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Research Article

A COMPARISION BETWEEN OLD AND LATEST SYSTEMS IN DPCO

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ABSTRACT

The present article deals about comparison between the DPCO act 1995 and DPCO act 2013. The new pricing guideline, DPCO is come in to effect from May 15, 2013. In past before implementing DPCO 2013, the prices of 74 bulk drugs are controlled by DPCO 1995, but when the DPCO 2013 is came into effect, 652 new drugs are added to the list national list of essential medicines (NLEM). It is the duty of government to make the lifesaving drugs affordable to the common man.

To achieve this government has to take steps as following:-

a. It has to reduce the prices of the drug which is needful for common man.

b. To improve the research and development of new drugs, it has to be liberal in fining the prices in such a way that the industries cannot be suffered and it has to support the research in the nation.

For this purpose the DPCO is came into effect:

a. It controls the market prices of the drugs.

b. It supports research by exempting the price control on new drugs by giving patent up to 5 years

Keywords: DPCO, National list of essential medicines (NLEM).

INTRODUCTION

Drugs are recognized as 'essential commodity' should always be available to the general public at a reasonable price In absence of any statutory control a manufacturer could sell a drug at exorbitant price which is not only against public interest but also against the concept of welfare state. To fix the maximum retail prices of drug formulations, to curb the exorbitant profiteering in drug manufacturing and distribution, the drug price control order has been promulgated.[1] Due to the DPCO the pressure on MNC'S regarding price determination is increased which helps the domestic companies to perform research. Prices of many MNC's off patent branded drugs are controlled by DPCO. [2]

The essential feature of DPCO covers the following queries:

- For the regulatory purposes, there are two prices fixed by the National pharmaceutical pricing authority as per the provisions of DPCO - Ceiling and Non Ceiling Price.
- Ceiling Price is the single maximum selling price fixed that is relevant throughout the country in the case of each bulk drug, which is under price control.
- Non-Ceiling Price fixed by National pharmaceutical pricing authority are specific to a particular pack size of scheduled formulation of a specific company.
- The non-scheduled drug prices are controlled by national pharmaceutical pricing authority.
- The maximum retailed prices are fixed to control wholesalers and retailers.[1]

DPCO 1995

Prior to 1962 the prices of drugs are fixed by MNC's, which cannot be controlled by government. In 1970, the DPCO came into act under the essential commodities act (1955), which is the pharmaceutical price directive in India. To legalize the prices of drugs, the DPCO 1995 is an order issued by government of India to control the prices of drugs under section 3 of the essential commodities act 1955.

The DPCO consists of:

a. List of drugs whose price is controlled by DPCO

b. Methods and steps involved in fixation of prices.

c. Implementation of prices fixed by government.

d. Other supplementary things.[2]

Objectives of DPCO 1995

- To provide the lifesaving drugs of good quality at reasonable prices, and in needed quantities.
- Strengthening the quality control system of pharmaceutical manufacturers in India.
- To support the research and development of Indian pharmaceutical manufacturers
- To produce cost effective medications.
- To increase the production capabilities of Indian pharmaceutical manufacturers.

Medicines and its preparations have been laid open to price control for more than three decades now. The economic reforms initiated by the Government of India in July 1991, trickled down to the Pharmaceutical Industry only in 1994 and that too moderately. Charge control in an enormous integer of trades has already been abolished. [3]

DPCO 2013

It gives the authorization to NLEM to fix the prices if drugs based on new market based values. The Prices of 652 drugs are controlled by DPCO, which are 74 before. DPCO facilitates the government to support the indigenous research and development of new drugs by providing patent to the innovations.

Objectives of DPCO 2013

- To increase the number of drugs from 74 to 652, whose prices are controlled by DPCO.

- To regulate and control the prices of 384 drugs by national pharmaceutical pricing policy, those are covered under national list of essential medicines (NLEM 2011).

- The innovative course of action diverges from the prevailing DPCO 1995 in that it is based on the simple average price (SAP) for all brands with a market share above 1% in their segment.

- The new policy also uses a market-based pricing mechanism against the earlier anticipated cost-plus method.

- At the core of the new regime lies the ceiling price. This would be considered by taking simple average of prices of all brands of a drug with a market share of 1% or more. The maximum retail price of a drug would factor in a margin of 16% to the chemist. The costs predominant in May 2012 will be taken as the reference point for calculating the caps.

- To ensure the fall of drug prices by

i. It does not allow the escalation in prices of drugs which are less than the prices fixed by DPCO

ii. To reduce the high selling prices of drugs according to new values.

- To allow the firms to sell their new drugs, at or below the prices fixed by the government.

- To control the manufacturing of existing drugs, the firms cannot stop their production without taking the permission.

- To allow the manufacturers to increase their maximum retail price annually. [4]

Drug Pricing Mechanism

i. Previously the prices of drugs are fixed by the manufacturers based on their manufacturing costs. But after implementation of DPCO (1995), the prices are fixed by the government, which led to a situation like most of the manufacturers has withdrawn their products from market and manufacturing levels have been decreased.

ii. After facing such situation, government of India implemented DPCO (2013), by which most of the drugs are came under national of essential medicines (NLEM).

iii. The prices are fixed by their simple average of all marketed products of that particular drug, which have a market share of more than 1%.

iv. The final MRP of the drugs at the retailer is increased with a factor of 16%

v. However, such as read patient groups argue that the previous price fixing mechanism of 1995 i.e., cost based pricing, is more significant than the present market based pricing. [3,5]

Drugs that not come under price control

DPCO 2013 strives to support, national research and development by giving of patent of five years for new innovations in India, exempting those drugs from DPCO for 5 years after starting commercial production.

Non-application of provisions of DPCO 2013

i. If the drug is developed through indigenous R&D, for a period of 5 years from the 1st day of commercial production.

ii. The manufacturers producing new drugs which are patented under Indian patent act 1970.

iii. New drug products manufactured by new development process

iv. New drugs involving new delivery system.

Table 1: Comparison of DPCO 1995 & DPCO 2013

S. No.	DPCO 1995	DPCO 2013
1	It is governed by Essential commodities act 1955	It is governed by national pharmaceutical pricing authority, based on national list of essential medicines
2	Prices of only 74 drugs were regulated by this act	Prices of 652 drugs are regulated by this act
3	If once the prices are fixed, they can't be changed as per the act	Based on simple average price (SAP) the highest prices can be lowered depending on the margins
4	Ceiling and non-ceiling prices of drugs are not specified	Ceiling and non-ceiling prices of drugs are specified
5	This act facilitates Win –Win situation for the government, but not for the industries	The prices of the drugs are fixed by the mutual agreement of government and industries for the welfare of the public

CONCLUSION

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 overcome 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 prices of some brands may fall by up to 70 present. It is anticipated that the policy will cover two-thirds of the Rs.60,000crore domestic industry. The impact over the industry can be analysed on short and long term basis.The large companies with established brands may be able to withstand better but there could be some loss of market segment. In the petite production lucrativeness could decline. However, despite the initial hit on cost-effectiveness, capacity growth over the next few years will help companies improve.

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