Review Of Research
ISSN:-2249-894X
Impact Factor : 3.1402(UIF)
Vol. 4 | Issue. 5 | Feb. 2015
Available online at www.lbp.world

IMPACT OF REGULATORY FRAMEWORK OF INDIAN PHARMACEUTIAL INDUSTRY AND ITS IMPACT ON BUSINESS STRATEGIES OF SMALL SCALE PHARMAUNITS

Sandeep Tare[1] and Dr. Anand Sapre[2]
[1]Resarch Scholor, IIPS ,UTD,DAVV, INDORE.
[2]Director & Professor ,IIPS,UTD,DAVV, INDORE.

ABSTRACT

The regulatory frame work operates at two levels: 1) Licensing and 2) Pricing. Licensing entails the needfor manufacturers to get approval from Drug Controller Commissions at state levels . The Drugs and Cosmetics Act 1940 governs the import, manufacturer, distribution and sales of drugs, in India. The Drug Controller General Of India (DCGI), an authority established under the Drug Cosmetic Act 1940 oversees the conduct of clinical trials and is also responsible for the approval and registration of drugs and issues manufacturing and marketing licenses for the same. Essential drugs pricing is fixed by Central Government. On a regular basis the list of drugs whose prices are controlled and the methodology of fixing prices is issued referred to as Drug Price Control Order (DPCO). In the last few year s only a few essential drugs prices are regulated and implementing authority as of now is the National Pharmaceutical Pricing Authority (NPPA) , the list of essential drugs are increasing day by day.

KEY WORDS : *DPCO,NPPA,DCGI,IPA,MAPE ,TNC ,FDA, CDAIL .*

INTRODUCTION:

The Indian Patent Act (IPA) and Drug Price Control Order (DPCO) were both passed in 1970. Under the IPA, substance used in foods and pharmaceutical could not be granted product patents. Only process patents were allowed for a period of five years from the date of grant of patent or seven years from the date of filling for patent , which ever was earlier. The introduction of the IPA provided a major thrust to growth of Indian pharmaceutical industry as well as key instrument in emergence and significant development and proliferation of small scale pharmaceutical units or sector.

The process of reverse engineering and synthesis began to produce bulk drugs and formulation at lower costs. The DPCO is an order issued by the Government, under Section 3 of the Essential Commodities Act 1955, empowering it to fix and regulate the prices of o essential bulk drugs and their formulations. The order incorporates a list of bulk drugs whose prices are

tobe controlled, the procedure for recovery of dues, the penalties for contravention and various other guidelines and directions.

The order is subject to the guide lines of Drug policy and supposedly aims to ensure equitable distribution, increased supply and cheap availability of bulk drugs and played a vital role in directing the pharmaceutical industry fortunes specially small scale pharmaceutical industry as a whole. The first DPCO was issued in 1970 revised in 1979,1987, 1995 , 2005 and also amended in 2012. In its introductory form DPCO was a direct control on the profitability of pharmaceutical business and only an indirect control on the prices of pharmaceuticals. It stipulated that a company's or unit per tax profit from its pharma business should not exceeds 15% of its pharma sales (net of excise duty and sales tax). In case profits will exceeds this sum, the surplus was deposited with the Government. So a pharma company had the freedom to decide the prices of its products. Product wise margins were also flexible, so long as the overall margin did not exceeds the stipulated norm. Since individual product prices did not require approval from the Government, bureaucratic hurdles were low.

DPCO 1970 effectively put a ceiling on prices of all mass-usage bulk drugs and their formulations. Its primary objective was to protect the interest of consumers, and ensures a reasonable return to manufacturer too. The order was land mark regulation and has had several implications in shaping the Indian pharmaceutical industry especially in the upbringing of small scale pharmaceutical units/ industry.

The revised DPCO stipulated ceiling price s for controlled categories of bulk drugs and their formulations. The retail prices of controlled formulation s were decided by applying the concept of MAPE (Maximum Allowable Post Manufacturing Expenses). These revised DPCO put 370 drugs under price control. These drugs were segregated into three categories, having different MAPEs. The most important drugs, including lifesaving drugs were put in category 1, which had the least MAPE. Through this DPCO around80% of Indian pharmaceutical industry (in valueterms)was bought under strict price control. However Transnational Corporations (TNCs) challenged the order.

In 1987 Kelkar committee reduced the number of drugs from the purview of price control, it significantly reduced from 370 to 142.In addition to that the categories were also reduced to two and higher MAPE was provided for each category of controlled drugs (75% and 100% respectively). However, around 75% of the pharmaceutical industry was still under price control.

