# National Pharmaceutical pricing Authority (NPPA)

## Drug Price control order 2013 (DPCO)

## Chapter – 9

**Introduction:-**

* Introduced by central Government in order to exercise the powers confirmed by section 3 of the essential commodities act, 1955.
* for enabling the Government to declare a ceiling price for essential & life saving medicines (as per prescribed formula) so as to ensure that these medicines are available at a reasonable price to the general public.
* The latest DPCO-2013) was issued on 15/05/2013.
* Drug prices are monitored and controlled by NPPA.
* All the powers of Government of pricing according to essential commodities Act have been delegated to it.
* Under DPCO 2013 the powers to review are entrusted with the Government. Hence, the department of Pharmaceuticals is the regulating authority whenever pharmaceutical companies file review petitions against any price fixation done by NPPA.

Pharmaceutical pricing policy (NPPP)
is the policy governing price control and DPCO (2)
is the order by which price control is enforced.

* The Drug price control orders are issued by Ministry of chemicals & fertilizers, which is the main nodal administrative ministry for pharmaceutical company.

History:-

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 submit its reports

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DPCO 1970 Replaced by DPCO 1979

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DPCO 1979 replaced by DPCO 1987

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DPCO 1987 replaced by DPCO 1995

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Finally DPCO 1995 replaced by DPCO 2013.



Objectives:-

* To achieve adequate production
* To regulate equal distribution.
* To maintain and increase supply of bulk drugs and formulations.
* To make these available at fair prices.

Definitions:-

(1) Active Pharmaceutical ingredients or Bulk drugs:-
Means any pharmaceutical, chemical, biological or plant product including its salts, esters, isomers, analogues and derivatives, conforming to pharmacopeial standards specified in the drugs and cosmetics Act, 1940 and which is used as such or as an ingredient in any formulation.

(2) Schedule Bulk drugs:- means a bulk drug specified in the first schedule

(3) Schedule formulations:- means any formulation included in the first schedule whether referred to by generic versions or brand name.

) Brand - means a name, term, design, symbol

trademark or any other feature that identifies one seller's drug as distinct from those of other sellers. (4)

(5) Ceiling price:- means a price fixed by the Government for scheduled formulations in accordance with the provisions of this order.

(6) Dealer:- means a person carrying on the business of purchase or sale of drugs, whether as a wholesaler or retailer and includes his agent.

(7) Distributor:- means a person engaged in the work of distribution of drugs and includes an agent or a stockist for stocking drugs for resale to a dealer.

(8) Generic Version of a medicine - means a formulation sold in pharmacopoeial name or the name of the active pharmaceutical ingredient contained in the formulation, without any brand name.

(9) Formulation - means a medicine processed out of, or containing one or more bulk drugs with or without use of pharmaceutical aids, for internal or external use or in the diagnosis, treatment, mitigation or prevention of disease in human beings or animals, but it

but it does not include -

* A. any Ayurvedic or Unani medicines
* B. Any Homeopathic medicines.
* C. any substance to which provisions of D & C act 1940 do not apply.

(10) Local taxes - means any tax or levy (except excise or import duty included in retail price) paid or payable to the Government or the State Government or any local body under any law for the time being in force by the manufacturer or his agent or dealer.

(11) Maximum retail price - means the ceiling price or the retail price plus local taxes and duties as appliable, at which the drug shall be sold to the ultimate consumer and where such price is mentioned on the pack.

12) Pharmacoeconomics - means a scientific discipline that compares the therapeutic value of one pharmaceutical drugs or drug therapy to another.

13) Price to retailer - means the price of a drug at which it is sold to a retailer which includes duties and does not include local taxes.

(14) Scheduled formulation – means any formulation, including those specified in the first Schedule whether referred to by generic versions or brand name.

(15) Schedule – Means a schedule appended to this order.

(17) Sale turnover – means the product of units of formulations sold by manufacturer or an importer in an accounting year multiplied by retail price inclusive of sales tax, if any paid on direct sales by the manufacturer or importer. It does not include excise duty and local taxes.

## II Price of Bulk drugs

* Government has right to fix the maximum sale price of the drugs.
* While fixing the price government shall take into consideration following :-

I. Post tax return of 14% on net worth OR

II. Return of 22% on capital employed OR

III) For new plant, a rate of Return of 12% based on long term marginal costing.

IV) In case of production is from basic stage, a post tax return of 18% on net worth or 26% on capital employed.

* Provided further that the option with regard

to the rate of return once exercised by a manufacturer shall be final and no change of rate shall be made without the prior approval of the Government.

* No person shall sell a bulk drug at a price exceeding the maximum sale price fixed as per the provision of this order plus local taxes if applicable.

Information required from manufacturer to the Government:-

* For the both scheduled and non-scheduled bulk drugs.
* List of drug produced with cost in form 1 and 2 respectively.
* But for scheduled Bulk drugs it should given by 30 september every year.

