their effectiveness in bringing down drug prices. Then it discusses trends taking place since 1990 that tend to alter the policy framework evolved thus far that are likely to affect the availability of drugs and their prices in the coming years such as liberalization of trade, investment and pricing policies, strengthening IPR regime under TRIPs Agreement, among other policies.

Literature Review

The Economic Reforms Process was set in motion in India since 1991. In a widely circulated document from the Ministry of Finance, Bhagwati and Srinivasan (1993) summarized the rationale for such a reforms process for the benefit of the public. Some excerpts are important to note. ‘The economic reforms initiated by the government in June 1991 have an excellent rationale. The ‘macroeconomic’ situation, both external (the balance of payments) and internal (the fiscal deficit), was unsustainable.....The cutting of developmental expenditure appears to us to be little beyond what appears prudent: growth later may be compromised by this, so the government needs to examine this question carefully. On the other hand, the Finance Minister has been accused of cutting ‘Social Expenditure’, thus stabilizing the economy at the expense of budgetary cuts in spending on the poor’ (pp. (ii) of the report).

While arguing for the much needed economic reforms, Bhagavati and Srinivasan have cautioned on the need for maintaining long term development expenditures. This was followed by a major study by Joshi and Little (1996). After arguing in favour of what all went in during 1991 to 1996 in terms of reforms in India, they seem to agree that something must be done for the poor. To quote their own words: ‘However, the major reforms we have applauded or advocated may have serious differing effects on different social and economic classes. These, especially the effects on the poor, cannot be ignored. Indeed the objective of any reform must be to benefit society, and this surely precludes reforms which harm many poor people belonging to that society.’ (pp.219) ‘In the long run, expenditure on primary

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education and primary health care may be more poverty-reducing than other more immediate measures-provided always that the economic, social, and legal systems are not biased against employment.’ (pp. 243)

Talking about macro-economic links and activities, ‘Health and Medical’ is treated as a social sector, just as several others like Education, Real estate and housing. According to Central Statistical Organisation (CSO) it includes all medical and health services, as deliverable to people. The sector is made up of activities emanating from professional and research institutions, hospitals, and clinical services rendered by the medical professionals for the better health care of people of the country. Drug and Pharmaceuticals is another sector, which is very closely linked to the Health sector. It is defined as manufacture of drugs and medicines-including allopathic, ayurvedic, unani, homoeopathic and others. Basically this sector deals with production of drug intermediates, formulations, medicines and medical accessories. Both these sectors (leaving away the retailing) are very closely linked to several other macro-economic sectors.

Evolution of the Policy Regime

The government has adopted a number of policies over the past four decades to ensure the availability of life saving medicines at affordable prices for the health system of country catering to the needs of the poor masses. The government policy towards pharmaceutical industry can be broadly classified into two categories- (i) industrial policy including policies relating to foreign investment and technology and (ii) pricing policy. The evolution of both these policies is discussed below. Although foundation of indigenous pharmaceutical industry were laid in 1901 when Prof. P.C. Ray established the Bengal Chemicals and Pharmaceutical Works (BCPW), the country was largely dependent on imports for most of her requirements of drugs and pharmaceuticals at the time of Independence. However, since the Independence, the pharmaceutical industry has received due policy attention given its importance for the health security of the poor.

In the first Industrial Policy Resolution 1948 (IPR, 1948) itself, the pharmaceutical industry was included in the list of 'basic industries' and its growth was subjected to plan targets and monitoring. However, the industry had little domestic technological base to start local production of modern drugs at that time. Whatever little growth impetus the industry had during the World War II was over by then. New therapeutic developments in the West with consequent replacement of many older drugs by newer drugs like sulpha, antibiotics, vitamins, hormones, antihistamine, tranquilizers, and psycho pharmacological substances had forced the nascent industry to stop production of many items that it was manufacturing before.

The status of the industry was increasingly dependent on imports of bulk drugs and its processing into formulations.

The Industrial Policy Statement, 1956, grouped the pharmaceutical industry in the schedule 'B' where both state and private sector could operate. Although FDI was welcomed and given national treatment in the industry, government was finding it difficult to push MNEs to start domestic manufacture of bulk drugs and reduce the dependence on imports. Since MNEs were reluctant to start production of important bulk drugs such as antibiotics in the country, the government set up Hindustan Antibiotics Ltd. in 1954 and Indian Drugs and Pharmaceuticals Ltd (IDPL) in 1961.

