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.

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.

- **"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

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. Panthonates and Panthenols
51. Furazolidone
52. Pyrithioxine
53. Sulphadiazine
54. Framycetin
55. Verapamil
56. Amikacin Sulphate
57. Glipizide
58. Spironolactone
59. Pentoxyfylline

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. Lynestranol
73. Salazosulphapyrine
74. Diosmine
75. Trimipramine
76. Mefenamic Acid

- **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

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 B_1 (Thiamine)
32. Carbamazepine
33. Vitamin B_2 (Riboflavin)
34. Theophylline
35. Levodopa
36. Tolnaftate
37. Vitamin E

- **"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.
- **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
- **"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.
- **"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

DPCO 2013

The government has notified the DPCO 2013 under the Essential Commodities Act, 1955, which will give power to the NPPA (**National Pharmaceutical Pricing Authority** (**NPPA**)to regulate prices of 348 essential drugs along with their specified strengths and dosages under NLEM 2011.

✓ ***Main Features of the DPCO 2013***

- The new order will bring 348 drugs & their 652 formulations under price control.
- The new policy uses a market-based pricing mechanism against the earlier proposed cost-plus method. The ceiling price would be calculated by taking the simple average of prices of all brands of a drug with a market share of 1% or more.

- Margins of wholesalers & retailers have been cut down to 8% & 16% respectively.

- Monitoring the M.R.P of Non-Scheduled formulation.
- Control over Bulk Drug manufacturer.

FUNCTIONS….

- To implement and enforce the provisions of the Drugs (Prices Control) Order in accordance with the powers delegated to it.
- To deal with all legal matters arising out of the decisions of the Authority.
- To monitor the availability of drugs, identify shortages, if any, and to take remedial steps.
- To collect/ maintain data on production, exports and imports, market share of individual companies, profitability of companies etc, for bulk drugs and formulations.
- To undertake and/ or sponsor relevant studies in respect of pricing of drugs/ pharmaceuticals.
- To recruit/ appoint the officers and other staff members of the Authority, as per rules and procedures laid down by the Government.
- To render advice to the Central Government on changes/ revisions in the drug policy.
- To render assistance to the Central Government in the parliamentary matters relating to the drug pricing

DPCO 1995	DPCO 2013
It is governed by Essential commodities act 1955	It is governed by national pharmaceutical pricing authority, based on national list of essential medicines
Prices of only 74 drugs were regulated by this act	Prices of 652 drugs are regulated by this act
If once the prices are fixed,they can't be changed as per the act	Based on simple average price (SAP) the highest prices can be lowered depending on the margins
Ceiling and non-ceiling prices of drugs are not Specified	Ceiling and non-ceiling prices of drugs are specified
This act facilitates Win –Win situation for the government, but not for the Industries	The prices of the drugs are fixed by the mutual agreement of government and industries for the welfare of the public

7.4. PROVISIONS OF THE ACT :

(I)	**PRICES OF BULK DRUGS** PRICES OF BULK DRUGS IN FIRST SCHEDULE (ESSENTIAL BULK DRUGS)
(II)	**RETAIL PRICES OF FORMULATIONS**
(III)	**PRICES TO WHOLESALER AND RETAILER**
(IV)	**SCHEDULES**

I. PRICES OF BULK DRUGS (ESSENTIAL BULK DRUGS)

Government is authorized to fix a maximum sale price of bulk drug after proper inquiry. Central Government established National Pharmaceutical Pricing Authority (NPPA) in Aug. 1997.

For the purpose of enquiry details in form 1 and additional details furnished by manufacturer twice a year.

In fixing price of a bulk drug government consider following things :

A post tax return of **14% on net worth** (18% if production is from basic stage) OR

* A return of **22% on capital** employed (26% if production is from basic stage) OR
* Internal rate return of 12% based on long term marginal costing for **a new plants.**

Manufacturer may exercise any option.

Once the option for the return is exercised by a manufacturer, it shall be final and for any change in the rate of return prior approval of the government shall be necessary.

— No person can sell a bulk drug at a price higher than the one fixed for it. Plus local taxes if any.

After this order if any manufacturer wishes to manufacture bulk drug. Or existing manufacturer wishes to manufacture additional bulk-drug, they have to give all necessary details within 15 days of the commencement of production so government can notify its price.

