Evolution of Drug Pricing Policies in the country

(By: NPPA Team)

A wide variety of products such as food grains, textiles, fertilizers etc., were regulated under the Essential Commodities Act, 1955 (EC, Act 1955) but not drugs. In the aftermath of World War-II there was shortage of essential medicines in the country and during the Indo-China war in 1962, the prices of medicines increased substantially. Therefore, the price control over drugs was first introduced in the country in 1962 under the Defence of India Act, 1915 with the promulgation of the Drugs (Display of Prices) Order, 1962 and the Drugs (Control of Prices) Order, 1963. These orders led to freezing of the prices of drugs with effect from 01.04.1963. Thereafter, a series of price control orders were notified through various orders in the country from time to time based on different principles. The span of control of prices as well as the nature of control of prices under various orders has varied as per the underlying principles in the respective Drug Policies.

Drugs Prices Display and Control Order, 1966

According to the Drugs Prices Display and Control Order of 1966, it was obligatory for manufacturers of drugs to obtain prior approval of the Government if prices of such formulations were to be increased. However, based on the industry representations regarding increase in prices of raw materials and packing materials, which were not frozen, the Government amended the 1966 Order in August 1968. According to this amendment[1]:

- Formulations sold under pharmacopoeia names were exempted from price approval
- Prices of existing formulations were increased on a case-by case basis after studying the cost structure and appropriateness for the increases sought by manufacturers
- New drugs developed through original research and marketed for the first time were also exempted from price control.

In the meantime, in 1966 itself the government also requested the Tariff Commission (TC) to examine the cost structure of 18 essential bulk drugs and their formulations. The TC submitted its **"Report on the Fair Selling Prices of Drugs and Pharmaceuticals"** to the Government in August 1968. Based on the Commission report, the government on 30th April 1970 undertook following steps[2]:

Prices of 18 bulk drugs, 49 formulations studied by TC and other formulations too were brought under price control based on "cost-plus" formula. Detailed formula for calculating the retail price was given along with the percentage of markup.

It was also informed that a suitable order incorporating the formula would be promulgated soon.

Drugs (Price Control) Order, 1970

Accordingly, Drugs (Price Control) Order, 1970 was promulgated on 16th May 1970 under the Section 3 of the EC Act, 1955 as was the Drugs Prices Display and Control Order, 1966. It was the first comprehensive price control order and the formula fixed was as under:

$$RP = (MC + CC + PC) \times (1 + MU \div 100)$$

Where, RP=Retail Price, MC=Material Cost, CC=Conversion cost or cost of formulation, PC=Packing charges and includes cost of packing material and packaging expenses, MU=Mark-up meant to cover forwarding charges, promotion expenses, after sales service and trade commission up to the retail level

The mark-up fixed ranged from 75% in the case of formulations to 150% for new drugs i.e. those containing new entities. The mark-up could be increased to 100% in case of new combinations of existing drugs. Manufacturers thus had the option of fixing prices within the ceiling of 75% mark-up for 18 essential drugs, and 150 for others. This was, however, subject to the condition that gross profit before tax did not exceed 15% of sales[3]. Hence, the DPCO, 1970 involved direct control on the profits of the companies and indirect control on selected essential drugs while capping remaining medicines at their prevailing price[4].

Drug Policy-1978 and the Drugs Prices (Control) Order, 1979

Based on the recommendations of Hathi Committee, the government evolved the first Drug Policy of India which was promulgated in March 1978 (DP, 1978) and the Drugs Prices (Control) Order 1979 (DPCO, 1979). The stated objectives of the DP, 1978 were[5]:

a. Country should be self-reliant in technology;

b. There should be self-sufficiency in drugs; and

c. Quality drugs should be adequately available at reasonable prices.

DPCO, 1979 was promulgated on 31st March 1979 and price control was imposed on 370 bulk drugs and formulations made therefrom. Based on Hathi Committee recommendations, the bulk drugs were classified into three categories based on their therapeutic efficacies. The three categories were authorized different levels of mark-ups as indicated below:

i. Category I of the third schedule of DPCO,1979 (Life-saving): 40% (23 No. of drugs)

ii. Category II of the third schedule of DPCO,1979 (Essential): 55% (20 No. of drugs)

iii. Category III of the third schedule of DPCO,1979 (Less essential): 100% (327 No. of drugs)

Formulations made from these 370 drugs constituted more than 80% of the market and the formulations considered most essential were given a lower mark-up so as to keep their prices low. The formula for working out the retail price was:

$$RP = (MC + CC + PM + PC) \times (MU + 100)/100 + \text{taxes}$$

Where, RP: Retail Price, MC: Material Cost, CC: conversion cost, PM: Packing Material Cost, PC: packing cost, MU: Mark-Up.

