

# Price Control on drugs in India

An over view

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# STATUTES APPLICABLE.

- DRUGS CONTROL ACT 1950
- DRUGS PRICES (DISPLAY & CONTROL) ORDER 1962
- DRUGS PRICES (DISPLAY & CONTROL) ORDER 1963
- DRUGS PRICES (DISPLAY & CONTROL) ORDER 1966
- DRUGS (PRICES CONTROL) ORDER 1970
- DRUGS (PRICES CONTROL) ORDER 1979
- DRUGS (PRICES CONTROL) ORDER 1987
- DRUGS (PRICES CONTROL) ORDER 1995

# **DRUGS (PRICES CONTROL) ORDER 1995.**

**An Order made under Section 3 of The  
Essential Commodities Act, 1955 vide  
S.O. No. 18 (E) Dated 6th January 1995  
and published in the Gazette of India,  
extraordinary, Part II.**

# SCHEME OF THE ORDER.

- 27 PARAS,
- THREE SCHEDULES.

- **1st schedule**

List of bulk drugs

76 in number - Subsequently  
deleted – 2 on 2.9.97.

# SCHEME . . .

- 2nd Schedule – Statutory forms I to IV
- Form I - Form of Information / Application for fixation or revision of prices of scheduled bulk drugs
- Form II – Do – In case of non – scheduled bulk drugs
- Form III - Form of application or revision of price of scheduled formulations
- Form IV - Do – In case of scheduled formulations – Imported
- Form V - Form of price list
- Form VI - Yearly information on Turn-Over and allocation of Sales & Expenses

# SCHEME . . . .

- 3<sup>rd</sup> SCHEDULE
- Category A – Large units over with turnover exceeding 6 crore per annum.
- Category B – Medium size units with turnover between Rs.1 crore to 6 crores.
- Category C - Other units with turnover less than Rs. one crore.

# DEFINITIONS.

- . Bulk Drug
- . Non scheduled Bulk Drug
- . Scheduled Bulk Drug
- . Manufacture
- . Manufacturer
- . Capital employed
- . Formulation
- . Drug
- . Non scheduled Formulation
- . Scheduled Formulation
- . Ceiling Price
- . Retail Price
- . Dealer

# DEFINITIONS . . . .

- . Distributor
- . Whole -Saler
- . Retailer
- . Price List
- . Local Tax
- . Sales Turn Over
- . Import
- . Free reserve
- . Government
- . Form
- . Net worth
- . Pre tax return
- . Schedule



# DEFINITIONS . . .

- **Bulk Drug:** Means any pharmaceutical, Biological or plant Product including its salts, Esters, Stereo Isomers and Derivatives, conforming to pharmacopoeial or other standards specified in the second schedule to the D & C Act 1940 and which is used as such or as an ingredient in any formulation.
- **Formulation:** Means a medicine processed out of, or containing one or more Bulk Drug or Drugs with or without the use of any pharmaceutical aids for internal or external use for or in the diagnosis, treatment, mitigation or prevention of diseases in human beings or animals.
- **Ceiling Price:** Means a price fixed by the Govt. for scheduled formulations in accordance with the provisions of paragraph 9.
- **Retail price:** Means the retail price of a drug arrived at or fixed in accordance with the provisions of this order and **includes a ceiling price.**

# Salient features . . .

Para 3: Govt. has the authority to fix maximum salable price of Bulk Drugs specified in Schedule I

- To regulate equitable distribution
- Available at fair price
- Publish in Gazette
- If manufactured from basic stage separate norms.
- No person shall sell at a price higher than the fixed.

# Salient features . . .

- **Para 4:** Manufacturers of **scheduled Bulk Drugs**
  - Should **submit the list** of scheduled bulk drugs manufactured
  - Should submit the details of each scheduled bulk drug produced
- **Para 5:** Manufacturers of **non-scheduled Bulk Drugs**
  - Should **submit the list** of non-scheduled bulk drugs manufactured
  - Should submit the details of each non-scheduled bulk drug produced
- **Para 6:** - Govt. can **direct** manufacturers of bulk drugs to **sell bulk drugs to other manufacturers** of Formulations.

