**Drug price control order**

With the objective to improvise and endow with the basic health care and availability of basic medicines at an affordable price across the country, the Department of Pharmaceuticals, Ministry of Chemicals and Fertilizers, notified the Drug (Prices Control) Order 2013("DPCO 2013") in May 2013, which may fluctuate the pricing of 348 essential medicines. Prior to the 2013 regime, the DPCO 1995 included 74 bulk medicines within its ambit and the pricing of the drugs were fixed on the basis of manufacturing costs declared by the drug manufacturers.

The DPCO 2013 empowers the National Pharmaceutical Pricing Authority ("NPPA") to regulate prices of 348 essential drugs. As per the new DPCO 2013, all strengths and dosages specified in the National List of Essential Medicines (NLEM) will be under price control. This article endeavors to provide an insight of the key aspects of the DPCO 2013 and discusses the manner in which such provisions have been implemented. Para 2(i) of the DPCO 2013 defines the term "Formulation" as a medicine processed out of or containing one or more drugs with or without use of any pharmaceutical aids, for internal or external use for or in the diagnosis, treatment, mitigation or prevention of disease and, but shall not include –

i. any medicine included in any bonafide Ayurvedic (including Sidha) or Unani (Tibb) systems of medicines;

ii. any medicine included in the Homeopathic system of medicine; and

iii. any substance to which the provisions of the Drugs and Cosmetics Act, 1940 (23 of 1940) do not apply;

As per the DPCO 2013, "Scheduled formulation" means any formulation, included in the First Schedule whether referred to by generic versions or brand name. "Nonscheduled formulation" has been defined as a formulation, the dosage and strengths of which are not specified in the First Schedule.

"Schedule" is the Schedule appended to the DPCO 2013.

**PRICING OF SCHEDULED FORMULATION:**

Para 4 of the DPCO 2013 provides formula for the calculation of ceiling price of a scheduled formulation as follows –

**Step1.** 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.)

**Step2.** 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

Calculation of Ceiling Prices of following has also been provided in the DPCO 2013.

a. Ceiling price of a scheduled formulation in case of no reduction in price due to absence of competition

b. Calculation of Retail price of a new drug for existing manufacturers of scheduled formulations.

**- PRICING OF NON-SCHEDULED FORMULATIONS:**

Apart from the price fixation of the Scheduled Formulations, the NPPA is also empowered to monitor the maximum retail prices (MRP) of all the drugs, including the non-scheduled formulations and ensure that no manufacturer increases the maximum retail price of a drug more than ten percent of maximum retail price during preceding twelve months and where the increase is beyond ten percent of maximum retail price, it is empowered to reduce the same to the level of ten percent of maximum retail price for next 12 months. The manufacturer shall be liable to deposit the overcharged amount along with interest thereon from the date of increase in price in addition to the penalty.

**- DISPLAY OF PRICES OF SCHEDULED & NONSCHEDULED FORMULATIONS AND PRICE LIST:**

Para 24 and 25 of the DPCO 2013 mandate that every manufacturer of a Scheduled & non-Scheduled formulation intended for sale shall display in indelible print mark, on the label of container of the formulation and the minimum pack thereof offered for retail sale, the maximum retail price of that formulation with the words "Maximum Retail Price" preceding it and the words 'inclusive of all taxes' succeeding it. Para 26 lays down that no person shall sell any formulation to any consumer at a price exceeding the price specified in the current price list or price indicated on the label of the container or pack thereof, whichever is less.

**- RECOVERY OF OVERCHARGED AMOUNT UNDER DPCO 1987 AND 1995:**

Para 23 states that notwithstanding anything contained in the order, the Government shall by notice, require the manufacturers, importer or distributor or as the case may be, to deposit the amount accrued due to charging of prices higher than those fixed or notified by the Government under the provisions of Drugs (Prices Control) Order, 1987 and Drugs (Prices Control) Order, 1995 under the provisions of this Order.

**- MARGIN TO RETAILER & MAXIMUM RETAIL PRICE:**

Para 7 lays down that while fixing a ceiling price of scheduled formulations and retail prices of new drugs, sixteen percent of price to retailer as a margin to retailer shall be allowed. Para 8 specifies that the maximum retail price of scheduled formulations shall be fixed by the manufacturers on the basis of ceiling price notified by the Government plus local taxes wherever applicable. Even the loose quantities of any formulation shall not be sold at a price which is in excess of pro-rata price of the formulation.

**CONCLUSION:**

Undoubtedly, the response to the new DPCO 2013 would always going to remain double coined as for the reason that whereas on one hand, it would prove as a boon to the common mass and would bring hopes to thousands of poor and needy ones who are usually deprived from the basic health care as the Government has assured of continued availability of medicines, however, on the other hand, the new pricing policy would never be appraised by the other category of the market which plays significant role in manufacture of the medicines and making them available to the public as it would certainly effect in the profit up gradation at large which would affect their growth and strength in expanding to the global market. Lately, it is reported that after the implementation of the DPCO 2013, apparently there has been decrease in the stock of the medicines in the market. Hospitals and doctors in most of the states are facing scarcity of the essentials medicines for the consumption of their patients. However, in a bid to overcome such situation being faced across the country, the government has been diligent in taking immediate steps to resolve the contentious issue of margins between the pharma industry and trade channels. In a first such communication, the department of pharmaceuticals which formulated the policy has directed top state government and state health officials to ensure the availability of medicines, stating that since these are essential commodities, their uninterrupted supply has to be ensured. Thus, considering the fact that the price domain of pharmaceutical market being leased by the policy has bought along both pros and cons across the country, however, it is worth appreciating that the Government has been prompt in taking initiatives and put further efforts to harmonize the benefit of both aspects i.e the maker of the drugs as well as the end-user of the drugs.