

National Pharmaceutical Pricing Authority

Drug Price Control Order 2013

Introduction

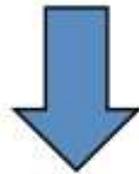
- Introduced by Central Govt. in order to exercise the powers confirmed by section 3 of the Essential Commodities act, 1955.
- For enabling the Government to declare a ceiling price for essential and life saving medicines (as per a prescribed formula) so as to ensure that these medicines are available at a reasonable price to the general public.
- The latest Drug Price Control Order ([DPCO-2013](#)) was issued on 15.05.2013

- Drug prices are monitored and controlled by the National Pharmaceutical Pricing Authority (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 reviewing authority whenever pharmaceutical companies file review petitions against any price fixation done by NPPA.

- **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 Fertilizers, which is the main nodal administrative ministry for pharmaceutical companies.
- They are issued under the “Essential Commodities Act 1955 whereby certain medicines could be declared to be essential commodities.

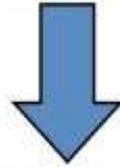
HISTORY

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



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

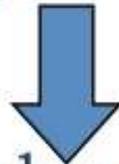
DPCO 1966 replaced by DPCO 1970.



In 1974, Hathi committee was formed and submitted its reports in 1975.



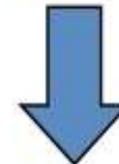
DPCO 1970 Replaced By DPCO 1979.



DPCO 1979 Replaced By DPCO 1987.



DPCO 1987 Replaced By DPCO 1995.



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

- **“Active pharmaceutical ingredients or Bulk drug”**- means any pharmaceutical, chemical, biological or plant product including its salts, esters, isomers, analogues and derivatives, conforming to pharmacopoeial standards specified in the Drugs and Cosmetics Act, 1940 and which is used as such or as an ingredient in any formulation.

- **Schedule bulk drug "** means a bulk drug specified in the First Schedule.
- **Scheduled formulation"** means any formulation, included in the First Schedule whether referred to by generic versions or brand name.

with the provisions of the Essential C

THE FIRST SCHEDULE

Bulk Drugs :

1. Sulphamethoxazole
2. Penicillins
3. Tetracycline
4. Rifampicin
5. Streptomycin
6. Ranitidine
7. Vitamin C
8. Betamethasone
9. Metronidazole
10. Chloroquine
11. Insulin
12. Erythromycin
13. Vitamin A
14. Oxytetracycline
15. Prednisolone
16. Cephazolin
17. Methyldopa
18. Aspirin
19. Trimethoprim
20. Cloxacillin
21. Sulphadimidine
22. Salbutamol
23. Famotidine
24. Ibuprofen
25. Metamizol (Analgin)
26. Doxycycline
27. Ciprofloxacin
28. Cefotaxime
29. Dexamethazone
30. Ephedrine
31. Vitamin B₁ (Thiamine)
32. Carbamazepine
33. Vitamin B₂ (Riboflavin)
34. Theophylline
35. Levodopa
36. Tolnaftate
37. Vitamin E

38. Nalidixic Acid
39. Griseofulvin
40. Gentamicin
41. Dextropropoxyphene
42. Halogenated Hydroxy Quinoline
43. Pentazocine
44. Captopril
45. Naproxen
46. Pyrental
47. Sulphadoxine
48. Norfloxacin
49. Cefadroxyl
50. Panthoates and Panthenols
51. Furazolidone
52. Pyrithioxine
53. Sulphadiazine
54. Framycetin
55. Verapamil
56. Amikacin Sulphate
57. Glipizide
58. Spironolactone
59. Pentoxifylline

60. Amodiaquin
61. Sulphamoxole
62. Frusemide
63. Pheniramine Maleate
64. Chloroxylenols
65. Becampicillin
66. Lincomycin
67. Chlorpropamide
68. Mebhydroline
69. Chlorpromazine
70. Methendienone
71. Phenyl Butazone
72. Lynestrinol
73. Salazosulphapyrine
74. Diosmine
75. Trimipramine
76. Mefenamic Acid

- **“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
- **“Ceiling price”** means a price fixed by the Government for Scheduled formulations in accordance with the provisions of this Order.

- **“Dealer”** means a person carrying on the business of purchase or sale of drugs, whether as a wholesaler or retailer and includes his agent.
- **“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.
- **“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.

➤ **“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 does not include:

➤ A. any Ayurvedic or Unani medicines

➤ B. any Homeopathic medicines

➤ C. any substance to which provisions of D and C act 1940 do not apply.

- **“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;
- **“Maximum retail price”** means the ceiling price or the retail price plus local taxes and duties as applicable, at which the drug shall be sold to the ultimate consumer and where such price is mentioned on the pack;
- **“Pharmacoeconomics”** means a scientific discipline that compares the therapeutic value of one pharmaceutical drug or drug therapy to another

- **“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.
- **Scheduled formulation"** means any formulation, included in the First Schedule whether referred to by generic versions or brand name.
- **“Schedule”** means a Schedule appended to this Order.
- **“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

Price of bulk Drugs

1. Govt. has right to fix the maximum sale price of the drugs
2. While fixing the price govt. 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.