(Captive requirements of the manufacturer is taken into consideration)

# Salient features . . . .

- **Para 7:** Calculation of **Retail Price of Formulations:**
- **MRP = RP + Local taxes**
- **R.P. = (MC + CC + PM + PC) x (1 + MAPE / 100) + ED**

Where,

RP = Retail Price

MAPE = Maximum allowable Post Manufacturing Expenses

MC = Materials Cost

CC = Conversion Cost

PM = Cost of packing material

PC = Packing Charges

ED = Excise Duty

# Salient features . . .

- **Para 8:**
- Govt. may from time to time **fix the retail price** of any **scheduled formulation.**
- Maximum retail price may be **revised** ,if the **price of bulk drug is revised.**
- Maximum retail price fixed **can not be increased** ,if not **permitted.**
- **No** manufacturer should **market** any such formulation **without price approval.**

# Salient features . . .

- Para 9: Govt. may fix **ceiling prices of scheduled formulations.**

Operates as a **ceiling** price for all such packs.

Both **brand name** and **generic name**.

If pack changed price is to be calculated as per norms fixed.

- Para 10: Govt. can **fix / Revise**

Price of any **formulations**

Including **Non-Scheduled** formulations.

# Salient features . . . .

- **Para 11:**

  - Non submission of information by manufacturers

  - Government fixes the retail prices on available information.

- **Para 12:** Government has the authority

  - To recover amount accrued under DPCO 1979

  - Deposit in DPEA

- **Para 13:** To recover amounts accrued under DPCO 1987

  - Deposit in DPEA

# Salient features . . . .

**Para 14:** Any price revision affected by Govt. should be implemented by the Manufacturers within fifteen days.

- Maximum retail price to be displayed on the labels
- Labels on packages offered for retail sale
- “MAXIMUM RETAIL PRICE” preceding the price  
“INCLUSIVE OF ALL TAXES” succeeding the price.
- Manufacturer shall issue price list
- Retailer shall display the price list so issued.



# Salient features . . .

- **Para 15:** Display of prices of non-Scheduled formulations and price list thereof
- **Para 16:** Prohibits the sale of Bulk Drug / Formulation at a price higher than the permitted one.
- **Para 17:** Sale of split quantities –  
Pro Rata Price + 5% thereof

# Salient features . . .

- **Para 18:**

- No manufacturer / Importer shall **refuse** to sell
- No dealer shall **refuse** to sell
- No retailer shall **refuse** to sell

- **Para 19:**

Price of formulations **sold to dealers**

- Scheduled formulations : (R.P. – ED) –16%
- At a price as fixed by the Central Government.  
( VAT IS TO BE TAKEN INTO CONSIDERATION .)

# Salient features . . .

- **Para 20:** Every manufacturer, importer, dealer shall **maintain records** as prescribed and produce for inspection.

## **Para 21: Power of entry, search & seizure –**

- **Gazetted officers of central / State Government.**
- Authorized by special / general **notification**
- **Enter, Search & Seize**

Drugs, Containers, Receptacles, Documents – cash or credit memos, Books of accounts etc.,

( **Section 100 of CRPC 1973.**)

# Salient features . . .

Para 22: Any person **aggrieved** by any notification

- May **apply** for a revision Within **15 days** of notification

Para 23:

- Central Govt. has the authority to issue guide lines

Para 24: **Penalties as per EC act 1955.**

Para 25: Government has power to exempt

Para 26: Government has also the authority to delegate any power vested in it ( Except 22,23,25 )

# PENALTIES.

- **DRUGS** were declared as **ESSENTIAL COMMODITIES** under clause (iv) (a) of Section 2 of E.C.ACT 1955

vide notification no. S.R.O. 828(E)

dated 9<sup>th</sup> April 1956.

The Penal Section is **7(i) (a) (ii)** of the Act.

# PENALTIES . . .

- **Section 7:** Penalties: if any person contravenes any order related to cl (h) or cl (i) of Sub-section 2

**Clause (i):** Cattle Fodder / Oil Cakes

Imprisonment one year and/ or Fine

**Other Clauses:** Imprisonment .....NLT 3 months which may extend to  
Seven years and also with Fine

Property Seized & Confiscated

Packing, Coverings, Receptacles Animals, Vehicle,  
Vessel or other conveyance used to transport the property –  
forfeited to Govt. – on order of court.

YOUR



PLEASE

WE

THANK YOU

HELP LINE : 09440897896