



DRUG PRICE CONTROL ORDERS (DPCO)

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ABSTRACT

Price controls are applicable to what is generally known as “Scheduled drugs” or “Scheduled formulations”. Since 2013, scheduled formulations consist of the “Essential Medicines” declared so by the Government through its National List of Essential Medicines (NLEM). It does not mean that all drugs brought under price control are essential medicines. As per Para 19 of the DPCO-2013, the Government may, in case of extra-ordinary circumstances and in public interest, fix the ceiling price or retail price of any drug, whether scheduled or non-scheduled or a new drug for such period, as it may deem fit. Exchanging prices among competitors can also violate the antitrust laws.

KEYWORDS: Price controls are applicable can also violate the antitrust laws.

Drug Price Control Orders (DPCO)

Price controls are applicable to what is generally known as “Scheduled drugs” or “Scheduled formulations” that is, those medicines which are listed out in the Schedule I of Drug Price Control Order (DPCO), issued by the Government of India from time to time.^[1] (It may be noted that the use of the word “Scheduled drugs” is a legacy of the DPCO-1995.^[2] The latest DPCO 2013 only uses the word “Scheduled formulation” to refer to medicines in its first schedule since some of the bulk drugs when used as a single ingredient also act as a formulation. Hence, generally these medicines are referred even now as “scheduled drugs” from the perspective of price regulation). Since 2013, scheduled formulations consist of the “Essential Medicines” declared so by the Government through its National List of Essential Medicines (NLEM).^[3] In fact, Schedule I of DPCO-2013 is the NLEM-2011 list. Thus, NLEM forms the basis of deciding which medicines should come under price control via DPCO. Any formulation based on combination of any one of these drugs appearing under NLEM can be subject to price fixation. In the earlier DPCOs (those prior to DPCO-2013), NLEM was not taken into consideration for price fixation or price monitoring.^[4] Further, in the earlier DPCOs, only the bulk drugs were mentioned in Schedule-^[5] and prices were fixed by the Government for both bulk drug as well as formulations based on any of these bulk drugs. Since 2013, all essential medicines (as defined under NLEM) are treated as scheduled formulations (under DPCO-2013). However, it does not mean that all drugs brought

under price control are essential medicines. As per Para 19 of the DPCO-2013, the Government may, in case of extra-ordinary circumstances and in public interest, fix the ceiling price or retail price of any drug, whether scheduled or non-scheduled or a new drug for such period, as it may deem fit. It also has powers to revise (either increase or decrease) the ceiling price or retail price of the drug which is already fixed and notified, irrespective of annual wholesale price index for that year (based on which companies are automatically permitted under DPCO to revise the prices annually).^[6] Price controls are applicable irrespective of whether it is generic or branded.^[7] National Pharmaceutical Pricing Policy (NPPP) is the policy governing price control and DPCO is the order by which price control is enforced. The Drug Price Control Orders are issued by Ministry of Chemicals and Fertilisers, which is the main nodal administrative ministry for pharmaceutical companies.^[8] Under the latest DPCO 2013, the prices of 348 drugs appearing in the National List of Essential Medicines-2011 covering around 628 formulations have been brought under the purview of price control^[9]

Drug Price Control Orders

The NPPA regularly publishes lists of medicines and their maximum ceiling prices. The latest DPCO was released in 2013 which has a list of 384 drugs.^[10,11,12,13,14,15]

Functions

- To implement and enforce the provisions of the Drugs (Prices Control) Order in accordance with the powers delegated to it.
- To deal with all legal matters arising out of the decisions of the Authority.
- To monitor the availability of drugs, identify shortages, if any, and to take remedial steps.
- To collect/ maintain data on production, exports and imports, market share of individual companies, profitability of companies etc, for bulk drugs and formulations.
- To undertake and/ or sponsor relevant studies in respect of pricing of drugs/ pharmaceuticals.
- To recruit/ appoint the officers and other staff members of the Authority, as per rules and procedures laid down by the Government.
- To render advice to the Central Government on changes/ revisions in the drug policy.^[16]
- To render assistance to the Central Government in the parliamentary matters relating to the drug pricing.^[17]

Price fixing is an agreement between participants on the same side in a market to buy or sell a product, service, or commodity only at a fixed price, or maintain the market conditions such that the price is maintained at a given level by controlling supply and demand. The intent of price fixing may be to push the price of a product as high as possible, generally leading to profits for all sellers but may also have the goal to fix, peg, discount, or stabilize prices. The defining characteristic of price fixing is any agreement regarding price, whether expressed or implied. International price fixing by private entities can be prosecuted under the antitrust laws of many countries. Examples of prosecuted international cartels are those that controlled the prices and output of lysine, citric acid, graphite electrodes, and bulk vitamins.^[18] In the United States, price fixing can be prosecuted as a criminal federal offense under Section 1 of the Sherman Antitrust Act.^[19] Private individuals or organizations may file lawsuits for triple damages for antitrust violations and, depending on the law, recover attorneys fees and costs expended on prosecution of a case.^[20,21,22] Under American law, exchanging prices among competitors can also violate the antitrust laws. That includes exchanging prices with the intent to fix prices or the exchange affecting the prices individual competitors set. Proof that competitors have shared prices can be used as part of the evidence of an illegal price fixing agreement.^[23] Experts generally advise that competitors avoid even the appearance of agreeing on price.^[24] Since 1997, US courts have divided price fixing into two categories: vertical and horizontal maximum price fixing.^[25] Vertical price fixing includes a manufacturer's attempt to control the price of its product at retail.^[26]