3. Provided further that the option with regard to the rate of return once exercised by a manufacturer shall be final and no change of rates shall be made without the prior approval of the Government.
4. 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 :-

$$R.P. = (M.C. + C.C. + P.M. + P.C.) \times (1 + MAPE / 100) + E.D.$$

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

- **“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- 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

Calculation of ceiling price of a scheduled formulation

Step1.- Calculation of Avg. price P(s) to retailer

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- Calculation of ceiling price P(c)

$P(c) = P(s).(1+M/100)$, 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

The ceiling price calculated as per sub-paragraph (1) and notified by the Government shall be applicable to scheduled imported formulations also.

POWER TO FIX RETAIL PRICE OF SCHEDULED FORMULATION

- government fix the retail price of scheduled formulation.
- 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 govt. fix retail price within 2 months.

Calculation of retail price of a new drug for existing manufacturers of scheduled formulations

- (1) The retail price of the new drug (P_s) 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)

of no reduction in price due to absence of competition

- (1) where the average price to retailer of a scheduled formulation, arrived at as per the formula specified in subparagraph (1) of paragraph 4, has the effect of,-
- (a) no reduction in average price to retailer with respect to the prices to retailer of the schedule formulation; and
 - (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** is available in the list of scheduled formulation, the average price to retailer shall be calculated as under

Step1: Calculation of Average Price to Retailer P(s)

- $P(s) = P_m \{1 - (P_{i1} + P_{i2} + \dots) / (N * 100)\}$
- P_m = Price to Retailer of highest priced scheduled formulation under consideration.
- P_i = % reduction in Average Price to Retailer of other strengths and dosage forms (calculated as in step1 of subparagraph (1) of paragraph 4) in the list of schedule formulations w.r.t the highest priced formulation taken for calculating the average price to retailer of such strengths and dosage forms.
- N = Number of such other strengths or dosage forms or both in the list of schedule formulations.

Step2. 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 step1 hereinabove and

M = % Margin to retailer and its value=16

- **Margin to retailer.**– 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.
- **Maximum retail price.**– (1) 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, as under:

Maximum Retail Price = Ceiling price + Local Taxes as applicable

- The **maximum retail price of a new drug** shall be fixed by the manufacturers on the basis of retail price determined by the Government plus local taxes wherever applicable, as under:

Maximum Retail Price = Retail Price + Local Taxes as applicable

WITHOUT APPROVAL OF GOVERNMENT

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

Power to Fix Ceiling Price of a scheduled

- government fix the ceiling price of scheduled formulation.
- $P_c = P_s \cdot (1 + M/100)$, 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 revised ceiling price for schedule formulation either on its own motion or on application made in prescribed form.

POWER TO REVISE PRICE OF BULK DRUG AND 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 application for fixation or revision of price or fails to give information within specified time period.
- then government fix price of the bulk drug.

POWER TO RECOVER OVERCHARGED AMOUNT

- if any manufacturer or importer charging higher price than the price fixed by government
- then government may recover the overcharged amount.

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%.

SCHEDULES RELATED WITH DPCO 1995

FIRST SCHEDULE

- first schedule includes 74 bulk drugs.
- penicillin, tetracycline, analgin, vitamin A, B1, B2, C & E, insulin etc.

Schedule-I

(See Paragraphs-2(t),2(zb))

Symbols P, S and T appearing in NLEM 2011 denote essentiality at Primary, Secondary and Tertiary levels respectively.

NATIONAL LIST OF ESSENTIAL MEDICINES 2011			
Section: 1 – Anesthesia			
1.1 General Anesthetics and Oxygen			
Medicines	Category	Route of Administration	Strengths
Ether	S, T	Inhalation	--
Halothane with vaporizer	S, T	Inhalation	
Isoflurane	S, T	Inhalation	
Ketamine Hydrochloride	P, S, T	Injection	10 mg / ml, 50 mg / ml
Nitrous Oxide	P, S, T	Inhalation	
Oxygen	P, S, T	Inhalation	
Thiopentone Sodium	S, T	Injection	0.5 g, 1 g powder

Second Schedule

- ❖ different forms included :-
 - Form- 1 :- application 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 :- application for approval/revision of price of scheduled formulation(7 copies).
 - Form-4 :- application for approval/revision of price of scheduled formulation imported in finished form(7 copies).
 - Form-5 :- form of price list
 - Form-6 :- yearly information on turnover and allocation of sales and expenses.

THIRD SCHEDULE

include,

Category 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 AND 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 which may extend to seven years and also be liable to fine.
- Retail price not to exceed or Local taxes extra