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Review on Drug Price Control Order

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ABSTRACT: ***Price regulation is one of the raging topics in the pharmaceutical sector. As every subject has its pros and cons, so is the case with Drug Price Control Orders (DPCO). After the initiation of DPCO in 1995, its revised version was implemented in 2013. DPCO 1995 accounted for about 74 bulk drugs. On the contrary, DPCO 2013 has almost 652 drugs under it. Hence, currently, all the medicines under DPCO are regulated by DPCO 2013. Also, it can be analyzed that the increase in the number of drugs under DPCO meansthere is ahigher demand for essential drugs.Thus,on abiggerpicture, itmeans that there is an increase in the diseases overall.***

Keywords-Drug Price Control Orders, Price control

I. INTRODUCTION

DPCO has encouraged the domestic drug manufacturers to manufacture generic variants of branded drugs at cheaper prices. This makes the essential drugs more convenient and preferable to consumers. The DPCO 2013 has acquired National Pharmaceutical Pricing Authority (NPPA) to control price of essential drugs. The main objective of formation of DPCO was the availability of essential and life-saving drugs ata minimal price to all the strata of the society who are in need of proper medication but cannot afford it. It also playsa crucial role to develop the proper healthcare infrastructure in India (Mahajan, 2018). NPPA orders drug manufacturers to lower the prices of listed drugs whenever the price goes above ceiling price. Ceiling price is the highest price decided by government for the drugs. There is also a 'National List for Essential Medicines (NLEM)' formulated which is basically a list comprising of all these essential medicines. Approximately, more than 348 drugs are listed in NLEM and it is increasing day-by-day due to new emerging diseases and life style related diseases along with their treatment (Majumdar, 2018).

DPCO is Drug Pricing Control Order of India which is regulated by NPPP andNPPA. The main objective of DPCO is to provide the essential and life-saving drugs at affordable prices to the people who are in need of such medicines. Accordingly, as discussed earlier, NLEM is formulated and revised from time to time. The DPCO hasfive revised versions but the two prominent revisions are DPCO 1995 and DPCO 2013.InDPCO1995,therewereonly 74drugsunderthepricecontrolbutinDPCO2013,there are almost 652 drugs and its formulations under price control. The common term used in pricing is the 'ceiling price'. The ceiling price is the maximum price which is allocatedby DPCO for the selling of that drug. Also, there were certain terms which were changed in DPCO 2013, like, formulations, scheduled drugs, scheduled formulations, etc. Formulations refer to the medicines which are processed for one or more drugs. They are developed with or without use of pharmaceutical techniques. Also, the term scheduled drugs is changed to scheduled formulations according to the recent developments in the pharmaceutical sector (Ministry of Chemicals and Fertilizers, 2013).

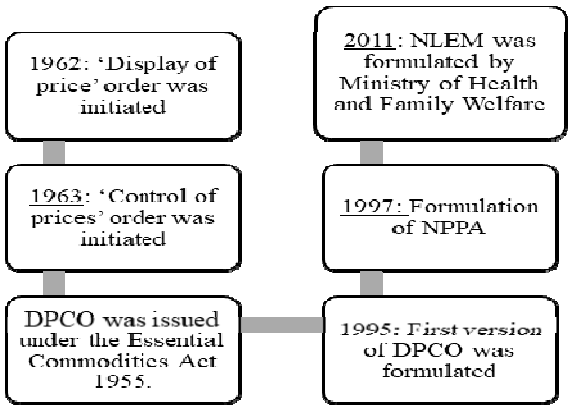


Figure1ThetimelineofeventsofDPCOfromitsorigincanbedemonstratedas

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NPPA is an organization of the Government of India which was established, inter alia, to fix/ revise the prices of controlled bulk drugs and formulations and to enforce prices and availability of the medicines in the country, under the Drugs (Prices Control) Order, 1995. The organization is also entrusted with the task of recovering amounts overcharged by manufacturers for the controlled drugs from the consumers. It also monitors the prices of decontrolled drugs in order to keep them at reasonable levels.

The **Drug Price Control Order** (**DPCO**) was enacted by the Government of India in 1955. The latest amendments to the policy and regulations were made in 2013 and termed as **DCPO**-2013 (National Pharmaceutical Pricing Authority, 2018). This regulation ensures the availability of essential drugs to the public at a reasonable and controlled price (Kumar, Gupta, and Kumar, 2014). The Drug Price Control Order identifies drugs as an essential commodity. The Drug Price Control Order poses a check on manufacturers and prevents them to sell their drugs at an exorbitant price (The Economic Times, 2017). No pharma company is authorized to sell any drug to a consumer at a price exceeding the tagged price by National Pharmaceutical Pricing Authority (NPPA) under **DPCO**-2013.