Any manufacturer, who desires revision of the maximum sale price of a bulk drug fixed, shall make an application to the government in form-1, after making enquiry, government fix a revised price (within 4 months).

— No manufacturer or distributor can refuse sale of a drug (bulk) to any dealer.

— The government can direct any manufacturer of bulk drug to sell the same to formulators.

II. RETAIL PRICES OF FORMULATIONS :

After NPPA was established in Aug. 1997 the prices of 665 formulation packs have been fixed/revised. In the case of 302 packs, prices were reduced. In the case of 269 packs, prices were increased and prices remained unchanged for 24 formulation packs.

The retail price (R.P.) of the formulaton shall be calculated in accordance with the following formula :

$$R.P. = \left[M.C. + C.C. + P.M. + P.C. \right] \times \left[1 + \frac{M.U.}{100} \right] + ED$$

(As per order 1979)

Sl. No.	Name of the Formulation / Brand Name	Dosage form & Strength	Unit	Retail Price (Rs.)	Review Order number and date	Existing SO number and date	Manufacturer & Marketing Company
1	Losartan + Chlorthalidone + Amlodipine Tablet (TRILOSAR 6.25)	Each film coated tablet contains: Losartan Potassium IP 50mg, Chlorthalidone IP 6.25mg, Amlodipine Besylate IP eq. to Amlodipine 5mg tablets	1 Tablet	6.85	31015/43/2018-Pricing dated 14.03.2019	5638(E) dated 02.11.2018 (at Sl. No. 39)	M/s GKM New Pharma Ltd. / M/s Unichem Laboratories Limited
2	Losartan + Chlorthalidone + Amlodipine Tablet (TRILOSAR 12.50)	Each film coated tablet contains: Losartan Potassium IP 50mg, Chlorthalidone IP 12.50mg, Amlodipine Besylate IP eq. to Amlodipine 5mg tablets	1 Tablet	7.1	31015/43/2018-Pricing dated 14.03.2019	5638(E) dated 02.11.2018 (at Sl. No. 40)	M/s GKM New Pharma Ltd. / M/s Unichem Laboratories Limited

$$R.P. = \left[M.C. + C.C. + P.M. + P.C. \right] \times \left[1 + \frac{MAPE}{100} \right] + ED$$

(As per order 1987)
(As per order 1995)

Where

R.P.	=	Retail Price
M.C.	=	Material Cost (drugs + pharmaceutical aids + overages + process loss)
C.C.	=	Conversion Cost
P.M.	=	Packing Material Cost
P.C.	=	Packing Charges
M.U.	=	Mark Up
M.A.P.E.	=	Maximum Allowable Post - Manufacturing Expenses
E.D.	=	Excise duty
Post Manufacturing Expenses (MAPE Includes)	=	All cost incurred by a manufacturer from the stage of ex-factory cost to retailing and include trade margin.

DIFFERENT VALUE OF MAPE (MU) - As per DPCO - 1991

- 75% in the case of Formulation of Category I of the Third Schedule.
- 100% in the case of Formulation of Category II of the Third Schedule.

CATEGORIZATION OF FORMULATION - AS PER DPCO-'91

- Category I formulation, if it contains any bulk drug either individually or in combination specified for category I formulations.
- Category II formulation if it contains any bulk drug either individually or in combination specified for Category II formulations.
- If formulation contains bulk drugs specified in both Categories I and II, it shall be deemed as category I formula.

VALUE OF MAPE - As per DPCO - 1995

- 100% in the case of formulation indigenously Manufactured Scheduled formulations.
- M.U. (Mark Up) includes –
  - Manufacturer's margin
  - Promotional expenses
  - Outward freight
  - Distribution cost
  - Trade Commission

For the case of an imported formulation, the landed cost shall forms the basis for fixing its price alongwith such margin.

- Selling/distribution expenses.
- Interest
- Importer's profit.

which shall not exceed 50% of the landed cost.

III. PRICE TO WHOLESALER AND RETAILER :

Type of Products	Wholesaler purchase price or manufacturer selling price	Retailer purchase price or wholesaler selling price
Scheduled	R.P. Minus 20%	R.P. Minus 16%

- Retail price should be displayed on label ____ R.P. not to exceed Rs____ local taxes extra.
- No dealer can sell loose quantity of a formulation higher by 5% of R.P.
- No dealer can refuse sale of a drug.

