

Drug Price Control Order (DPCO) w.r.t. National Pharmaceutical Pricing Policy 2012

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Abstract

Government of India under the Ministry of Chemicals and Fertilizers has issued an order called Drug Price Control Order (DPCO) to fix the prices of essential drugs to provide affordable medicines to the populations of India. This paper gives overview of drug price control order and highlights the key principles of national Pharmaceutical Pricing policy, 2012 along with key elements for implementing the same.

Keywords

Drug Price Control Order, National Pharmaceutical Pricing Policy, Essential Medicines, Generic Medicines



Greentree Group

[Received](#)02/01/17[Accepted](#)01/03/17[Published](#) 10/03/17

INTRODUCTION

DRUG PRICE CONTROL ORDER:

It is an order issued by Government of India under the ministry of Chemicals and Fertilizers, Department of Pharmaceuticals to fix the prices of some essential bulk drugs and their formulations.

It was initially introduced in the India in the repercussion of Chinese aggression with the declaration of the drugs (Display of prices) order 1962 and the drugs (Control of Prices) order 1963. Latter one, a series of price control programmes were notified through various orders in the country from time to time based on different principals depending on span of control or prices and nature of control of prices. The Drugs (Price Control) order was then issued in 1970 under the “Essential Commodities Act 1955 by declaring drugs to be essential commodities under the EC act, 1955”.

In 1994, the Drugs (Price Control) Order was revised in the context of the liberalization of economy and the abolishment of industrial licensing as well as foreign investment in drug industry. In 2002, it was revised again due to foreign direct investment (FDI) in the pharmaceutical sector which further liberalised the economy and limit raised up to 100%. Thereafter the Ministry of Health

and Family Welfare revised the list of medicines in the National List of Essential Medicines (NLEM) earlier notified in 1996 and issued new NLEM, 2003. Thereafter, various drug policies adopted from time to time based to cope up with the challenge of striking a balance between the requirements of enabling industry to grow and at the same time ensuring affordable and reasonably priced medicines to the customers.

The Government of India then replaced the Drug Policy pronounced in September 1994 as “Modifications in Dug Policy 1986” in 2012 as NPPP-2012 (National Pharmaceutical Pricing Policy). Main objective of NPPP-2012 is to implement regulatory framework for pricing of drugs for availability of essential medicines as affordable prices and along with that providing sufficient opportunity for innovation and competition to support the growth of industry.

MAIN PRINCIPLES OF NPPP-2012:

- Essentiality of Drugs
- Control of Formulation Prices
- Market Based Pricing
- Span of Price control as per dosages and strengths listed in NLEM 2011

- Ceiling price (A price fixed by the Govt. for scheduled formulations in accordance with the provisions of this order) of NLEM Medicines.

Ceiling Price (CP) of NLEM Medicines (P_s) = Sum of prices of all the brands of the medicine having market share more than and equal to 1% of the total market turnover of that medicine / Total number of manufacturers producing such brands of the medicine

- Ceiling price is applicable only to formulations. Manufactures are free to fix any price of their product equal to or below CP

- Ceiling Price is fixed based on readily monitorable market based data (MBD) which is available with the pharmaceutical market data specializing company – IMS health.

- Ceiling price of a scheduled formulation in case of no reduction in price due to absence of competition – overall % reduction in the price of same molecule with other dosage and strength will be applied or overall % reduction in the price of medicines in the same therapeutic category will be applied.

- Non- Price Control drugs: Price control regime monitored the prices of Non-scheduled drugs in case the prices of such drug increases by more than 10% in year.

- Imported Drugs: Ceiling Price of Imported drugs are fixed similar to ceiling price of NLEM Medicines.

- Overlap Drugs between DPCO 1995 and NLEM 2011: Prices of overlap drugs were frozen for one year and thereafter a maximum increase of 10% / annum is allowed.

- Patented Drugs: The Pricing of Patented Drugs is based on the recommendation the Committee constituted by the Govt of India order dated 1st Feb, 2007.

- Exemption: To promote innovation and R&D following drugs are given exemption under price control order for a period of 5 years from the date of commencement of its commercial production in the country

- A new drug patented under the Indian Patent Act, 1970

- A drug developed by new process under the Indian Patent Act,1970

- A formulation developed by new delivery system under the Indian Patent Act, 1970

- A new drug is added under Drug Price control order on the recommendation of Ministry of Health and Family welfare.

- Drugs are prescribed based on their generic names only

- Jan Aushadhi stores are opened to provide affordable generic drugs to public

ESSENTIAL KEY ISSUES FOR IMPLEMENTING POLICY:

Key elements to provide affordable medicines to public are not only drug price control but also innovative drug research which plays equally important part in provision of affordable healthcare to majority of the populations. Along with this Government has to provide insurance plans, healthcare programs and all-encompassing pharma control policies. Some of such key issues are

- Government Healthcare plan with insurance cover

- Special scheme for BPL and APL families for specific treatment like anticancer, Anti HIV etc

- Strong and transparent drug purchase policy for bulk drug by the Government for

determining reasonable ceiling price for NLEM drugs

- Low cost Pharmacy Chain through Jan Aushadhi Program

- Public awareness towards medicines by prescribing non-branded generic drugs along with branded generic drugs

- Accessibility of low price drugs to low income families

- Drug Bank

- Strengthening of Pharmaceutical Industry by

- Implementing Drug Regulations through regulatory authorities

- Encouragement of research and development in Pharmaceuticals through funding and subsidies

- Implementation of GMP/GLP and GCP standards

- Developing Human Resources

- Rationalization of excise duties on pharmaceuticals

- Development of Pharma cluster or pharma parks

- Strengthening of Pharma supply chain

IMPLEMENTATION OF DPCO:

A national Pharmaceutical pricing authority is responsible for implementing a new drug price control order for effective, speedy and transparent manner.

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