These two enterprises have played an important role in not only starting domestic production of key bulk drugs but have had substantial spillovers in the form of generation of a new breed of entrepreneurs. One survey has shown that founders of one third of the 200 domestic enterprises surveyed had initially worked at IDPL including the founder of immensely successful Dr Reddy's Laboratories Ltd. (DRL) [Felker et al 1997]. The high tariffs also encouraged MNEs to set up local subsidiaries and indigenize the domestic processing of imported bulk drugs and other raw materials.

The Drugs and Pharmaceutical industry was included the Appendix I of the Industrial Licensing Policy (1973). This priority status meant that under the Foreign Exchange Regulation Act (FERA) 1973, MNEs could retain up to 74 per cent ownership in their

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affiliates in India against a general limit of 40 per cent on maximum foreign shareholding permissible. However, keeping in mind the critical importance of building a self-reliant pharmaceutical industry, the government appointed a Committee to examine the status of the industry and make recommendations in the early 1970s. The Committee popularly called as the Hathi Committee, after its chairman Mr Jaisukhlal Hathi made extensive investigations into the factors that were preventing achievement of greater extent of self-reliance in the pharmaceutical industry in the country and made a number of recommendations in its Report published in 1975 (Hathi Committee 1975; also see Kumar and Chenoy 1982 for a discussion).

A New Drug Policy 1978 was announced to implement some of the recommendations of the Hathi Committee. The Policy had three stated objectives, namely, self-sufficiency in drugs production, self-reliance in drugs technology and accessibility of quality drugs at reasonable prices. In order to achieve these objectives, the pressure was built on MNE affiliates to indigenize the production of bulk drugs from the basic stage. Thus the higher level of 74 per cent foreign equity was made applicable only to those MNE affiliates producing high technology drugs and others producing low technology drugs or processing imported/domestically purchased bulk drugs were required to reduce their foreign equity holding to 40 per cent.

Foreign companies producing finished formulations from imported bulk drugs or from penultimate stage were required to start production from the basic stage within a two year period. Further, licenses to foreign companies were to be given only if the production involves high technology bulk drugs and formulations based thereon. In 1981 the government took the decision of abolishing brand names for five categories of drugs as mentioned under Drug Policy, 1978, which includes analgin, aspirin, chlorpromazine, ferrous sulphate, and piperazine along with its salt. However, the move was blocked by MNEs with a court injunction.

Another aspect of the government policies concerning the drugs and pharmaceutical industry was canalization of imports of bulk drugs. After the detection of a number of cases

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highlighting the substantial overpricing in imports of bulk drugs by MNEs from their parents or affiliated sources, the government started canalizing the imports of these bulk drugs through IDPL and State Chemicals and Pharmaceuticals Trading Corporation, (a subsidiary of the State Trading Corporation) and MNE affiliates were required to lift their requirements from them.

The drug policy has been revised in 1986, however, broad objective of strengthening the indigenous production capability of drugs for ensuring their abundant availability at reasonable prices continued to remain intact. Price Controls on prices has been an important feature of the Indian pharmaceutical industry right from the 1960s to ensure affordability of drugs to poor masses. The drug price controls have gradually evolved with Drugs (Display of Prices) Order, 1962, Drugs (Control of Prices) Order, 1963 and Drugs (Display and Control) Order, 1966. The attempt to control prices by the government met with resistance from the industry that argued that the controls will hamper the growth of the industry and in the long run limit its ability to meet rising demands for drugs.

In view of the above criticisms, the government requested the Tariff Commission to examine the prices of 18 basic drugs and their single ingredient formulations in August 1966. Following the submission of the Tariff Commission report in August 1968, the first Drugs (Prices Control) Order was issued in May 1970. The Order had the prime objective of balancing the welfare of consumer and that of producers i.e. reducing the prices of essential drugs and at the same time ensuring reasonable profits for the growth of the industry by taking account of the prices of materials, conversion cost, packing charges, mark-up, excise duty and sales tax in the calculation of the retail price of a formulation. The government has acquired both the rights to fix the maximum selling prices of essential bulk drugs (those included in the Schedule I of the appendix of the Order) and to change its composition. These 18 essential bulk drugs brought under the purview of DPCO 1970, accounted for less than 9 percent of total value of drugs marketed. The sale prices of other bulk drugs were frozen at the level prevailing immediately before the issue of the Order.