In the case of the imported formulations[6], the prices were fixed differently. The landed cost was to form the basis for fixing its price along with such margin as the government may allow from time to time. Usually, a maximum margin of 50% on the landed costs was provided for fixing maximum retail prices (MRPs). Provisions in DPCO-1979 were made for encouraging R&D activity by way of exempting the prices of locally conducted research and R&D-developed new products from control.

The concepts of fixation of the retention price and pooled price and fixation of leader prices of formulations were introduced in DPCO, 1979. A provision of Drug Prices Equalization Account (DPEA) for collecting excess amounts from companies was also introduced. If the companies had utilized bulk drugs produced at lower

prices than the prices allowed/considered for price fixation of their formulations, excess amount was to be deposited in DPEA. However, the implementation of DPEA created different kinds of administrative problems and led to litigation[7]. Currently, Department of Pharmaceuticals (DoP), Government of India is the custodian of the DPEA.

Drugs Prices (Control) Order, 1987

The **Drug Policy 1986** was implemented through the Drugs Prices (Control) Order, 1987 (DPCO, 1987) and it also drew from the recommendations of the Kelkar Committee Report. In DPCO, 1987, the numbers of bulk drugs under price control were significantly reduced from 370 to 142.

As laid down in the DP, 1986; in the DPCO 1987, two categories of formulations and bulk drugs (required to make such formulations) were promulgated to be price controlled. The terminology of "mark-ups" was changed to MAPE.

Drugs Prices (Control) Order, 1995 (DPCO,1995)

Based on the New Drug Policy, 1994, the new DPCO was announced in 1995. 74 bulk drugs were identified (listed in Schedule-I) for which the prices were to be controlled under DPCO, 1995. These represented 40% of the total market[8]. NPPA was also set-up in 1997 and it continued with the implementation of DPCO, 1995. The NPPA fixed/revised the prices on the basis of the DPCO formula giving MAPE of 100% on the ex-factory cost of the medicine. Under DPCO-1995, the prices of bulk drugs and formulations were fixed on the basis of actual costs plus a mark-up and the prices of formulations (final drugs) were fixed on a cost based formula, as follows :

$$\text{Retail Price} = (\text{M.C} + \text{C.C.} + \text{P.M.} + \text{P.C.}) \times (1 + \text{MAPE}/100) + \text{E.D.}$$

Where M.C denotes material cost including drug cost and other pharmaceutical aids; C.C. indicates conversion cost; P.M. means packing material cost of formulation; P.C. connotes packing of shipment; MAPE denotes Maximum Allowable Post-Manufacturing Expenses which includes trade margin as well as distribution and promotion costs and E.D. indicates excise duty.

National Pharmaceutical Pricing Policy, 2012 (NPPP, 2012)

NPPP, 2012 was notified on 07.12.2012. The key principles for regulating the prices of essential drugs were identification of 'essentiality' of medicines/formulations; intent to control the prices of essential formulations only and not the bulk drugs used in the making of such formulations; and the prices of essential medicines to be determined based on 'market based' information.

The NPPP-2012 was essentially the 'modified' concept of Drug Policy-2002 where the intention announced was to control the price of 'essential medicines' based on the market capture of such formulations as determined and published by reputed private organizations like the ORG-MARG utilizing the MAT values of essential formulations in each therapeutic category. The NPPP, 2012 envisages regulation of the prices of formulations only, identified on the basis of essentiality of drugs. Further, the basis of fixing the ceiling price of formulations has been changed from cost based to Market Based Pricing (MBP) in NPPP-2012. Thus, as per NPPP-2012, the three aspects of the regulation of prices of drugs are as follows:

- **Essentiality of drugs** as specified under National List of Essential Medicines (NLEM): Price of medicines is fixed because they are considered essential.
- **Regulating the prices of formulations only** (i.e., medicines used by consumers and not applicable to any

upstream products such as bulk drugs or intermediaries), as opposed to regulation of both bulk drugs and their formulations under DPCO-1995.

- Fixing the ceiling price of formulations through Market Based Pricing (MBP) as opposed to cost based pricing in DPCO-1995 as it is easy to obtain price data than cost data.

Drugs (Prices Control) Order, 2013 (DPCO-2013)

Based on the principles of NPPP, 2012, the DPCO-2013 was notified on 15th May, 2013 under section 3 of the EC Act, 1955. It marked the shift from Cost Based Pricing (CBP) to Market Based Pricing (MBP). Also, prices of formulations were to be fixed instead of bulk drugs.

