

# The Decontrol of Drug Prices in India

## Implications for the Indian Pharma Industry

### Introduction

The drug prices in India are controlled using what is called the Drugs (Prices Control) Order (DPCO). The DPCO is an order issued by the government under Section 3 of the Essential Commodities Act, 1955<sup>1</sup> empowering it to fix and regulate the prices of essential bulk drugs<sup>2</sup> and their formulations<sup>3</sup>. The order incorporates a list of bulk drugs whose prices are to be controlled, the procedure for fixation and revision of prices, the procedure for implementation, the procedure for recovery of dues, the penalties for contravention and various other guidelines and directions. The order is subject to the guidelines of Drug Policy and supposedly aims to ensure equitable distribution, increased supply and cheap availability of bulk drugs.

In this paper, I seek to examine the nature of deregulation of drug prices that has occurred in India over time and the impact of the same on the pharmaceutical industry.

### Control and Decontrol of Drug Prices – A Historical Account

The DPCO was first passed in 1970 and then revised in 1979, 1987 and 1995. Individual as well as comparative analysis of all the DPCOs illustrates that there has been a measured but sturdy decontrol of drug prices in India. This analysis has been presented below.

#### 1947-1970

At the time of independence, the bulk drug industry in India was in the infancy stage with a meager investment of Rs. 10 crore and a production worth just Rs. 26 crore. Most of the bulk drugs and formulations were imported.<sup>4</sup> Till 1962, the drug industry was bereft of any price control. In 1962, there was Chinese aggression on India and Emergency was declared. The government feared that, as a result, drug prices might rise. Accordingly, for the first time, under the Defense of India Act of 1915, statutory control was imposed on the prices of drugs and pharmaceuticals. The Drugs (Display of Prices) Order, 1962 and the Drugs (Control of Prices) Order, 1963 were promulgated. Under the Drugs Prices (Display and Control) Order of 1966, it was made obligatory for the manufacturers to obtain prior approval from the government before increasing the prices of any formulation.<sup>5</sup>

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<sup>1</sup> The Essential Commodities Act, 1955 was enacted for the control of production, supply, distribution, trade and commerce in certain commodities that were declared essential by the Central Government. The Act defines 'Essential Commodities' to include drugs since they are considered essential for the health of society. Section 3 of the Act authorizes the Central Government to regulate or prohibit the production, supply, distribution, trade and commerce in any of the 'essential commodities' if the same is necessary for maintaining or increasing supplies of these commodities for securing their equitable distribution and availability at fair prices. (Source: The Essential Commodities Act of 1955)

<sup>2</sup> A bulk drug is any pharmaceutical, chemical or biological product including its salts, esters, stereo-isomers and derivatives, conforming to pharmacopoeia or other standards and which is used as such or as an ingredient in a formulation. (Source: The Drugs Prices Control Order, 1995)

<sup>3</sup> A formulation is a medicine processed out of bulk drug/s for internal or external use for or in the diagnosis, treatment, mitigation or prevention of disease in human beings or animals, but shall not include any medicine included in the Ayurvedic, Homeopathic or Unani system of medicines. Hence, the DPCO is applicable only to allopathic drugs. (Source: The Drugs Prices Control Order, 1995)

<sup>4</sup> This particular statistic was obtained from the website of The Bulk Drug Manufacturers Association cited at <http://www.bdm-assn.org/aboutus.html>.

<sup>5</sup> "History of Drugs Price Control," *Role of NPPA in Drug Pricing*, published by National Pharmaceutical Pricing Authority.

