National Pharmaceutical Pricing Authority DPCO Act

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- Drugs play an important role in the health of both people and the economy of a country.
- People and Governments willing to spend money on drugs for many reasons so, it must be safe, effective and of good quality and used appropriately. Problems relating to drug safety and efficacy exist in many places around the world today in developing and developed countries.
- This means, that development, production, importation, exportation and subsequent distribution of drugs must be regulated to ensure that they meet prescribed standards. Therefore, effective drug regulation is required to ensure the safety, efficacy and quality of drugs as well as accuracy and appropriateness of the drugs.

In 1966, parliament members felt that manufacturers charging high rate on drugs.

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To control on high drug rates, DPCO 1966 was passed under section 3 of Essential Commodities Act 1955.

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DPCO 1966 replaced by DPCO 1970.

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In 1974, Hathi committee was formed and submitted it's reports in 1975. → DPCO 1970 Replaced By DPCO 1979.

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DPCO 1979 Replaced By DPCO 1987.

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Finally, DPCO 1995 Replaced By DPCO 2013.

Objectives

- To achieve adequate production and distribution.
- To ensure availability of essential medicines at reasonable price
- To meet the goals of employment and shared economic growth of all.
- To provide sufficient opportunity for innovation and competition to support the growth of industry.
- Promoting the rational use of drug in the Country to encourage cost-effective Production with Economic sizes
- To Ensure availability at Reasonable Prices of essential and life saving Medicine of Good Quality

DEFINITIONS UNDER THE ACT

1. API or BULK DRUG: It means any pharmaceutical, chemical, biological or plant product including its salts, esters, isomers, analogues and derivatives, conforming to standards specified in D & C Act, 1940 and used as such or as an ingredient in any formulation.

2. FORMULATION: Medicine processed out or containing one or more bulk drugs with/without pharmaceutical aid for internal/external use for/in diagnosis, treatment, mitigation or prevention of disease in human/ animals. (not include ayurvedic, sidhha, unani, tibbi and homeopathic system of medicine.)

3. NEW DRUG: means a formulation launched by an existing manufacturer of a drug of specified dosage and strength as listed in NLEM by combining the drug with another drug listed/not listed in the NLEM or formulation launched by changing the strength, dosage or both of the drug listed in NLEM.

DEFINITIONS UNDER THE ACT

4. CEILING PRICE: Price fixed by government for scheduled formulation accordance with the provisions of this order.

2. RETAIL PRICE: means the price fixed by government for a new drug.

3. SCHEDULED FORMULATION: means any formulation, included in first schedule whether referred as generic version or brand name.

4. NONSCHEDULED FORMULATION: means a formulation, the dosage and strength of which are not specified in first schedule.

5. MRP – ceiling price or retail price plus local taxes or duties as applicable, at which the drug shall be sold to the ultimate consumer or where such price is mentioned on the pack.

MRP of scheduled formulation = Ceiling price + local taxes.

MRP of new drug = Retail price + local taxes.

SCHEDULES RELATED WITH DPCO 2013

FIRST SCHEDULE

Divided in **27** sections

first schedule includes **74** bulk drugs.

penicillin, tetracycline, vitamin A, B1, B2, C & E, insulin etc.

SECOND SCHEDULE

Form 1:- application for price fixation/ revision of a new drug formulation related to NLEM.

Form 2:- Performa for submission of revised prices for scheduled formulations.

Form 3:- Performa for quarterly return in respect of production/import and sale of NLEM drugs.

Form 4:- Performa for the submission of the details in respect of discontinuation of the production and import of scheduled formulations.

Form 5:- form of price list

Type of Pharmaceutical Company

Category A: - large unit with turnover More than Rs **6 crores** per annum.

Category B: - medium sized unit turnover between Rs **1 crore** to **6 crore** per annum.

Category C: - other units with turnover of less than **Rs 1 crore** per annum.

Sale Prices of Bulk Drugs

- The Government notifies the Official Gazette and on periodic intervals fixes a maximum sale price at which the bulk drug should be sold.
- This is done to control the equitable distribution, increase the supplies of a bulk drug given in the First Schedule and make it available at a reasonable price from different manufacturers.

