CHAPTER-4

REGULATORY FRAMEWORK OF POLICY AND PRICING IN INDIAN PHARMACEUTICAL INDUSTRY

4.1 Pharmaceutical Policy in 2002:

Pharmaceutical Policy in 2002, which aims to bring new incentives into the sector beyond those enumerated in the drug Policy, so that policy inputs are directed more towards promoting accelerated growth of the pharmaceutical industry and towards making it more internationally competitive. Some of the salient features of this policy are:-

- Abolition of Industrial licensing for all bulk drugs cleared by Drug Controller General (India), all their intermediates and formulations, subject to stipulations laid down from time to time in the Industrial Policy, except in the cases of:-
  I. Bulk drugs produced by the use of recombinant DNA technology
  II. Bulk drugs requiring in-vivo use of nucleic acids as the active principles and
  III. Specific cell/tissue targeted formulations.

- Permission of foreign investment up to 100 per cent, subject to stipulations laid down from time to time in the Industrial Policy, through the automatic route in the case of all bulk drugs cleared by
Drug Controller General (India), all their intermediates and formulations, except those referred in the above point, kept under industrial licensing.

- Availability of automatic approval for ‘Foreign Technology Agreements’ in the case of all bulk drugs cleared by Drug Controller General (India), all their intermediates and formulations, except those referred in the first point, kept under industrial licensing for which a special procedure prescribed by the Government would be followed.

- Measures to give impetus to R&D in the drugs sector are as follows:-
  I. Constitution of the Pharmaceutical Research and Development Support Fund (PRDSF) and the Drug Development Promotion Board (DDPB)

II. A manufacturer producing a new drug patented under the Indian Patent Act, 1970, and not produced elsewhere, if developed through indigenous R&D, would be eligible for exemption from price control in respect of that drug for a period of 15 years from the date of the commencement of its commercial production in the country

III. A manufacturer producing a drug in the country by a process developed through indigenous R&D and patented under the Indian Patent Act, 1970, would be eligible for exemption from price control
in respect of that drug till the expiry of the patent from the date of the commencement of its commercial production in the country by the new patented process etc.

- The system of the price control would be operated through a single list of price controlled drugs selected on the basis of criteria as laid down in the policy and formulations based thereon, with a Maximum Allowable Post-manufacturing Expenses (MAPE) of 100% for indigenous formulations and margin upto 50% for imported formulations.

- Ceiling prices may be fixed for any formulation, from time to time, and it would be obligatory for all, including small scale units or those marketing under generic name, to follow the price so fixed.

- Setting up of the ‘National Institute of Pharmaceutical Education and Research (NIPER)’ as an institute of national importance in order to achieve excellence in pharmaceutical sciences and technologies, education and training. Besides tackling problems of human resources development for academia and the indigenous pharmaceutical industry, the institute seeks to make efforts to maximize collaborative research with the industry and other technical institutes in the area of drug discovery and pharma technology development.
4.2 National Pharmaceutical Pricing Policy (NPPP) 2011

- In November 2011, the Department of Pharmaceuticals released a draft note on National Pharmaceutical Pricing Policy (NPPP) 2011 with the objective to replace the existing pricing policy and bring a wider gamut of drugs under the pricing control. The proposed policy was structured around three key principles – a) covering all the essential drugs under the span of price control, b) moving away from a cost-based pricing to a market-based pricing mechanism and c) controlling prices of only formulations as compared to bulk drugs earlier. The policy aimed at widening the ambit of medicines under price control by including all the 348 essential drugs (forming part of the National List of Essential Medicines (NLEM) in comparison to only 74 bulk drugs that form part of the present policy regime. In addition, it marked an important shift by computing price ceilings using market-driven pricing compared to the archaic cost-based approach. Besides ensuring affordability of medicines through effective price control mechanism, the proposed policy also aims strengthen the drug distribution and availability mechanism through various measures. Some of the prominent initiatives proposed by the policy included:
- Streamlining the drugs procurement mechanism by the Government through a strong and transparent drug purchase policy.
- Improving direct healthcare access by expanding healthcare cover through State healthcare systems.
- Promoting usage of generic drugs through various channels including the ‘Jan Aushadhi’ programme.
- Supporting the industry by introducing policies to encourage investments into Research & Development (R&D); improve access to capital for start-ups, set up of pharma development parks, rationalize tax structure as well the pharmaceutical retail trade and
- Improving the access to drugs used for specialized treatments particularly anti-cancer, HIV etc. The pricing policy also proposed that non-essential drugs should not be under a controlled regime and the prices should be decided by market dynamics. However, the policy does aim to keep the overall drug prices under check and monitor the prices on regular basis. It further suggests that the price hike should not be more than 15% p.a. or the increase in WPI, whichever is higher. For imported drugs, it doesn’t propose a differential ceiling mechanism, while it remains unclear on the patented drugs. The prices of bulk drugs and their formulations under
the scope of the DPCO are proposed to be held constant for two years. Thereafter, the price revision will be linked to the changes in WPI. [Source: http://pharmaceuticals.gov.in/, INDIAN PHARMACEUTICAL SECTOR, October 2012, ICRA RESEARCH SERVICES.]

4.3 Observation and analysis

Due to various policy measures taken by the Government in recent past, research and development (R&D) activities in this sector has not only increased quantitatively but also qualitatively. Presently, at least 10 leading Indian pharma companies are into new drug discovery and some of them have increased their R&D spending by over 5 per cent of their respective sales turnover. There are other efforts like providing fiscal incentives to R&D units in pharma sector as well as streamlining procedures related to development of new drug molecules, clinical research and new drug delivery systems. As a result, India is emerging as an alliance and outsourcing destination of choice for global pharma companies across the value chain. Hence, the drugs and pharmaceutical is one of the most diversified of all the industrial sectors. The accumulated knowledge of traditional medicinal system and large bio-diversity of India offers great advantage to the drug industry. The rapidly changing economic, trade and intellectual property
scenario, nationally and internationally, poses many challenges to it, including the challenge of becoming leaders and competitors globally.

This necessitates a shift in the approach of the industry, that is, moving away from manufacturing only known drugs to discovering and commercializing new molecules through innovative process routes. It would mean that the Indian pharma industry has to focus more on R&D, so as to enable India to maintain its status in the world pharma market and move ahead to become a global leader. In other words, the strength of the industry lies in leveraging the country’s power in organic synthesis and process engineering as well as developing cost-effective technologies in the shortest possible time for drug intermediates and bulk activities, without compromising on quality.

**Figure 4.1: Trend of cost effective technologies adapted by Indian pharmaceutical companies**

![Graph showing trend of cost effective technologies adapted by Indian pharmaceutical companies](image)

Source: INDIAN PHARMACEUTICAL SECTOR, October 2012, ICRA RESEARCH SERVICES.