In 1994 the new Drug policy was announced. The new Drug policy liberalized the criteria for selecting bulk drugs, or formulations, for price control. Department of Pharmaceuticals came out with a notification on 22/7/2013 to replace DPCO 1995 bringing 348 more formulation in DPCO .The new DPCO says that manufacturers intending to scheduled formulation should issue a public notice and also intimate government in this regards.

As per new DPCO the department will also monitor the production and availability scheduled formulation and active ingredient in to, on quarterly basis. That provision is of great public interest, but many of MNCs and large companies is not happy with the same and also the baskets of product.

In addition industrial licensing was abolished for bulk drugs. All hindrances to capacity expansions were removed, it was expected that as a result, supply would rise, resulting in higher competitive pressures. Foreign investment up to 51% was also permitted in the case of bulk drugs their intermediates and formulations.

Under New Drug policy National Pharmaceutical Pricing Authority (NPPA) is appointed to implement and enforce the provisions of Drugs(prices control) order . Thus the objective of the Government was to decontrol in order to induce increased competition and to make essential drugs affordable to the weaker sections of country.

However in recent times every aspects of Indian pharmaceutical industry's functioning was affected and continue to be affected by events which could not have been predictedeven a decade back. Several regulatory mechanisms have been initiated by Government of India (GOI) including a major revamping of the Drugs and Cosmetics Act 1940 and the setting up of Central Drug Authority (CDAIL) similar to US . FDA.

As Indian pharmaceutical industry has always been for good reasons and termed as most regulated industrial sector all over the world. The major components of industry activities are

1) R&D for the discovery and development of new drugs with or without association of MNCs,
2) Product development of both the API as well as their generic forms,
3) Marketing of pharmaceutical products,
4) Post marketing surveillance,
5) Providing medical or necessary information's to medical professionals and patients too,
6) Last but most important pricing of pharmaceutical products.

All regulations are applicable equitably both on big corporations as well as SSPUs of the country. During the last one year, a large numbers of statutory controls and regulatory measures have been brought in Indian pharmaceutical industry either as law or guidelines encompassing the various activities.

HYPOTHESIS FORMULATION:

Null Hypothesis - H01, Food and Drug Administration positively influences the business strategies of Small scale pharmaceutical units.

Alternate Hypothesis - Ha1, Food and Drug Administration negatively influences the business strategies of Small scalepharmaceutical units.

Null Hypothesis - H02, DPCO/NPPA positively influence the business strategies of Small scale pharmaceutical units.

Alternate Hypothesis - Ha2, DPCO/NPPA negatively influence the business strategies of Small scale pharmaceutical units.

Null Hypothesis - H03, Tax/excise holiday scheme for SEZ/SPZ, positively influence the business strategies of Small scale pharmaceutical units in other parts of country.

Alternate Hypothesis- Ha3, Tax/excise holiday scheme for SEZ/SPZ, and negatively influence the business strategies of Small scale pharmaceutical units in other parts of country.

RESULTS AND FINDINGS:

It is found that small scale pharmaceutical units in majority is not highly satisfied with the regulatory and legal frame work as if now and refer to figure 7.2.1.1 and also concludes from hypothesis 1. Food and Drug Administration is not positively influence the business strategies of small scale pharmaceutical units. As centralization of FDA is the new initiative than earlier state FDA's. As state FDA's are working on tight restrictions and limitations, whereas central FDA is principal body of DCGI, this arrangement increases thebeurocracy as well delays in getting approvals for new products ,increase expenses, imposition of multiple and strict regulations which poses negative impact on profitability and growth of small scale pharmaceutical units.

Similarly refer to figure no. 7.2.1.2 and 7.2.1.3 and hypothesis no.2and3 pertaining to DPCO/NPPA and SEZ/SPZ. As DPCO/NPPA is to maintain, ceiling and rationalization of prices of pharmaceutical products for domestic as well as MNC's, if this can be done in rationalize manner, it will be helpful to small scale pharmaceutical units to make substantial space to sell the products on considerable profit margin, but as if now DPCO/ NPPA increases their list of finished products but not able to control the prices of API's , so that it will result the low margins for domestic small scale pharmaceutical units , further more DPCO/NPPA not enforce the same on MNC's pharmaceutical products, as their products are research and development driven.

This study also revel the scheme promote by Government of India to have SPZ/SEZ in specific are of country played havoc for small scale pharmaceutical units of other parts of country, Govt. have two choices left with them ,either they shift to such places by making huge investment or close their operation, as tax /excise(on MRP) and its exemption limit (as per turn over slab) not allows small scale pharmaceutical units.