## **DPCO, 1970**

On 16<sup>th</sup> May, 1970, a comprehensive order was promulgated under Section 3 of the Essential Commodities Act and in super session of all the earlier orders on the subject. This order was called The Drugs (Prices Control) Order, 1970.<sup>6</sup> In its introductory form, DPCO was a direct control on the profitability of a pharmaceutical business, and an indirect control on the prices of pharmaceuticals. The government stipulated that a company's pre-tax profit from its pharma business should not exceed 15% of its pharma sales (net of excise duty and sales tax). In case profits exceeded 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 exceed the stipulated norm. Since individual product prices did not require approval from the government, bureaucratic hurdles were low. At that time, the Indian pharmaceutical industry was largely dominated by MNC affiliates and subsidiaries. These MNCs were hardly affected by the relatively mild form of DPCO and continued operating in the domestic market. However, FERA which came in mid 70's did curb the operations of MNCs. Overall, the Indian pharma industry prospered from 1970 to the next DPCO in 1979.<sup>7</sup>

## **The Hathi Committee, 1974**

In 1974, the Gol appointed a Committee under the chairmanship of Rajya Sabha MP Jaisukhlal Hathi to enquire into the conditions prevailing in the sphere of pharmaceuticals in the country. The Committee submitted its report in 1975 which is widely known as the Hathi Committee report. The report strongly emphasized greater role for the public sector in the manufacturing of drugs. The DPCO, 1979 was loosely based on the recommendations of the Hathi committee but many a provisions were not implemented.<sup>8</sup>

## **DPCO, 1979**

The Drugs Prices Control Order of 1979 was issued on 31<sup>st</sup> March.<sup>9</sup> In its revised version, the DPCO stipulated ceiling prices for controlled categories of bulk drugs and their formulations. In fixing the price, the government continued to advocate the profitability ceiling and an upper limit was put on the return on net worth or capital employed for pharma companies.

The retail prices of controlled formulations were decided by applying the concept of MAPE (Maximum Allowable Post manufacturing Expenses). It was a mark-up on ex-factory costs, provided to cover selling and distribution costs including retail and wholesale trade margins. The pricing formula was retail price<sup>10</sup> = (MC+CC+PM+PC) x (1+MAPE/100) + excise duty, where MC was the material cost including cost of bulk drugs/excipients, CC was the conversion cost as per the dosage form is, PM was the cost of packing material suitable to dosage form and PC was the packaging charge worked out in accordance with established costing procedures.

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<sup>6</sup> "History of Drugs Price Control," *Role of NPPA in Drug Pricing*, published by National Pharmaceutical Pricing Authority.

<sup>7</sup> "Drug Price Control Order (DPCO)," *Pharmaceutical Industry*, published by India Info line Limited.

<sup>8</sup> This section is based on my conversation with Mr. Arya of Indian Drug Manufacturers Association.

<sup>9</sup> "History of Drugs Price Control," *Role of NPPA in Drug Pricing*, published by National Pharmaceutical Pricing Authority.

<sup>10</sup> This was not the Maximum Retail Price (MRP) of the formulation. Local Taxes were added at the time of sale.

The 1979 DPCO put 370 drugs under price control. These drugs were segregated into three categories, having different MAPE. See the table below. The most important drugs, including life saving drugs were put in Category I which had the least MAPE.

Category	MAPE
I	40%
II	55%
III	100%
IV	60%

Through this DPCO, around 80% of the Indian pharma industry (in value terms) was brought under strict price control. The MNCs were the worst hit. With profitability falling steeply, they discontinued many products, especially the life saving products in Category I. In addition, the industrial licensing requirements made it impossible for MNCs to introduce new products. The local players were, nonetheless, in a better position. They could obtain licenses much easily than MNCs could. They were also able to speedily introduce new drugs. The local players, as a result, were able to keep the coverage of DPCO low and fight the might of established MNCs. However, profitability wise, the Indian pharma sector went through its worst phase from 1979 to 1987.<sup>11</sup>

#### **The Kelkar Committee, 1984**

In 1984, the Kelkar Committee came out with its report in which it recommended the exclusion of a number of drugs from the purview of price control. Various suggestions were made for determining the criteria for inclusion and exclusion. The committee stressed the need to liberalize the strict profitability curbs that were acting as a hurdle to the growth of the pharma sector.<sup>12</sup>