➢ National List of Essential Medicines

(1) Any dosage form of a medicine, other than the dosage form included in this Schedule, but in same strength, and route of administration, which does not have significant difference in terms of pharmacokinetics or pharmacodynamics or efficacy-safety profile over the dosage form mentioned in the list shall be considered as included. To elaborate, if a tablet is included, other dosage forms like conventional tablets and capsules are considered as included.

However, such different dosage forms should be considered differently for purposes such as procurement policy, pricing, etc. This principle also applies to all other dosage forms e.g. oral liquid dosage forms, injectable, topical dosage forms, etc.

(2) Innovation in medicine must be encouraged. The formulations developed through incremental innovation or novel drug delivery systems like lipid/liposomal formulations, sustained release/controlled release etc. should be considered as included only if specified in the list against any medicine. Such different formulations should be considered differently for purposes such as procurement policy, pricing, etc.

(3) In cases, where vaccines or immunoglobulin or sera are listed in this Schedule, irrespective of variation in source, composition and strength, all the products of the same vaccines or immunoglobulin or sera as approved by the licensing authority are considered included.

(4) In general, medicines have been mentioned with respect to their active moieties, without mentioning the salts and, in cases where there is significant difference between the salts, the medicine finds mention as its specific salt.

(5) In cases where an active moiety is available as different isomers or analogues or derivatives, they are considered as separate entities, and inclusion of one does not imply inclusion of all isomers or analogues or derivatives.

(6) For injectable preparations, the pack size (single and multi-dose packs) has not been mentioned. It is suggested that the single and multi-dose pack sizes be considered as separate entities for purposes such as procurement/ pricing etc.

The Core-Committee through a series of meetings and consultations across the country, deliberated and revised the National List of Essential Medicines (NLEM) 2011.

There were 348 medicines listed in NLEM 2011. A total of 106 medicines have been added, and 70 medicines have been deleted to prepare NLEM 2015 which now contains a total of 376 medicines.

Medicines in NLEM are listed with reference to the levels of healthcare, namely, Primary (P), Secondary (S) and Tertiary (T). There are 209 medicine formulations listed for all levels of health care (P, S, T), 115 medicine formulations for secondary and tertiary levels (S, T) and 79 medicine formulations for the tertiary level (T). It is to be noted that formulations of certain medicines are listed at different levels but as item, they are counted as one. The total number of medicines remains 376.

The essentiality of a medicine has been considered in terms of its dosage form and strength also.

The NLEM 2015 has been prepared adhering to the basic principles of Efficacy, Safety, Cost-Effectiveness; consideration of diseases as public health problems in India. The list could be called as a Best-Fit List

MEDICINES ADDED IN THE NLEM - 2011

S.No.	Name of the medicine
1.	25% Dextrose
2.	5-Amino salicylic Acid (5-ASA)
3.	Allopurinol
4.	Amoxicillin+Clavulinic acid
5.	Atorvastatin
6.	Betamethasone
7.	Carboplatin
8.	Cefixime
9.	Cetrizine
10.	Chlorambucil
11.	Clindamycin
12.	Clopidogrel
13.	Dacarbazine
14.	Daunorubicin
15.	Diazepam
16.	EMLA cream
17.	Enoxaparin
18.	Famotidine
19.	Fentanyl
20.	Filgrastim
21.	Hydroxychloroquine phosphate
22.	Ifosfamide
23.	Imatinib
24.	Ipratropium bromide
25.	Leflunomide
26.	Lorazepam
27.	Mefloquine
28.	Mesna
29.	Misoprostol
30.	N-acetylcysteine
31.	Olanzapine
32.	Oxaliplatin
33.	Pantoprazole
34.	Permethrin
35.	Piperazine
36.	Premix Insulin 30:70 injection
37.	Propofol
38.	Sevoflurane
39.	Stavudine+Lamivudine
40.	Tramadol
41.	Vecuronium
42.	Zidovudine+Lamivudine+Nevirapine
43.	Zinc Sulfate

Section: 2 - Analgesics , Antipyretics, Nonsteroidal Anti-inflammatory Medicines, Medicines used to treat Gout and Disease Modifying Agents used in Rheumatoid Disorders			
2.1: Non-Opioid Analgesics, Antipyretics and Nonsteroidal Anti-inflammatory Medicines			
Medicines	**Category**	**Route of Administration**	**Strengths**
Acetyl Salicylic Acid	P, S, T	Tablets	325, 350 mg
Diclofenac	T T	Tablets	50 mg
	T	Injection	25 mg / ml
Ibuprofen	P, S, T	Tablets Syrup	200 mg, 400 mg 100mg/5ml
	P, S, T	Injection	150 mg / ml
	P, S, T	Syrup	125 mg / 5ml
	P, S, T	Tablets	500 mg

