

Drug Pricing Control and Strategies by Pharma Companies: Study in Indian Perspective

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Abstract—This study attempts to analyse the purpose and consequences of drug pricing control by the Government of India on the pharmaceutical industry's strategy and growth prospects for its retailing. The study has been done on two of the major drugs manufactured by the top notch drug manufacturing companies in the world like Bayer and Novartis. The study has further analysed the effect of drug pricing control by the Government on the pharmaceutical industry as a whole. The rationale behind selection of these companies is their considerable market share in the world pharmaceutical industry and the wide range of life saving drugs being offered by them. Based on the existing list of 348 drugs which have been brought under Drug Pricing Control in 2013, 60-70% of the industry has come under price control which is squeezing the margins of wholesalers, retailers up to the extents of 50 percent. The profit cuts have led to shortage of these medicines in market as wholesalers and retails have slowed down the buying rate due to low margins. Hence, we can say Drug Pricing which has been introduced for a noble cause has also caused havoc in people's life, thus Government should regulate compulsory licenses in India to manufacture these essential lifesaving drugs instead of controlling prices by stringent mechanisms. However excessive price control reduces the attractiveness of the pharmaceutical industry and dampens the growth prospects of the drug manufacturing companies as they face cost constraints as domestic manufacturers make generic drugs at a much cheaper price.

The drug manufacturing companies like Roche, Bayer, Novartis, Glen mark & Pfizer have lost market share and now face cost constraints. This is because they have lost patent fights and now domestic drug manufacturers produce generic drugs which are much cheaper than the specific version.

Keywords: Drug pricing control, Price ceiling, Patents, Pharmaceutical Industry, Strategy

1. INTRODUCTION

Drug pricing control is basically implemented by the Government to ensure that certain life-saving drugs are available for the public and there is proper healthcare infrastructure in the country. There is an existing list of 348 drugs which are under price control by the **National Pharmaceutical Pricing Authority (NPPA)**. The NPPA asks the manufacturer to lower the prices of these listed drugs whenever the prices go above the ceiling price. A price ceiling is the highest price that the Government has set for a particular drug to be sold at. The Government also exercises control on

the grant of patents to international drug manufacturers. This enables the domestic drug makers to manufacture a generic drug at a much cheaper cost and thus this facilitates better availability and affordability of these otherwise highly expensive drugs in the domestic market. Currently Govt of India is trying to cap the prices of essential drugs only on the basis of simple formula with sales more than 1 percent. The DPCO 2013 has empowered the National Pharmaceutical Pricing Authority ("NPPA") to regulate prices of 348 essential drugs. As per the new DPCO 2013, all strengths and dosages specified in the National List of Essential Medicines (NLEM) will be under price control. This case study endeavors to provide an insight of the key aspects of the DPCO 2013 and discusses the manner in which such provisions have been implemented.

2. GLOBAL PHARMACEUTICAL INDUSTRY

As per estimates of World Health Organization, the volume of Global Pharmaceutical trade has been measured up to the extent of US\$300 billion a year and this is expected to rise to 40-50 percent by next three years. WHO further says that the 10 largest drugs companies control over one-third of pharmaceutical market of world with sales of more than US\$10 billion a year and profit margins of about 30%. It is predicted that North and South America, Europe and Japan will continue to account for a full 85% of the global pharmaceuticals market well into the 21st century. Companies currently spend one-third of all sales revenue on marketing their products - roughly twice what they spend on research and development. The revenue from entire worldwide Pharmaceutical market has been estimated up the extent of almost 1000 US billion, out of which 44 per cent share contribution is done by North America and another 35-40% by three regions i.e. Asia and Australia. It has also been estimated that the US share of global pharmaceutical spending will decline from may decline to 31% in 2015 while the share of spending from the top five European national markets (i.e., Germany, France, Italy, Spain, and the United Kingdom) will decline from 20% to 13% during the same period. Meanwhile, 17 high-growth emerging markets, led by China, will contribute 28% of total spending by 2015, up from only 12% in 2005, according to IMS.