#### **DPCO, 1987**

The DPCO, 1987 was promulgated on 26<sup>th</sup> August on the basis of the Drug Policy of 1986 and the Kelkar Committee Report. In DPCO, 1987 the number of bulk drugs under price control was significantly reduced from 370 to 142. 20 drugs were taken off from Category I and 122 from Category II.<sup>13</sup> In addition, the categories of control were reduced to two and higher MAPE was provided for each category of controlled drugs. See the table below. The MAPE for Category I and Category II was increased from 40% and 55% respectively to 75%. The MAPE for Category IV was increased from 60% to 100%. Even the new drugs that were brought under price control got a liberal 75% MAPE.

Category	MAPE
I	75%
II	100%

<sup>11</sup> "Drug Price Control Order (DPCO)," *Pharmaceutical Industry*, published by India Info line Limited.

<sup>12</sup> This section is based on my conversation with Mr. Arya of Indian Drug Manufacturers Association.

<sup>13</sup> "History of Drugs Price Control," *Role of NPPA in Drug Pricing*, published by National Pharmaceutical Pricing Authority.

Furthermore, industrial licensing norms were made softer thereby improving the situation of MNCs desirous of amending their product mix. As a result of all these factors, profitability improved. However, around 75% of the pharma industry was still under price control.<sup>14</sup>

### **The Drug Policy of 1994**

In September 1994, the new drug policy was announced. It is the Drug Policy of the government that decides the criteria for selecting bulk drugs or formulations for price control. The New Drug Policy liberalized these criteria. In addition, industrial licensing was abolished for all bulk drugs. All hindrances to capacity expansions were removed and it was expected that, as a result, supply would rise resulting in higher competitive pressures. Foreign investment up to 51% was also permitted in case of all bulk drugs, their intermediates and formulations. FDI above 51% was to be considered on a case to case basis. Nevertheless, five bulk drugs - Vitamin B1, Vitamin B2, Folic Acid, Tetracycline and Oxytetracycline - were reserved for the public sector till 1998.<sup>15</sup>

### **DPCO, 1995**

The latest Drug Price Control Order was passed on 6<sup>th</sup> January 1995. The basic structure of this DPCO is the same as that of the earlier two orders. Nevertheless, the span of price control under DPCO 1995 has been liberalized considerably from 142 drugs to just 76.<sup>16</sup>

The Pricing of Bulk Drugs: The 76 bulk drugs, the prices of which are controlled under DPCO 1995, have been enlisted in the First Schedule annexed to the order. The methodology through which prices of DPCO-controlled bulk drugs are fixed is as follows. While fixing the maximum sale price of a bulk drug, the government has to provide either a post-tax return of 14% on net worth or a return of 22% on capital employed.<sup>17</sup> Each company can choose one of the two methods mentioned above as per its own free will. So, the choice of method is company-specific and not product-specific. Then based on the chosen method, each company submits to the government, a detailed working of the prices of various bulk drugs that it requires. The prices submitted by the companies are such that the allowed profitability parameters are achieved. The government subsequently studies the applications made by the major players for every bulk drug and cost audits reports of manufacturers, before arriving at the final price. The price so decided will be binding on all manufacturers, irrespective of their actual cost of production.

The Pricing of Formulations: The Drug Price Control Order covers all the formulations that utilize the bulk drugs listed in the First Schedule. The methodology through which prices of formulations are fixed is as follows. Under DPCO 1995, a uniform MAPE of 100% is given on all formulations under price control. This is in contrast to the earlier practice of giving a MAPE of 75% on some formulations. In the new system, the retail price of a DPCO formulation is fixed equal to  $(MC+CC+PM+PC) \times 2 + \text{excise duty}$ . It is this price that is printed on the pack of a DPCO-controlled formulation. This price is not the Maximum Retail Price (MRP). Local taxes are additional. In order for the government to decide the price of a controlled formulation, each manufacturer is supposed to submit to the government details of material cost, manufacturing process etc. The ceiling prices, once decided, are notified in the Official Gazette.