Fixation of ceiling price of scheduled formulations.–

- ✓ The Government shall fix and notify the ceiling prices of the scheduled formulations in accordance with the provisions of the paragraphs 4 and 6, as the case may be, and no manufacturer shall sell the scheduled formulations at a price higher than the ceiling price (plus local taxes as applicable) so fixed and notified by the Government.

- ✓ Where any manufacturer sells a scheduled formulation at a price higher than the ceiling price(plus local taxes as applicable) fixed and notified by the Government, such manufacturers shall be liable to deposit the overcharged amount along with interest thereon from the date of such overcharging.

- ✓ The Government shall revise the ceiling prices of scheduled formulations as per the annual wholesale price index (WPI) for preceding calendar year on or before 1st April of every year and notify the same on the 1st day of April every year.

- ✓ The manufacturers may increase the maximum retail price (MRP) of scheduled formulations once in a year, in the month of April, on the basis of the wholesale price index with respect to previous calendar year and no prior approval of the Government in this regard shall be required.

✓ Information about the revision, if carried out, shall be forwarded to the Government in either electronic or physical form in Form-II within a period of fifteen days of such revision and non-submission of information under this sub-paragraph shall be construed as non revision of maximum retail price (MRP) and the concerned manufacturer shall be liable to deposit the amount charged over and above the pre-revised maximum retail price (MRP), along with interest thereon from the date of overcharging.

✓ In case of decline in wholesale price index, there shall be a corresponding reduction in the maximum retail price and in case of scheduled formulations produced or available in the market before the date of notification of revised ceiling price, the manufacturers shall ensure within a period of forty-five days of the date of such notification that the maximum retail price (MRP) of such scheduled formulation does not exceed the revised ceiling price (plus local taxes as applicable) and information about the revision shall be sent to the Government in either electronic or physical form in Form-II within a period of fifteen days of such revision.

✓ Non-submission of information under the sub-paragraph (4) shall be construed as non reduction in maximum retail price (MRP) and the concerned manufacturer shall be liable to deposit the amount charged over and above the maximum retail price revised based on decline in wholesale price index, along with interest thereon as overcharged amount from the date of overcharging.

- **Fixation of retail price of a new drug for existing manufacturers of scheduled formulations.–**

(1) The Government shall form a Standing Committee of such Experts, as it may deem fit, within sixty days of notification of this order with a view to recommend the retail prices of new drugs on the principles of "Pharmacoeconomics".

(2) Where an existing manufacturer of a drug with dosages and strengths as specified in National List of Essential Medicines launches a new drug, such existing manufacturers shall apply for prior price approval of such new drug from the Government in Form-I specified under Schedule-II of this Order.

(3) On receipt of the application under sub-paragraph (2), in the event of the new drug available in domestic market, the Government shall fix the retail price of the new drug in accordance with the provision of sub-paragraph(1) of paragraph 5 and in the event of the new drug not available in domestic market, the Government shall forward the same to the Standing Committee of Experts who shall examine the application on the principles of "Pharmacoeconomics" and make recommendations of retail price of the new drug to the Government within thirty days of the receipt of application.

(4) The Government shall, on receipt of recommendation under subparagraph (3), within thirty days, fix the retail price of such new drug and such price shall be applicable to such applicant of such new drug.

(5) Where existing manufacturer of scheduled formulation fails to apply for prior approval of the price of the new drug in Form-I, such manufacturer shall be liable to deposit the overcharged amount over and above such price fixed and notified by the Government, if any, along with interest thereon from the date of launch of the new drug, in addition to the penalty.

(6) No existing manufacturer of a scheduled formulation shall sell such a new drug at a price higher than the retail price (plus local taxes as applicable) fixed by the Government for such new drug and in case such a manufacturer is found to sell such a new drug at a price higher than the retail price (plus local taxes as applicable) fixed by the Government, such manufacturer of the new drug shall be liable to deposit the overcharged amount along with interest from the date of overcharge, in addition to the penalty.