ONE shot

COMPLETE CONCEPT

PHARMACY INDIA

B.PHARMA | 5 SEMESTER

PHARMACEUTICAL JURISPRUDENCE

DRUG AND MAGIC REMEDIES 1954

PREVENTION OF CRUELTY TO ANIMALS ACT 1960

NATIONAL PHARMACEUTICAL PRICING AUTHORITY

UNIT-4

B. PHARMA 5TH SEM ONE SHOT NOTES

UNIT-4

Unit	Syllabus
4	**Study of Salient Features of Drugs and Magic Remedies Act and its rules:** Objectives, Definitions, Prohibition of certain advertisements, Classes of Exempted advertisements, Offences and Penalties. **Prevention of Cruelty to animals Act-1960:** Objectives, Definitions, Institutional Animal Ethics Committee, CPCSEA guidelines for Breeding and Stocking of Animals, Performance of Experiments, Transfer and acquisition of animals for experiment, Records, Power to suspend or revoke registration, Offences and Penalties **National Pharmaceutical Pricing Authority:** Drugs Price Control Order (DPCO)-2013. Objectives, Definitions, Sale prices of bulk drugs, Retail price of formulations, Retail price and ceiling price of scheduled formulations, National List of Essential Medicines (NLEM)

DRUGS AND MAGIC REMEDIES ACT AND ITS RULES

IMPORTANT DATE

Act passed	**1954**
Rule passed and came into force	**1st April 1955**

- To control the certain kind of advertisement related to drugs.
- To control certain kind of advertisement related to magic remedies, which falsely claims and mislead public.

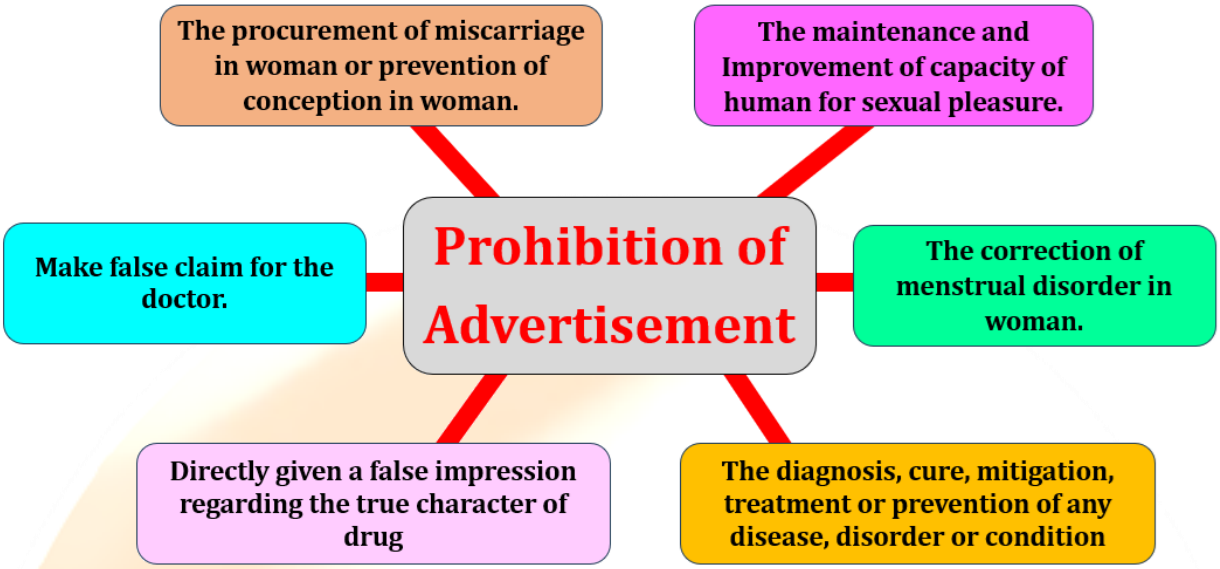
IMPORTANT SECTION

Section 3	No advertisements for Certain drugs for treatment certain disease and disorder.
Section 4	Misleading advertisement relating to drugs.
Section 5	Magic remedies for treatment of certain disease and disorder.

DEFINITION

Advertisement: It include any notice, circular, label, wrapper, or other document and any announcement by light, sound, and orally.

Magic remedy: It include talisman, mantra, kavach, and any other charm of any kind which is alleged to possess miraculous power for or in the diagnosis, cure mitigation, treatment.



CLASSES OF EXEMPTED ADVERTISEMENT

S.NO.	CLASS OF EXEMPTED ADVERTISEMENT	CONDITION
1.	Advertisement relating to the drug printed or published by the Govt. or any person with prior permission of the government	If it is needed to spread the awareness
2.	Leaflet or literature accompanying packaging of drugs.	Advertisement contain only formulation for RMP following 1. Therapeutic indication of drugs. 2. Administration 3. Dosage 4. Side effect 5. Precaution
3.	Advertisement in journals	Responsibility to prove the any claim of advertisement in respect to the not false.
4.	Price list of manufacturers, distributer, importer of drugs	Advertisements only contain technical information for guidelines for RMP
5.	Advertisement of chemical contraceptive for oral	Advertisement to the chemical contraceptive.