The DPCO 1970 was revised in 1979 following the promulgation of the Drug Policy of 1978 based on the Hathi Committee recommendations. The revised DPCO categorized drugs into four categories: Life-saving, Essential, Less Essential, and Non-Essential/Simple Remedies. Of these the first three categories came under the ambit of price controls with mark-up (profits allowed) of 40 per cent, 55 Per cent and 100 per cent respectively. In all, 347 drugs came under the purview of DPCO accounting for 90 per cent of the industry.

The tighter price controls on the first two categories of drugs led MNEs to increase their focus on the production on the less essential and non-essential formulations. Growing resistance of the industry to the DPCO 1979 led the government to issue a modified DPCO in August 1987 that reduced the scope of DPCO to 166 drugs from 347 besides enhancing the stipulated mark-up for the included formulations.

IPR Regime and Incentives to Domestic R&D Activity Amendment of the Patent Act

India had inherited The Patents and Designs Act 1911 from the colonial times that provided for protection of all inventions except those relating to atomic energy and a patent term of 16 years from the date of application. However, a few domestic chemical and pharmaceutical enterprises that tried to develop their own technology in the 1960s ran into trouble with foreign patent owners.

A number of cases highlighted that foreign patent owners were neither using their patents for domestic manufacture nor allowing them to be used by local firms. That led to a build-up of pressure in the late 1960s for a new patent law.

Desai (1980) in a questionnaire survey of 53 firms conducted in 1969 found that by and large foreign firms were against any liberalization of patent laws, Indian firms were not against patents but wanted greater access to patented know-how especially when patent owners not allowing their patents to be used. The conflict of views was sharper in chemicals and pharmaceuticals where patents had been used to prevent entry of Indian firms.

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Therefore, a new Patents Act was adopted in 1970 that reduced the scope of patentability in food, chemicals and pharmaceuticals to only processes and not products. Since virtually any chemical compound can be made by a variety of processes, the scope of patent protection was greatly reduced.

The term of process patents was reduced to 7 years in food, drugs and chemicals and to 14 years for other products. The compulsory licenses could be issued after three years. It is by now widely recognized that the abolition of product patents in chemicals and pharmaceuticals has facilitated the development of local technological capability in chemicals and pharmaceutical industry by enabling the domestic firms in their process innovative activity.

A number of quantitative studies have shown that the innovative activity of Indian domestic enterprises was facilitated by the softer patent regime under the 1970 Act (see Fikkert 1993, Haksar 1995, Kumar and Saqib 1996).

Reforms and Implementation of WTO Commitments

The industrial, trade and technology policy framework evolved over the 1950-90 has considerably changed in the 1990s as a part of the economic reforms undertaken by the government and also the implementation of the commitments undertaken by the country under the WTO Agreements. The important changes have been brought about in the industrial policy and FDI policy, trade policy, regime governing the exchange rates and capital markets, patent protection and price controls. In what follows we summarize the changes that have been brought about particularly those relevant for the pharmaceutical industry. The New Industrial Policy (NIP) announced on 24th July 1991 and subsequent amendments brought far-reaching changes in the policy regime governing the industrial investments.

Although the NIP dismantled the industrial licensing (or approval) system by abolishing the requirement of obtaining an industrial license from the government, drugs and

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pharmaceuticals industry is included among the 14 specified industries that continue to remain under the ambit of licensing given the social well-being consideration. NIP accords a much more liberal attitude to foreign direct investments (FDI) than ever in the post Independence India. The Policy allows automatic approval system for priority industries by the Reserve Bank of India within two weeks subject to their fulfilling specified equity norms. As one of the select priority industries specified in Annexure III-C of NIP, foreign ownership up to 51 per cent was to be allowed on automatic basis for pharmaceutical industry for manufacture of bulk drugs and formulations thereof. Later on, the pharmaceuticals industry was included in the list for automatic approval up to 74 per cent in March 2000 and to 100 per cent in December 2001.