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<sup>14</sup> "Drug Price Control Order (DPCO)," *Pharmaceutical Industry*, published by India Info line Limited.

<sup>15</sup> "Drug Price Control Order (DPCO)," *Pharmaceutical Industry*, published by India Info line Limited.

<sup>16</sup> This section is largely based on the information gathered from the following book: "Drug Price Control Order (DPCO)," *Pharmaceutical Industry*, published by India Info line Limited.

<sup>17</sup> In respect of a new plant, an IRR of 12% based on long-term marginal costing is allowed and where production is from basic stage, a post-tax return of 18% on net worth or a return of 26% on capital employed is allowed.

For imported drugs and formulations, the landed cost including customs duty and clearing charges is the benchmark to fix prices. The margin allowed to the importer is such that selling and distribution expenses including interest and profit are covered. However, the margin allowed cannot exceed 50% of the landed cost.

## Implications of Drug Price Control and Decontrol for the Pharma Industry

The impact of drug price control and decontrol on the Indian pharmaceutical industry can be analyzed on the following three fronts.

### Profitability

Of all the parameters that can be used to judge the impact of drug price control and decontrol on the pharma industry, the parameter of profitability is the most important. Consider Exhibit 1.

**Exhibit 1**



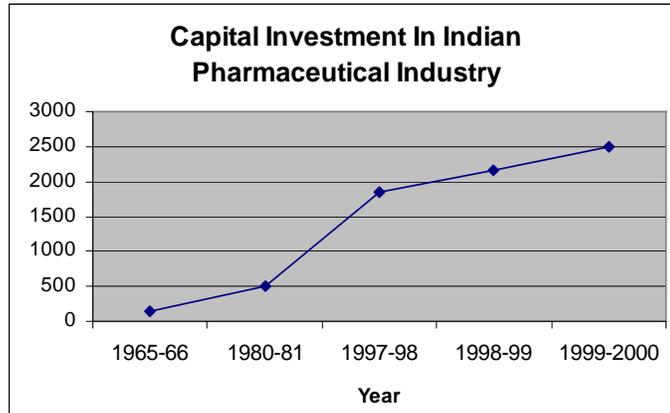
The diagram<sup>18</sup> depicts the profit before tax (as % of sales) for the Indian pharma industry for the period 1982-1998. The illustration is unique in that we get an unambiguous 'V-shaped' graph. It is obvious from the graph that the profits of the pharma industry plummeted over the period 1982-1991 and thereafter registered a stupendous increase. The control and decontrol of drug prices played an important role in this trend.

Till 1987, 90% of all drugs produced in India were controlled as regards their prices. This put severe strain on the profit margin of the industry. There might have been other factors as well but drug price control was certainly a major factor responsible for the decline in industry profits in the pre-1990 period. The post-1987 period saw the DPCO being revised twice – first in 1987 and then in 1995. In the first revision, price control on drugs was eased and made applicable to 65% of all drugs as opposed to 90% earlier. In the second revision, this came down to 40%. With the strain on profit margin being eased, the industry's profits skyrocketed.

As the industry became more profitable and viable, capital investment into the Indian Pharma Industry increased. See Exhibit 2.

<sup>18</sup> This diagram is based on the statistics obtained from the website of the Organization of Pharmaceutical Producers of India cited at <http://www.indiaoppi.com/profitablechart.htm>. The source of data for different years are the following: The NCAER Study for the years 1982 and 1983, A.F. Ferguson's Study for the year 1984, OPPI's Estimate for the years 1985 and 1986, OPPI's Surveys for the years 1987, 1988, 1989, 1990, 1991, 1992, 1993 and 1994, and OPPI's Estimate for the years 1995, 1996, 1997 and 1998.