3. INDIAN PHARMACEUTICAL INDUSTRY

Indian Pharmaceutical market is unique by some of its own characteristics like the generic drug market which dominates the industry with 70-80 per cent retailing. Apart the tax free, subsidy free manufacturing zones being declared by Govt. of India, makes a significant presence of Local players in manufacturing with capacity to drive formula and investment at low scale with tax free soaps. The third most important feature of Indian market is its low price level due to intense competition and existence of supply chain links at multilevel. The size of Indian pharma Industry which has witnessed the growth of 12 to 14 percent for previous one decade and is expected to reach 30 billion by end of 2016, by increasing from 24 billion in 2015. One of the highly organized sector, that ranks very high in terms of technology, research, quality and a vast range of medicines that are manufactured. Ranging from simple headache medicines to complex molecules, everything is being manufactured in the country. India is now one of the top five emerging markets of the world. According to India Ratings, a Fitch company, the Indian pharmaceutical industry is expected to increase at 20 per cent compound annual growth rate (CAGR) over the coming five years.

4. DRUG PRICING CONTROL

A price control occurs when the government puts a legal limit on the maximum selling price of a product in a country. The main focus of pharmaceutical health policies in India is to focus on the progression of the industrial sector while the issues of availability, pricing, and affordability of drugs remain ignored. Although, it is a common notion that drug prices in India are relatively low, studies have reported that medications in India are overpriced and unaffordable. The margin in medication sales across the same generic class of medications is extremely high, often ranging from 1000% to 4000%. In 1997, the National Pharmaceutical Pricing Authority (NPPA) was established under the ministry of chemicals and fertilizers, Government of India with the aim of controlling the prices of medicines and ensure its availability. As a result by the year 2013 the prices of the 348 essential medicines were reduced dramatically, and they were made available to the public at low cost. Almost a year later NPPA controlled the prices of other 108 life-saving drugs and hence the patient friendly policy significantly reduced the prices of some important life-saving drugs for disease conditions such as cancer, HIV/AIDS, tuberculosis, cardiovascular diseases, diabetes, etc. However on May 29, 2014, NPPA withdrew 108 drugs under price control policy and this exclusion of these 108 drugs from the price control list was believed to negatively influence public health. World Health Organization recently stated that cardiovascular disorders, diabetes mellitus, and cancer were among the major causes of mortality in India. The NPPA order asks manufacturers of these scheduled formulations to reduce the maximum retail price of the drugs wherever the existing rate exceeds the ceiling. For prices

already below the ceiling, manufacturers can maintain the existing maximum retail price. The manufacturer may add local taxes only if these have been actually paid or are payable. **India has extended price control on medicines used to treat diseases such as diabetes, infections, digestive disorders and pain among others, in an effort to make them affordable.** Some of the medicines, which have been put under price control, include Ciprofloxacin Hydrochloride, Cefotaxime, Paracetamol, Domperidone and Metformin+ Glime. The Supreme Court of India in a statement on July 2015, has asked the central government to reexamine its pricing policy for essential medicines after a group of non-governmental organizations challenged the provisions. The Supreme Court labelled the formula by which prices of essential medicines are currently being fixed in India as "unreasonable and irrational". The government currently caps the prices of more than 500 essential medicines. But the All India Drug Action Network (AIDAN), a group of NGOs, alleged in a public interest litigation that prices are fixed at very high levels, which makes drugs unaffordable for many. AIDAN has also alleged that India's current national list of essential medicines does not include many life-saving drugs (Source: Article by Thomson Reuters July 2015).