In September 1994, government announced a revision of the Drug Policy 1986 which includes measures like abolishing industrial licensing requirements for majority of drugs barring few; removing restriction on the imported bulk drugs, scrapping the linkage requirement (where a stipulated percentage of bulk drug production need to be supply to non associated formulators), and limiting the scope of price control and providing for establishment of the National Drug Authority to monitor quality and the National Pharmaceutical Pricing Authority to fix prices of both bulk drugs and formulations. On 15 February 2002, the government unveiled the Pharmaceutical Policy 2002 to take into account the emerging challenges in the wake of WTO Agreements and hence the need for new initiatives 'towards promoting accelerated growth of pharmaceutical industry and towards making it more internationally competitive'.

This covered implementation of the recommendations of two committees that the Government had appointed in 1999. These include the Pharmaceutical Research and Development Committee (PRDC) under the Chairmanship of Dr R.A. Mashelkar, DG, CSIR, and the other Drugs Price Control Review Committee (DPCRC) headed by the Secretary, Department of Chemicals and Petrochemicals. The 2002 Policy has abolished the industrial licensing requirements for all bulk drugs cleared by Drugs Controller General (India), all intermediates and formulations except for those produced by recombinant DNA technology, that requiring in-vivo use of nucleic acids as the active principles, and specific cell/ tissue

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targeted formulations. Automatic approval for foreign ownership up to 100 per cent and foreign technology agreements will also be available for all the cases except those included in the industrial licensing requirements.

The TRIPs Agreement of WTO accommodates the demands of the industrialized countries for higher international standards of protection by mandating the extension of patentability to virtually all fields of technology recognized in developed country patent systems, by prolonging the patent protection for a uniform term of twenty years, and by providing legal recognition of the patentee's exclusive rights to import the patented products. The patent rights are enjoyable without discrimination as to the place of invention, the field of technology and whether products are imported or locally produced. All the signatories to the trade negotiations are, therefore, obliged to harmonize their IPR regime and to provide product patents for pharmaceuticals and chemicals.

The coverage of the patent protection has also been expanded by the provision for patents on micro-organisms and protection of plant varieties either by patents or by an effective sui generis system or by any combination thereof. The TRIPs Agreement of WTO is likely to have major implications for the drugs and pharmaceutical industry. India will have to extend the scope of patenting to chemical and pharmaceuticals and increase the term of patents to 20 years from the present 7 and 14 years. However, developing countries not providing product patents are given a 10 years transition to evolve product patents. However, in the interim period a mailbox mechanism must be set up to provide exclusive marketing rights (EMR) to applicants for product patents. In order to comply with the India's commitments under the TRIPs Agreement, amendments have been brought in the Indian Patents Act 1970. A 1999 Amendment has been brought to provide for exclusive marketing rights (EMRs) a pipeline mechanism during the transition period to adopt product patents. India has a ten years transition to provide product patents viz. till the end of 2004. A Bill for Second Amendment to the Indian Patents Act 1970 to extend the term of patents to 20 years is in the Parliament. India has also joined the Paris Convention and the Patent Cooperation Treaty in 1998. These changes in the IPR regime are likely to have important implications for the pharmaceutical industry.

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Conclusions

The above discussion has shown that the integrated policy framework that the government evolved over the 1970-90 has been successful in developing a highly vibrant and self-reliant industry that not only meets the local demand of nearly all critical medicines at affordable prices but also generates increasing amount of net exports by exporting pharmaceutical products to over 60 countries.

The ability of Indian enterprises to develop cost effective processes has attracted the attention of leading MNEs to the country for entering into strategic alliances with local companies for process development. This remarkable success was achieved within two decades and was facilitated in large measure by the soft patent regime that the country adopted in 1970. The liberalization of the industrial, trade and price policies in the 1990s has started to affect the prices of medicines. Even trade liberalization and reduction of tariffs actually lead to higher rather than lower prices of medicines due to peculiar nature of the industry.

The adoption of product patents by the end of 2004 as a part of the implementation of the commitments of India under WTO's TRIPs Agreement is likely to have a major impact on the prices of medicines according to a number of simulation exercises available. It is also likely to adversely affect the technological activity of Indian companies, curb exports, lead to income transfers from the country. On the other hand the favourable effects of stronger IPR regime that are claimed namely higher innovative activity and greater inflows of FDI may not materialize.

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