Fig. 7.2.1.1

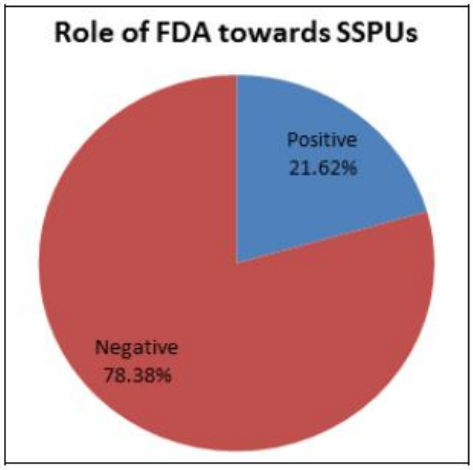


Fig. 7.2.1.2

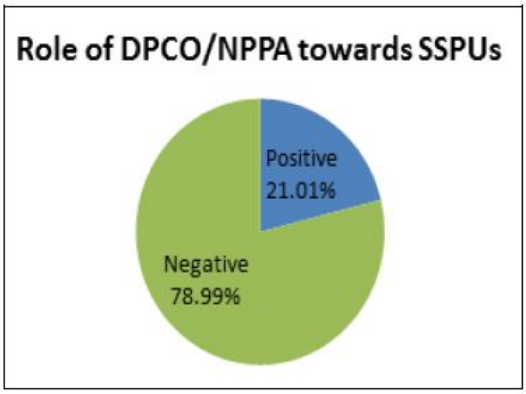
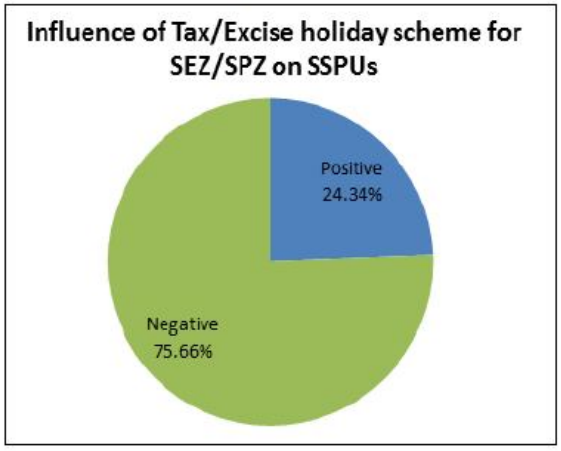


Fig. 7.2.1.3



CONCLUSION:

Indian pharmaceutical industry, especially small pharma sector is a highly regulated sector and in last decade severely hampered negatively by regulators under tremendous global pressure, must try to consolidate themselves, state wise/industry wise and strongly negotiate with respective authorities for necessary flexibility, since SSPI sector is still maximum job producing sector in the country. The small scale pharmaceutical units can also used the platform of SME exchange for financial independency also need separate ministry for Pharmaceutical industry on priority basis.

It was found during the study Food and Drug administration (FDA), negatively influence the business strategies, results in delays in getting product approvals, imposition of tight and restricted norms which ultimately increases the expenses.

The findings implicate that, DPCO/NPPA control the prices of finished products but do not have any control on prices of APIs and finish product(s) of MNCs. It severely impacted on cost-price structure of products manufactured by small scale pharmaceutical units.

During study researcher observed that government decision on Tax/Excise holiday schemes in some specific areas of country, leads to severe drop in profit margins, financial break down and subsequent closer down of hundreds of small pharma units in other parts of country.

REFERANCES :

1.J K Sharma & A K Singh (2012) *Change & Competitive Advantage : An Investigative Study of Indian Pharmaceutical Industry*, The IUP Journal of Business Strategy, Vol.ix, No,3,2012

2.B.S. Rau & Dr. J. Vijaya Ratna (2012) *A Pilot Survey & Study of Status of Small Scale Pharmaceutical Industry in India*, Pharma Times---Vol 44 – No 04 –April-2012.

3.Bhushan Jatania (2012), *Pay for Delay: A Potential Competition Concern in Indian Pharmaceutical Industry*, Research Paper for The Competition Commission of India

4.Pharmabiz.com June 26, 2013, *DPCO & Enforcement*.

5.Sushmi(October 7, 2012), *Turf war in the pharma industry*, Business Standard. 31. SIDBI/BSE/D&B (2013), *MSME Financial Literacy & Education workshop.*