II. HISTORY OF DPCO

The Pharmacy education in our country has witnessed tremendous expansion in last one decade. However, the standard in education have been eroded by rising tides of mediocrity. There is an urgent need to initiate an academic exercise aimed at attaining revamping of curriculum, keeping in pace with current and emerging trends in the field of pharmacy.[1]

1) DPCO, 1970:

A comprehensive order under Section 3 of the Essential Commodities Act was issued on May 16, 1970, and it replaced any earlier orders on the subject. The Drugs (Prices Control) Regulation, 1970 was the name given to this order. In its initial form, DPCO turned into a direct assault on a pharmaceutical company's ability to make a profit as well as an indirect attack on the cost of drugs. The government mandated that a corporation could no longer make more pre-tax profit from its pharmaceutical business than 15% of its pharmaceutical income (net of excise duty and income tax). Any additional revenue would need to be lodged with the authorities. Therefore, a pharmaceutical company was free to choose the prices it would charge for its goods. Product-smart margins have also been accommodating, provided that. At that time, the Indian pharmaceutical enterprise become in large part ruled with the aid of using MNC associates and subsidiaries. These MNCs have been hardly ever tormented by the fairly moderate shape of DPCO and continued running with inside the home market. However, FERA which got here in mid 70's did lessen the operations of MNCs. Overall, the Indian pharma enterprise prospered from 1970 to the following DPCO 1979.[2]

2) DPCO, 1979:

The Drugs Prices Control Order of 1979 become issued on 31st March. In its revised version, the DPCO stipulated ceiling expenses for managed classes of bulk tablets and their formulations. In solving the price, the authorities endured to endorse the profitability ceiling and a top limit become placed on the go back on internet really well worth or capital hired for pharma companies. The retail expenses of managed formulations had been determined via way of means of making use of the idea of MAPE (Maximum Allowable Post Manufacturing Expenses). It becomes a mark-up on ex- manufacturing facility charges, supplied to cowl promoting and distribution charges together with retail and wholesale exchange margins

3) DPCO, 1987:

The Drug Policy of 1986 and the Kelkar Committee Report served as the foundation for the promulgation of the DPCO, 1987, which took effect on August 26. The number of bulk tablets available for free manipulation in DPCO, 1987, fell from 370 to 142.[2]

Table 2: The Drugs Prices Control Order of 1987.[2]

Category	MAPE
1	75%
2	100%

4) The Drug Policy of 1994:

The brand new drug coverage was announced in September 1994. It is the drug policy of the authorities that sets the standards for deciding on bulk pills or formulations for charge management.

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The new drug policy liberalised those standards. In addition, business licencing was abolished for all bulk pills. All impediments to capability expansions had been removed, and it was predicted that as a result, supply would surge upward, resulting in higher aggressive pressures. Foreign funding in the amount of 51% turned out to be authorised in the case of all bulk pills, their intermediates, and formulations. FDI in excess of 51% is considered on a case-by-case basis. Nonetheless, until 1998, five bulk pills—Vitamin B1, Vitamin B2, Folic Acid, Tetracycline, and Oxytetracycline—were reserved for the general public.[2]

5) DPCO, 1995:

On January 6, 1995, the modern-day Drug Price Control Order was issued. The primary shape of this DPCO is similar to that of the earlier orders. Nevertheless, the span of charge management under DPCO 1995 has been significantly liberalized, going from 142 pills to simply seventy-six. The Pricing of Bulk Drugs The seventy-six bulk pills, the costs of which might be managed under DPCO 1995, were enlisted within the First Schedule annexed to the order.[2]

Main Features of DPCO 2013 Are:

- It brought 348 drugs and their 652 formulations under price control.
- The new policy uses a market-based pricing mechanism against the prior proposed cost-plus method.
- Margins of wholesalers and retailers have been cut down to 8% and 16%, respectively.
- To monitor the M.R.P. of non-schedule formulations.
- Control over bulk drug and formulation manufacturers.[8]

What is Ceiling price:

Means a price constant through the Government for Scheduled formulations in according with the provisions of paragraph 9.

Calculation of ceiling price of a scheduled formulation:

The ceiling price of a scheduled formulation of specified strengths and dosages as specified under the first schedule shall be calculated as under:

First Step: First the Average Price to Retailer of the scheduled formulation i.e. P(s) shall be calculated as below:

Average Price to Retailer,

P(s) = (Sum of prices to retailer of all the brands and generic versions of the medicine having market share more than or equal to one percent of the total market turnover on the basis of moving annual turnover of that medicine) / (Total number of such brands and generic versions of the medicine having market share more than or equal to one percent of total market turnover on the basis of moving annual turnover for that medicine.)

Second Step: Thereafter, the ceiling price of the scheduled formulation i.e. P(c) shall be calculated as below:

P(c) = P(s).(1+M/100)

Where, P(s) = Average Price to Retailer for the same strength and dosage of the medicine as calculated in step1 above.