- To conclude, it can be opined that enabling provisions for drug price control are embedded in different statutes as indicated in **Figure1 below.**

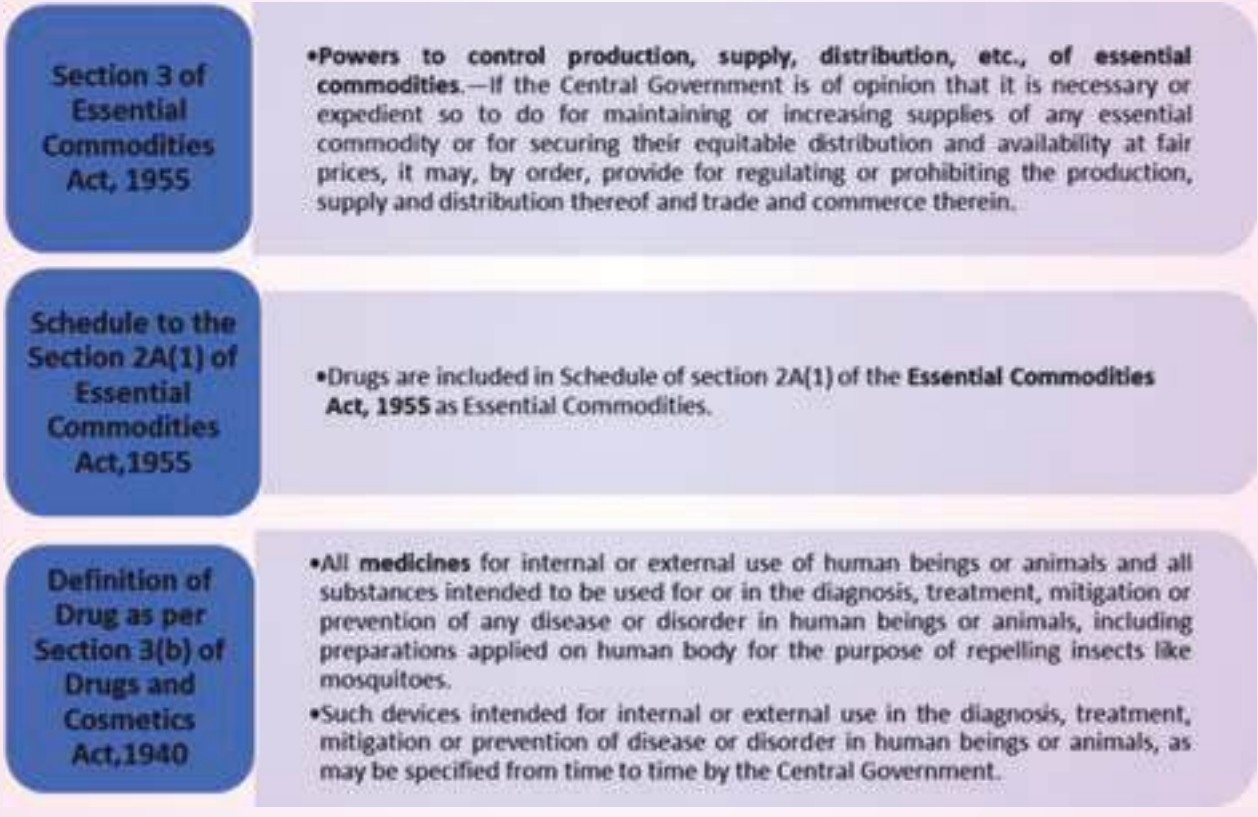

Figure 1: Enabling provisions for Drug Price Control

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[1] Discussion paper#236: Government's Policies and Growth of Pharmaceutical Industry in India 1947-2018: A Review Prasanta Kumar Ghosh, RIS

[2] https://indianculture.gov.in/flipbook/1032

[3] Joseph, R.K. (2015). Pharmaceutical Industry and Public Policy in Post-reform India

[4] Ajay Bhaskarabhatla, 2018. "Regulating Pharmaceutical Prices in India," India Studies in Business and Economics, Springer, number 978-3-319-93393-1, June.

[5] https://www.epw.in/journal/1978/21/special-articles/new-drug-policy.html

[6] Discussion paper#236: Government's Policies and Growth of Pharmaceutical Industry in India 1947-2018: A Review Prasanta Kumar Ghosh, RIS

[7] ibid

[8] https://pharmaceuticals.gov.in/policy/pharmaceutical-policy-2002