Maximum retail price

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 and Bangladesh.^[27,28]

All retail products in India must be marked with MRP. Shops cannot charge customers over the MRP. Some shops may charge slightly below MRP to draw more customers to their stores. In some remote areas, tourist spots, and in situations where a product is difficult to obtain, consumers are often charged illegally over the MRP.^[29]

In April 2015, it was reported that milk vendors in Mumbai were threatening a boycott after it was discovered they had been charging above MRP and the Maharashtra state government threatened to intervene.^[30]

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Calculation of retail price of formulation

The retail price of a formulation shall be calculated by the Government in accordance with the following formula, namely: - $R.P. = (M.C. + C.C. + P.M. + P.C.) \times (1 + MAPE/100) + ED$ Where "R.P." means retail price; "M.C." means material cost and includes the cost of drugs and other pharmaceutical aids used including overages, if any, plus process loss there on specified as a norm from time to time by notification in the Official Gazette in this behalf; "C.C." means conversion cost worked out in accordance with established procedures of

costing and shall be fixed as a norm every year by notification in the Official Gazette in this behalf; "P.M." means cost of the packing material used in the packing of concerned formulation, including process loss, and shall be fixed as a norm every year by notification in the Official Gazette in this behalf; "P.C." means packing charges worked out in accordance with established procedures of costing and shall be fixed as a norm every year by notification in the Official Gazette in this behalf; "MAPE" (Maximum Allowable Post-manufacturing Expenses) means all costs incurred by a manufacturer from the stage of ex-factory cost to retailing and includes trade margin and margin for the manufacturer and it shall not exceed one hundred per cent for indigenously manufactured Scheduled formulations; "E.D." means excise duty: Provided that in the case of an imported formulation, the landed cost shall form the basis for fixing its price along with such margin to cover selling and distribution expenses including interest and importer's profit which shall not exceed fifty per cent of the landed cost. Explanation: For the purpose of this proviso, "landed cost" means the cost of import of formulation inclusive of customs duty and clearing charges.

CONCLUSION

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 and Bangladesh. The NPPA regularly publishes lists of medicines and their maximum ceiling prices. NLEM forms the basis of deciding which medicines should come under price control via DPCO. price fixing can be prosecuted as a criminal federal offense under Section 1 of the Sherman Antitrust Act.

REFERENCE

1. Scheduled drugs does not mean the drugs appearing in the various schedules to Drugs & Cosmetic Act and Rules, 1945.
2. DPCO had only used the words "Scheduled Bulk drugs" and "Scheduled formulations". "Scheduled drugs" was the umbrella term commonly used to refer to both "Scheduled Bulk drugs" and "Scheduled formulations" which were brought under price control., 1995.
3. "National List of Essential Medicines" is defined in the Drug Price Control Order to mean National List of Essential Medicines, published by the Ministry of Health and Family Welfare as updated or revised from time to time and included in the first schedule of DPCO by the Government through a notification in the Official Gazette., 2011.
4. Out of the 348 medicines listed in the NLEM-2011, only 34 drugs were included amongst the 74 drugs listed in the First Schedule of "The Drugs (Prices Control) Order, 1995 DPCO 1995.
5. NLEM consists of items like insulin, ibuprofen, sulphamethoxazole, rifampicin, streptomycin, Ranitidine, etc which are bulk drugs and at the same time medicines or formulations as well when these are manufactured as single ingredient formulations. The NLEM contains the generic name or salts or chemical names.
6. An internal guideline issued under para 19 of DPCO on 29.05.2014 outlining the criteria and methodology for fixing / revising prices of non-scheduled formulations on the basis of inter-brand price differentials and for fixing the launch prices of new non-scheduled formulations was withdrawn on However, this withdrawal does not take away the powers of the Government as mentioned in Para 19 of DPCO-2013 to fix the prices of non-scheduled formulations. It was generally perceived that the guideline went beyond the scope of para, 22 September 2014; 19.
7. In India, we also have branded generic medicines.
8. The M/o Health and Family Welfare and Ministry of AYUSH also govern various aspects relating to pharmaceutical companies.
9. Total Number of NLEM Medicines comes to 680. However, 52 medicines appear in more than one therapeutic group. Hence, the net number of medicines subject to price fixation is 628 (as mentioned in Annual report of Department of Pharmaceuticals 2014-15.
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