

DRUG (PRICE CONTROL) ORDER 1995

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INTRODUCTION

DPCO ACT, 1995



**CONFIRMED BY SECTION 3 OF
ESSENTIAL COMMODITIES ACT, 1955.**

HISTORY

IN 1966, PARLIAMENT MEMBERS FELT THAT MANUFACTURERS CHARGING HIGH RATE ON DRUGS.

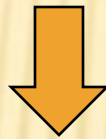


TO CONTROL ON HIGH DRUG RATES,
DPCO ACT 1966 WAS PASSED UNDER SECTION 3 OF
ESSENTIAL COMMODITIES ACT 1955.

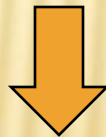
DPCO ACT, 1966 REPLACED BY DPCO ACT, 1970.



IN 1974, HATHI COMMITTEE WAS FORMED AND
SUBMITTED IT'S REPORTS IN 1975.



DPCO ACT, 1970 REPLACED BY DPCO ACT, 1987.



FINALLY DPCO ACT, 1987 REPLACED BY DPCO ACT,
1995.

OBJECTIVES

- ✓ TO ACHIEVE ADEQUATE PRODUCTION
- ✓ TO REGULATE EQUAL DISTRIBUTION
- ✓ TO MAINTAIN AND INCREASE SUPPLY OF BULK DRUGS
- ✓ TO MAKE AT FAIR PRICES.

DEFINITIONS

BULK DRUGS :-

IT MEANS ANY PHARMACEUTICAL, CHEMICAL AND BIOLOGICAL OR PLANT PRODUCT CONFORM TO PHARMACOPOEIAL STANDARDS SPECIFIED IN D & C ACT, 1940.

CEILING PRICE:-

PRICE FIXED BY GOVERNMENT FOR SCHEDULED FORMULATION.

DRUG :-

SUBSTANCE INTENDED TO BE USED FOR OR IN THE DIAGNOSIS, TREATMENT, OR PREVENTION OF ANY DISEASE OR DISORDER IN HUMAN OR ANIMAL.

RETAIL PRICE :-

RETAIL PRICE OF DRUG FIXED IN ACCORDANCE WITH PROVISIONS OF DPCO 1995 AND INCLUDE CEILING PRICE.

SCHEDULED BULK DRUG :-

IT MEANS BULK DRUG SPECIFIED IN FIRST SCHEDULE.

PRICES OF BULK DRUGS

- ❑ GOVERNMENT HAS POWER TO FIX THE MAXIMUM SALE PRICE.

WHILE FIXING THE SALE PRICE GOVERNMENT SHALL TAKE INTO FOLLOWING CONSIDERATIONS:-

- POST-TAX RETURN OF 14% ON NET WORTH.
- RETURN OF 22% ON CAPITAL EMPLOYED.
- ON THE BASIC STAGE OF PRODUCTION, POST TAX RETURN OF 18% ON NET WORTH OR 26% ON CAPITAL EMPLOYED

-
- AT THE TIME OF PRODUCTION OF DRUG, MANUFACTURER FILL DETAIL IN FORM-1 AND GIVE NECESSARY INFORMATION TO GOVERNMENT WITHIN 15 DAYS.
 - MAKE NECESSARY INQUIRY AND THEN GOVERNMENT FIX MAXIMUM SALE PRICE IF BULK DRUG AND NOTED IN OFFICIAL GAZETTE.
 - GOVR. ALSO FIX OR REVISE THE PRICE OF NON-SCHEDULED BULK DRUGS.

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 RESP.
- BUT FOR SCHEDULED BULK DRUGS IT SHOULD GIVEN BY 30 SEPTEMBER EVERY YEAR.

RETAIL PRICE OF FORMULATION

CALCULATION :-

FORMULA :

$$\text{R.P.} = (\text{M.C.} + \text{C.C.} + \text{P.M.} + \text{P.C.}) * (1 + \text{MAPE} / 100) + \text{ED.}$$

WHERE, R.P. = RETAIL PRICE

M.C.= MATERIAL COST

C.C.= CONVERSION COST

P.M.= PACKAGING MATERIAL COST

P.C.= PACKING CHARGES

ED = EXCISE DUTY

MAPE= MAXIMUM ALLOWABLE POST
MANUFACTURING EXPENSES

POWER TO FIX RETAIL PRICE OF SCHEDULED FORMULATION

- GOVERNMENT FIX THE RETAIL PRICE OF BULK DRUG.
- AND MANUFACTURER USE DRUGS IN SCHEDULED FORMULATION.
- FOR PRICE REVISION OF SUCH FORMULATION MANUFACTURER SHOULD APPLY WITHIN 30 DAYS.

- FROM DATE OF RECEIPT OF COMPLETE INFORMATION GOVT. FIX RETAIL PRICE WITHIN 2 MONTHS.
-

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 SCHEDULED FORMULATION

- GOVERNMENT FIX THE CEILING PRICE OF SCHEDULED FORMULATION.
- CEILING PRICE FOR FORMULATION INCLUDING THOSE SOLD UNDER GENERIC NAME.
- FIXED REVISED CEILING PRICE FOR SCHEDULE FORMULATION EITHER ON IT'S 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 OF FORMULATION THEN THE SCCHEDULED AND NON-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.**

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 ACT, 1995

FIRST SCHEDULE

- FIRST SCHEDULE INCLUDES 76 BULK DRUGS.
- Eg. PENICILLIN, RANITIDINE, CHLOROQUINE ETC.

SECOND SCHEDULE

- ❖ DIFFERENT FORMS INCLUDED :-
 - FORM- 1 :- APPLICATION FOR FIXATION/ REVISION OF PRICE.

 - FORM- 2 :- INFORMATION RELATED WITH PRICE OF NON-SCHEDULED BULK DRUG.

 - FORM-3 :- APPLICATION FOR APPROVAL/REVISION OF PRICE OF SCHEDULED FORMULATION.

 - FORM-4 :- APPLICATION FOR APPROVAL/REVISION OF PRICE OF SCHEDULED FORMULATION IMPORTED IN FINISHED FORM.

 - FORM-5 :- FORM OF PRICE LIST

 - FORM- 6 :- YEARLY INFORMATION ON TURNOVER AND ALLOCATION OF SALES AND EXPENCES.

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—

- ❑ HE 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.

REFERENCES:

- ❑ A Textbook of Forensic Pharmacy, by B.M. Mithal, Vallabh Prakashan, page no. 172-176
- ❑ Pharmaceutical Jurisprudence, by B.S. Kuchekar, Nirali Prakashan, page no.141-152
- ❑ http://seednet.gov.in/Material/Essential_Commodity_Act_1955