M = % Margin to retailer and its value =16.[9]

III. CONCLUSION

Price control was needed for regulation of prices as multinationals were imposing ahigher price for drugs. DPCO is an initiative taken by the NPPA in accordance with NLEM. Several amendments have been carried out and the DPCO is upgraded according tocurrenttrendsandfutureforecasting.ThecomparisonbetweenDPCO1995andDPCO 2013 elaborates different aspects of change such as pricing strategy, number of formulations under DPCO, etc. This has provided with the information of increase in demand of drugs. DPCO provides essential drugs at less expensive prices to the patients who cannot afford the treatment. Thishas alsobeen amotive in many other countries and formulation of different price control agencies has taken place. Developed countries like the USA, the UK, Japan, etc. are also keen to launch different price control initiatives for the enhancement of healthcare sector. A maximum retail price (MRP) is a manufacturer calculated price that is the highest price that can be charged for a product sold in India. The NPPA regularly publishes list of medicines and the maximum ceiling prices. NLEM forms the basis of deciding which medicines should come under price control via DPCO.

This Act is very much helpful for patient who take regular medicine so, they can afford medicine in minimum price. Due to that the patient compliance is achieve. According to the need of the drug the medicine should place in essential medicine list.

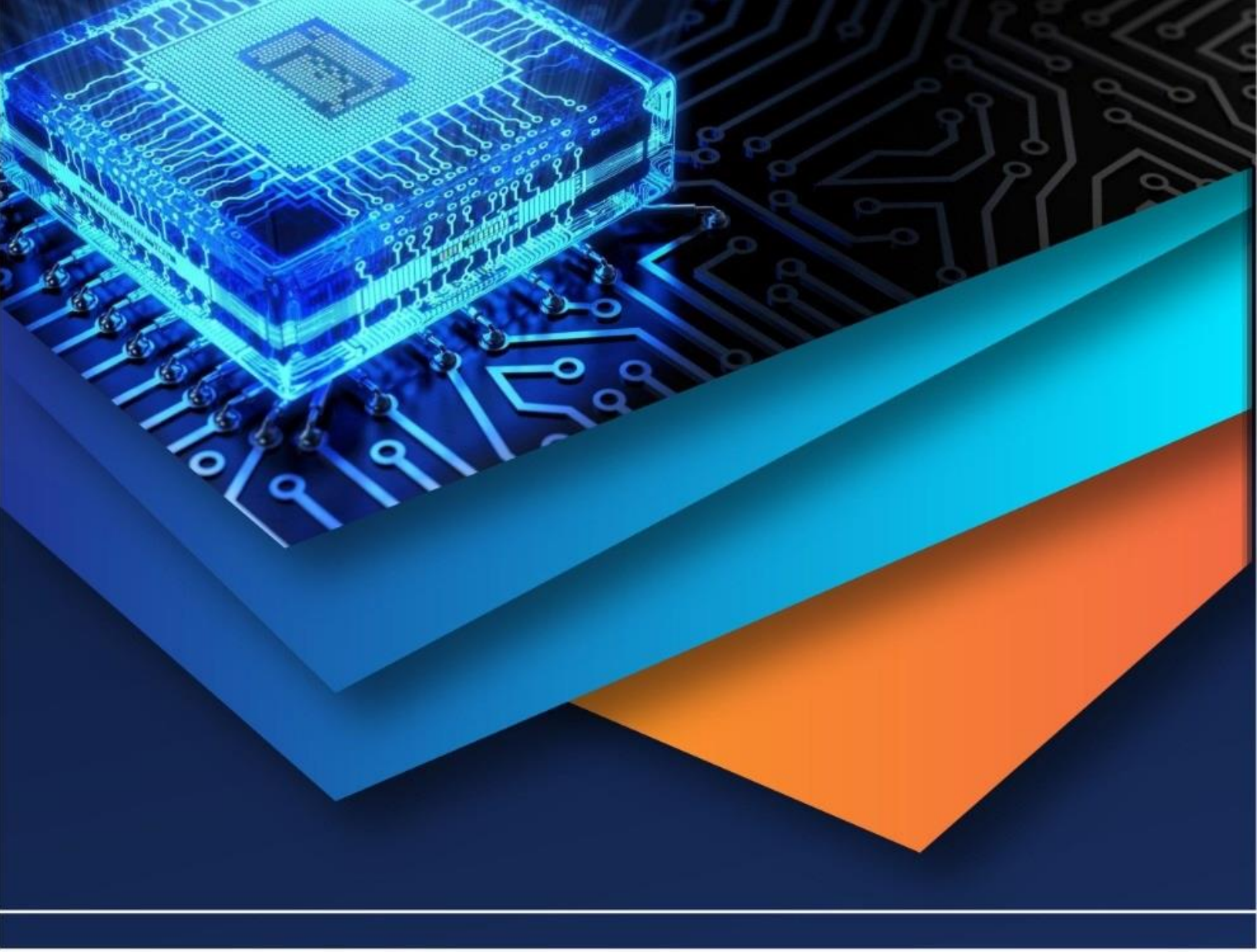
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DPCO 1995 is a win – win situation for the manufacturers where government has no control over the fixation of prices of drugs, where the prices of the drugs are fixed by manufacturing cost mechanism. DPCO 2013 has over come this problem by involving government in fixing the prices by simple average market price mechanism, by which the most of the lifesaving drug prices are fixed by government, which is a win-win situation for manufacturer and patient. There is no doubt that the Indian customer will be the biggest beneficiary under the new drug pricing control order 2013 (DPCO 2013). The impact over the industry can be analysed on short and long term basis.

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