SCHEDULED FORMULATION

CALCULATION OF CEILING PRICE OF SCHEDULED FORMULATION.

$$P(c) = P(s) (1+ m/100)$$

Where,

M = % Margin to retailer 16%

P(s)= .Average price to retailer of the schedule formulation for the same strength and dosage of the medicine.

- **If the other strength or dosage forms of the same schedule formulation are available in the list of schedule formulation, then the average price to retailer shall be calculated as under**

$$P(s)= Pm ((1-(Pi+Pi2+…)/N*100))$$

Where,

Pm= Price to retailer of highest priced schedule formulation under consideration.

Pi = % Reduction in average Price to retailer of other strength and dosage forms in the list of schedule formulations.

N= Number of such other strength or dosage forms or both in the list of schedule formulations.

RETAIL PRICE OF FORMULATION

R.P.=(M.C.+C.C.+P.M.+P.C.) x (1+ MAPE /100)+E.D.

Where,
R.P. = retail price
M.C.= material cost
C.C.= conversion cost
P.M.= packaging material cost
P.C.= packing charges
E.D = excise duty
MAPE= maximum allowable post manufacturing expenses

Margin to retailer.

- 16% to retailer allowed while fixing the ceiling prices of scheduled formulation and retail prices of new drug.

Pricing of scheduled formulation covered under DPCO 1995.

- Fixed and notified up to 31st May 2012 and shall remain effective 30th May 2013, can be revised by manufacturer as per annual wholesale price index.
- Fixed and notified after 31st May 2012 and shall remain effective for 1 year from the date of notification, can be revised by manufacturer as per annual wholesale price index. Same criteria applicable to scheduled formulation which are in DPCO 1995 but not in first schedule of this order.

Price of formulation listed in NLEM.

- Manufacturer shall fix the price of formulation (branded or generic) equal or below to ceiling price.

Price of scheduled formulation for exiting manufacturer.

- If selling on higher than ceiling than government reduce up to ceiling price.
- If formulation available in market before the publication of ceiling price manufacturer should revise within 45 days.

Revision of ceiling price of scheduled formulation.

- Government may revise on the basis of WPI before 1st April of every year and notify on 1st day of April every year.
- Manufacturer may increase the MRP on WPI basis once in every year. Inform the government. Within 15 day about it in form II.

NONSCHEDULED FORMULATION

Monitoring the prices of nonscheduled formulations.

- No manufacturer increases the MRP of drug more than 10% of MRP during preceding 12 months and where the increase is beyond 10% of MRP it shall reduce the same to the level of 10% for next 12 months.

Display of price of nonscheduled formulation and price list.

- The MRP of the formulations must be printed with the words “maximum retail price” or “including of all taxes”.
- Every manufactures must issue a price list/supplementary price list to the dealers, SDC and government indicating changes time to time.
- Every dealer/retailer must display the price list on a conspicuous part of premises.

SCHEDULED AND NONSCHEDULED FORMULATION

Power of entry and search :

Any gazette office of central/state government can enter and search, seize any drug along with container, package or covering and seize any documents.

Power to review:

notification may apply to government for review within 30 days of the publication/notification.

Exemptions: The provisions of act not applicable to

New drug produced by new process which patented under IPA 1970, for a period of 5 years from its commercial production in the country.

WITHOUT APPROVAL OF GOVERNMENT

- Manufacturer should not increase retail price of drug.
- Manufacturer should not market new formulation.
- No person shall sell imported scheduled formulation.

FIXATION OF PRICE UNDER CERTAIN CIRCUMSTANCES

- If any manufacturer of bulk drug fails to submit the application for fixation or revision of price or fails to give information within specified time period.
- Then government fix price of the bulk drug.

NLEM: National List of Essential Medicine

- Brought price of **348** essential drugs mentioned in NLEM and their **652** formulation of DPCO 2013.
- India maintains its own **NLEM** just like other countries and it is reviewed in every few years by a national committee.
- The Government appointed **Hathi Committee** in **1975**. This committee had recommended the development of an **NLEM** and took actions to ensure their production.
- The committee also suggested the removal of irrational drugs.