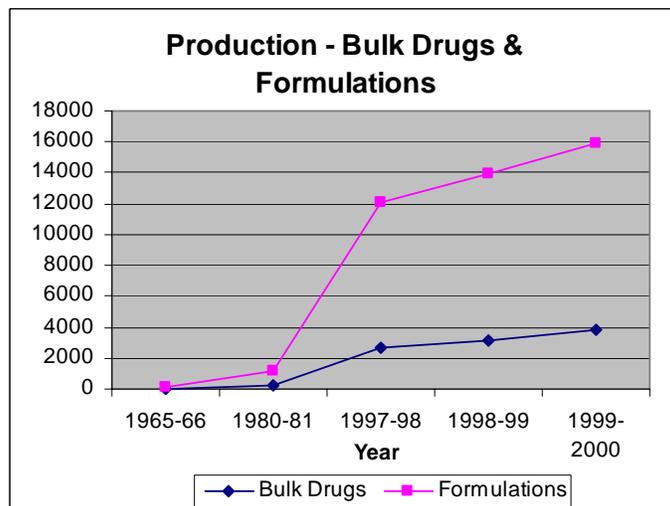
## Exhibit 2



## Manufacturing

Consider Exhibit 3.

## Exhibit 3



The diagram depicts the production of bulk drugs and formulations by the Indian Pharmaceutical Industry over the period 1965-2000. It is clear from the graph that the manufacture of drugs and formulations in India for the first 15 years was meagre and it was only in the last decade that the industry picked up in terms of production capacity. Again, drug price control and decontrol was a major feature in this trend.

In the Drug Price Control Order of 1979 which stayed enforced till 1987, 90% of all drugs were under strict price control. With such massive regulation on the prices of most drugs and thereby on the profitability of the manufacturing companies, the production of scheduled drugs became unfeasible. For instance, no export orders were taken on controlled drugs since their supply had to be under certain parameters. As a result, the level of manufacture by the pharma industry declined.

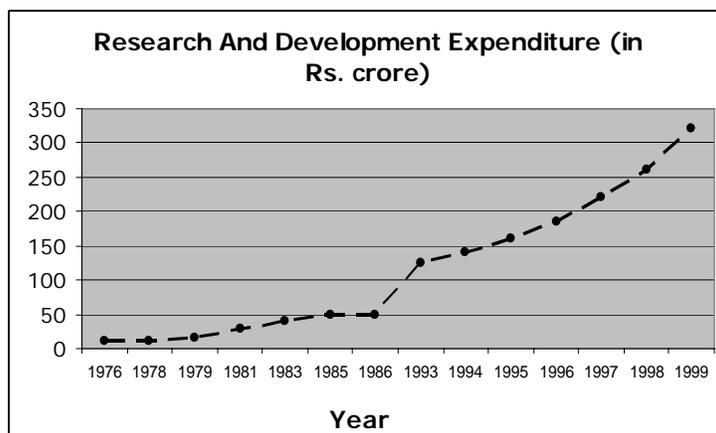
In the DPCO of 1987 and then in the DPCO of 1995, the proportion of drugs under price control declined to 65% and to 40% respectively. With a large number of drugs being taken out of price

control, the production of these drugs became feasible again. As a result, the manufacture of these drugs increased.

## Research and Development (R&D)

Consider Exhibit 4.<sup>19</sup>

**Exhibit 4**



The diagram illustrates the expenditure on research and development incurred by the Indian Pharmaceutical Industry over the period 1965 – 2000. It is patent from the diagram that for the first 15 years, expenditure on R&D was almost stagnant and it was only in the 1990s that expenditure on this front really picked up. The control and decontrol of drug prices is a major explanatory factor of this trend.