5. HOW DRUG COMPANIES STRATEGIZE

Pharma companies strategize to bear the pressure of drug price control, yet to maintain their revenues. Under regulation of government Pharma companies have to accept the price cut but, *there are battles to be fought now, and where payers can see a battle they can win, they will definitely attempt to increase effectiveness in fighting them.*

5.1 Prominent Strategies

Here are some of the prominent strategies being adopted,

1. **Specialized Focus:** *To specific beneficial areas instead covering all, in the wake of mounting pricing pressure due to patent cliffs and strict price control regulations in emerging markets*
2. **Restructuring R&D divisions:** *In order to improve efficiency and focus on core areas rather than non-specialities, companies have restricted their R&D divisions.*
3. **Shifting from R&D to S&D (Search and Development)-Outsourcing:** *Merck has shifted from R&D to S&D (search and development), by externally scouting innovations through "innovation hubs", thereby trimming down its internal R&D jobs.*
4. **Strategic Alliances**
5. **Investment in Innovative Companies:** *For example, Sanofi acquired 12% stake in US-based Alnilam Pharmaceuticals to strengthen its new-drug pipeline in the first quarter of 2014.*

6. **Changed Strengths and dosages:** *This strategy helps companies not only to work within budgets but introduce new products as well.*

Learning from Companies :The case study further highlights examples of few prominent drug manufacturers putting insigne into the strategies they adopted with the price regulations,

Drug Name: GLIVEC **Company Name:** NOVARTIS

Novartis considers Glivec as its major medical breakthroughs of the 20th century, which has been replicated with minor process adjustments in India. The drug is used to treat gastrointestinal cancers and leukemia.

Novartis decision by Judiciary system of India The Supreme Court of India had rejected the plea of Novartis for patent protection for its anti-cancer drug sold in the name of Glivec or Gleevec. The judgment had evoked extreme reactions. While some greeted it as a landmark judgment which will make medicines more affordable, others condemned it as harmful for innovation and foreign investment.

The Indian Patent Office had rejected the patent application of Novartis for the β -polymorphic form of imatinib mesylate on various grounds in 2006, including that a patent could not be granted for the β -polymorphic form under section 3(d) as it did not have any increase in efficacy over the previously known substance. Novartis appealed against the rejection of the patent by the Patent Office before the Intellectual Property Appellate Board (IPAB) in 2007, but the appeal was dismissed in 2009. Aggrieved by this dismissal, Novartis went to the Supreme Court which has now confirmed the rejection of the patent. The judgment has been welcomed by many, as it prohibits global pharma firms from repeatedly claiming a patent on the same drug by making minor changes to it. That allows domestic companies to come out with cheaper generic versions, Novartis's shares fell by over 4 per cent following the Supreme Court's verdict making lifesaving drugs affordable to a large section of patients in a developing country like India. (Reference : articles.economicstimes.indiatimes.com > Collections)

Novartis Strategy : The Novartis supply chain is run on a global basis. So instead of thinking on a country-by-country basis, global plan is formulated on worldwide level and *then* it is executed country by country. In spite of these setbacks on the IPR and pricing front, Novartis continued to launch new products in India to meet unmet medical need. These setbacks also did not prevent Novartis from continuing and expanding its patient access programmes and India-specific pricing strategy. Novartis launched its blockbuster diabetes drug Galvus, at a significant lower price .The patient access programme for Glivec, through which more than 17,000 patients who are on Glivec continue to receive the drug free of charge i.e. more than 90 per cent of patients with chronic myeloid leukemia (CML) who are prescribed Glivec get it free. As a market penetration strategy for Novartis' products,

across branded generics OTCs and pharmaceuticals, the company has developed perfect business sense, tapping into a large market. Rural India makes up 11 per cent of the global population with huge unmet medical needs.