## Retail Price of formulation

Formula for calculation:-

$$R.P. = (M.C. + C.C. + P.M. + P.C.) \times \left(1 + \frac{MAPE}{100}\right) + E.D$$

where, R.P. = Retail price
M.C. = Material cost.
C.C. = Conversion cost.

P.M. = Packaging Material cost.
P.C = Packaging charges.
E.D = Excise duty.
MAPE = Maximum allowable post manufacturing expenses.

## Calculation of ceiling price of a scheduled formulation:-

Step 1- calculation of Avg. price PCs) to retailer

Avg. price to Retailer (Ps) = 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 No 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.

Step 2- Calculation of ceiling price P(c)

$$P(c) = P(s) \cdot \left(\frac{1+m}{100}\right)$$

Where,

P(s) = Average price to retailer for the same strength and dosage of the medicine as calculated

in Step 1 above.

M = % Margin to retailer and its value = 16.

## Power to fix Retail Price of scheduled formulation

* Government fix the retail price of scheduled formula
* Price once fixed can not be increased by manufacturer without prior approval from government.
* Application for revision of retail price should submit in form 3 & 4.
* from date of receipt of complete information government fix retail price within 2 months.

## Calculation of Retail price of a new drug for existing manufacturer of scheduled formulation :-

* 1) The retail price of the new drug (Rs) available in domestic market shall be calculated as provided in sub paragraph (1) of paragraph 4.
* 2) (i) The price to retailer of a new drug, not available in domestic market, shall be fixed by the Government on the principles of "Pharmacoeconomics" of the new drug, on the recommendation of a standing committee of experts.

(ii) The retail price of such new drug shall be fixed by adding 16% margin to retailer on the price

to retailer as fixed in item (i)

Ceiling price of a scheduled formulation in case of no red$^n$ in price due to absence of competition

ii) where the average price to retailer of a scheduled formulation, arrived at as per the formula specified in sub-paragraph (1) of paragraph 4, has the effect of -

a) No Red$^n$ in avg. price to retailer with respect to the prices to retailer of the scheduled formulation; &

b) There are less than five manufacturers for that formulation having one percent or more market share, the ceiling price shall be calculated as under:-

i) In the event of other strengths or dosage forms of the same scheduled formulation in available in the list of scheduled formulation the average price to retailer shall be calculated as under.

Step-1 Calculation of Average price to Retailer P(s).

* $P(s) = Pm [1 - (Pi1 + Pi2 + \ldots) / (N * 100)]$

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

$Pi$ = % Red$^n$ in Average Price to Retailer.

$N$ = No. of dosage forms or strengths.

Step 2 - Calculation of ceiling price of the scheduled formulation i.e. P(c).

$P_{(c)} = P_{(s)} \cdot (1 + M/100)$, where

$P_{(s)}$ = Average price to Retailer of the scheduled formulation as calculated in step 1 here in above and

M = % Margin to Retailer & its value = 16.

Power to fix ceiling price of a scheduled

* Government fix the ceiling price of scheduled formulation.

$$P_c = P_s \cdot \left(\frac{1+M}{100}\right).$$

M = Margin to retailer 16%.

$P_{(s)}$ = sum of the prices to retailer of all Branded and generic version of said medicine / Total no. of Branded and generic version of medicine.

* Ceiling price for formulation including those sold under generic name.

* Fixed amount ceiling price for schedule formulation either on its own motion or on appn made in prescribed form.

## Power to Revised Price of Bulk Drug & formulation

* Government fix or revise retail price of one or more formulation
* As the pre-tax return on sales turnover does not exceed maximum pre-tax return specified in the third Schedule.

### Fixation of Price under certain circumstances:-

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

### Control of sale prices of Bulk drug and formulation:-

* No person or retailer shall sale the drug / formulation to any customer at increasing price specified in current price list indicated on container label.

### Sale of split quantity of formulation:-

* No dealer shall sell the loose quantity of formulation
* At price exceeding pro-rata prices of formulation plus 5%.

## Schedule Related with DPCO 1995

## First schedule

* First schedule includes 74 Bulk drugs
* Penicillin, tetracycline, analgin, vitamin A, $B_1$, $B_2$, C & E, Insulin etc.

## Second Schedule

Different forms included –

Form 1 – appⁿ for fixation / Revision of price of scheduled Bulk drug (in duplicate)

Form 2 – information Related with price of non-scheduled Bulk drug (in duplicate)

Form 3 – appⁿ for approval / Revision of price of scheduled formulation (7 copies)

Form 4 – appⁿ for approval / Revision of price of scheduled formulation imported in finished form (7 copies)

Form 5 – form of price list.

## Third Schedule

include,

category A → A large unit with turnover exceeding 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.

## Offences & Penalties

### Penalties -

* Shall be punishable with imprisonment for one year and also liable to fine
* In the case of any other order, with imprisonment for not less than three months but ~~not~~ which may extend to ~~ten~~ seven years and also be liable to fine.