Until around the 1990s, the drug prices were strictly controlled. This stifled expenditure on R&D in more ways than one. First of all, the profit margin of the industry came down. With an inadequate profit margin, the industry never ventured out in the field of R&D. Secondly, it dissuaded foreign players and MNCs from entering the market. In fact, the share of foreign companies in the domestic drug market has continuously declined. See Exhibit 5.<sup>20</sup> Also, the imports and exports were meager. See Exhibit 6.<sup>21</sup> With the local players hardly getting any competition from foreign drug manufacturers, they never felt the need of investment in R&D. There were also reasons other than the control of drug prices for the slack R&D expenditure. For instance, process patents had been granted to the industry under the Indian Patent Act of 1970 and the domestic manufacturers simply had to reverse engineer<sup>22</sup> drugs made abroad. They were able to foray into various therapeutic segments and there was no need to indulge in any R&D.

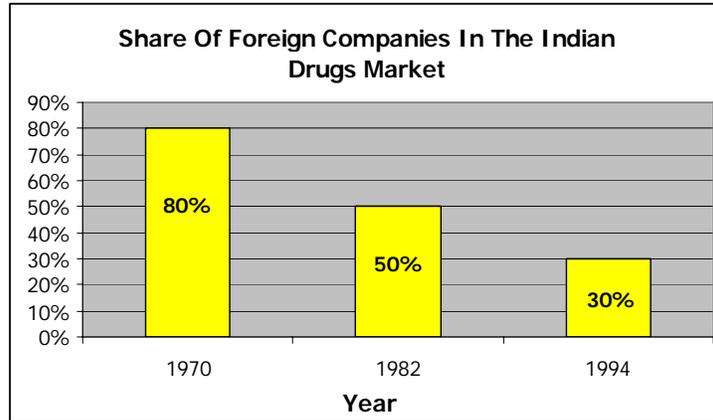
<sup>19</sup> This diagram is based on the statistics obtained from the website of the Organization of Pharmaceutical Producers of India cited at <http://www.indiaoppi.com/researchchart.htm>.

<sup>20</sup> This diagram is based on the statistics obtained from 'Indian Pharmaceutical Industry – Issues And Options' published by FICCI.

<sup>21</sup> This diagram is based on the statistics obtained from the website of the Organization of Pharmaceutical Producers of India cited at <http://www.indiaoppi.com/importcompchart.htm> and <http://www.indiaoppi.com/exportschart.htm>.

<sup>22</sup> Reverse engineering effectively implies pirating somebody else's technology by dismantling an existing product, and reproducing its parts and construction to manufacture a replica.

### Exhibit 5



### Exhibit 6



However, things changed in the 1990s, when controls on drug prices were eased. First of all, profit margin for the domestic drug manufacturers increased thereby enabling local players to provide for R&D. Secondly, foreign trade in drugs increased (see Exhibit 3) thereby raising the level of competition in the domestic and international market and necessitating greater R&D. However, there were factors other than the decontrol of drug prices which propelled R&D. For instance, under the TRIPS agreement, process patents were replaced with product patents. This shut the door on reverse engineering and made expenditure on R&D an inevitability for the local players.

### Conclusion

It is patently clear from the historical analysis that successive Indian governments have steadily decontrolled drug prices in India. In the last 14 years, the degree of drug price regulation has dipped by 50%. So far as the speed of deregulation of drug prices is concerned, it is a matter of debate.

It is also clear from the above discussion that the Indian Pharmaceutical Industry has heavily benefited from deregulation. Not only has the drug market in India become more profitable and viable, the production capacity and the research and development expenditure of Indian companies has also witnessed a significant increase.

This paper, however, remains deficient in one respect. It doesn't analyze the impact of deregulation of drug prices on the Indian consumer. My efforts in this regard have been unsuccessful largely due to the difficulty involved in collecting and compiling data on inter-temporal prices, accessibility and quality of drugs. Only a comprehensive and discreet investigation into this particular aspect will reveal the true nature of the impact of drug price deregulation.

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