Drug Name: NEXAVAR, **Company Name:** BAYER

What went Wrong: Natco Vs Bayer was the first case of compulsory licensing being obtained in India. Bayer invented a drug named Sorafenib. Indian Generic pharmaceutical company Natco filed an application with Bayer for the voluntary license of the drug Nexavar (Sorafenib) with reasonable commercial terms and agreements. The request was denied and so Natco filed an application in the Controller of Patents for Grant of compulsory license. As a result of issuance of compulsory licence, no bottles of Nexavar were imported in India during the year 2008-2010. The importance of time period lies in the fact that Government of India granted Bayer a patent on drug Nexavar in the year 2008 after assessing that Bayer will fulfil the minimal requirements of public during that period. Also Bayer did not manufacture the drug in India, as it focused on imports of its bottles. The price of drug at the time of decision was Rs. 2,80,248 per month as compared to generic price drug of Rs. 8800/- per month of Natco.

6. CONCLUSION

To conclude it can be said that excessive drug pricing control is not good for the pharmaceutical industry. The purpose with which the Government undertakes drug pricing control is to make the drugs affordable, available and accessible. However excessive price control reduces the attractiveness of the pharmaceutical industry and dampens the growth prospects of the drug manufacturing companies as they face cost constraints as domestic manufacturers make generic drugs at a much cheaper price.

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Consumers and physicians in India are very brand conscious, even when it comes to medications. As a result, currently, higher drug prices don't necessarily lead to lower market share. Indeed, for almost half of product categories under the DPCO (47%), the most commonly used drug is also the most expensive.

The pricing control does not impact all product categories equally: it has a smaller impact on currently economically efficient categories. Under the pricing control, simple price averages will become new price ceilings. This means that for categories for which a low cost alternative to an expensive branded agent has much higher utilization (i.e. economically efficient), the weighted average of prices, and thus actual

spend, will not change significantly. Perhaps this is intentional as it will allow the economically efficient part of India's healthcare market to remain unaffected.

The control may impact locally-manufactured generic alternatives as it reduces the price of the MNC branded options, thus decreasing the price gap and perhaps making the MNC brand more attractive. This will lead to a decrease in the number of "branded generic".

Thus to conclude the purpose of the Government to provide drugs to the poor is not being fulfilled. There should be an exhaustive list of drugs under price control so that it doesn't hamper the pharmaceutical industry's growth. There is an impact on the changes in the pharmaceutical industry, the supply chain strategy and market size of the pharmaceutical sector. The strict pricing control in India would not only affect MNCs to market their products but will have adverse effect on their R&D, as already MNCs prefer to setup their research centres outside India.

Nearly 70 per cent of Indian healthcare expenses are paid out of pocket by patients or their families. Western drug makers often accuse India of using public health as a pretext for boosting the country's big generic pharmaceuticals industry. They worry that cheap copies of patent-protected medicines will be exported to other markets and that India's approach risks undermining global drug development.

Thus price control is a double edged sword and has both its benefits and drawbacks. It should be used effectively to benefit everything, with

7. RECOMMENDATIONS

For the pharmaceutical industry, price is the most important factor contributing to profit, more than any other component of its activity. There have been regular complaints from pharmaceutical industry associations in India that the Drug Prices Control Order (DPCO) of the government, which seeks to impose a ceiling on the maximum retail price of selected drugs, is a major obstacle to investment in the pharmaceuticals sector.

- There is a need to review the implementation of DPCO 2013 to resolve genuine practical problems of implementation. The government may implement a predictable and stable price control mechanism through a consultative approach with the industry
- International import prices of all new drugs should be verified before fixing the selling prices in Indian market.

- Instead of considering drug pricing by way of decreasing it forcibly, Government should issue compulsory licenses to firms in India to manufacture medicine which are otherwise available at very high cost.
- Denying patent protection for certain drugs and issuing compulsory licenses is another way to tackle this situation.
- Licenses should be issued to some local manufacturers so that some drugs which are out of reach for some people are easily accessible.
- If 'drug price control' is abolished in India, it is expected that pharma companies would grow at a much faster rate in volume with commensurate increase in consumption, than what they have recorded during 'limited price control' regime in the country
- Up to the maximum extent, generic drugs should be promoted at all levels.
- One most important effort that Government should focus upon is strengthening our R&D sector in the country and making it more lucrative for foreign firms to invest in Pharmaceutical sector.

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