OFFENCES AND PENALTIES

S.NO.	OFFENCES	PENALTIES
1.	**First conviction:** Whoever contravenes any provision of this act or rules	Imprisonment up to 6 month or with fine or both

2.	**Second conviction:** Subsequent of the first conviction	Imprisonment up to one year or fine or both any subsequent
3.	**By company:**	• Every person who at the time of commission of the offences was in charge and responsible for the conduct of company business liable for the punishment. • However such person is not liable for the punishment if he proves that offences was committed without his knowledge or that he has taken all the precaution to prevent the commission.

PREVENTION OF CRUELTY TO ANIMALS ACT-1960

- The Prevention of Cruelty to Animals Act is an Act of the Parliament of India enacted to prevent the infliction of unnecessary pain or suffering on animals and to amend the laws relating to the prevention of cruelty to animals.

IMPORTANT DATES

Act passed	1960
Rule passed	1998
Rule and regulation	Extend to whole India except Jammu and Kashmir

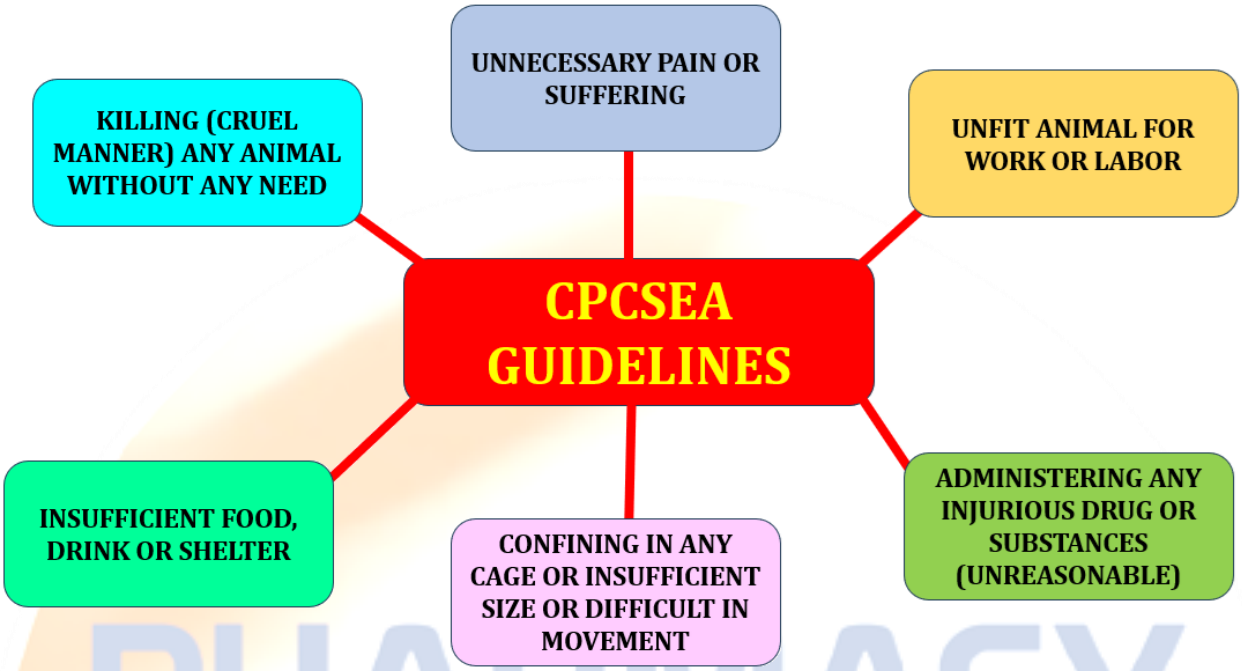
DEFINITION

- **Board:** It means the animal welfare board establishment under section 4 of the Act.
- **Breeder:** Means a person including an institute which breed animals for the purpose to authorized institution for performing experiment.
- **Committee:** Means the committee constitute under section 15 of the Act for control and supervision on animal.
- **Institute animal ethics committee:** Means a body comprises of a group of person recognized and registered by the committee for the purpose of control and supervision on animal performs in an establishment which is constituted and operated in accordance with procedures specified for the purpose by the committee.

INSTITUTIONAL ANIMAL ETHICS COMMITTEE (IAEC)

- A biological scientist.
- Two scientist from different biological disciplines.
- Veterinarian invited in the case of animals.
- The scientist in charge of animal facility of the establishment concerned.
- Scientist from outside the institution.
- Nonscientific socially aware member.
- Representative or nominee of the committee.

COMMITTEE FOR THE PURPOSE OF CONTROL AND SUPERVISION OF EXPERIMENTS ON ANIMALS (CPCSEA)



BREEDING AND STOCKING OF ANIMALS

Only registered establishment can carry on the business of breeding of animal for purpose of experiment

↓

Apply for registration within 60 days from the date of experiment

↓

For the registration of establishment/breeders (including universities and college) the Govt. of India has set up the committee for the purpose of control and supervision of experiment on animal (CPCSEA) under the ministry of social Justice and empowerment, shastri bhavan, New Delhi.

PERFORMANCE OF EXPERIMENT

All experiment shall be performed by or under the supervision of duly qualified person Degree holder.

RECORDS

Every establishment /institutional animal ethics committee shall maintain a records of the animal under the control and custody and furnish information.

Transfer of animals for experiment:

Transfer of any animal for sale purpose to an unregistered breeder is not permitted.

A breeder can't acquire any animal by sale except from a registered breeder.

Acquired animal can't be sale except from registered breeder.

Experiment in production breed improvement programme, animals may be given out by breeder institution for domestic use.

Genetic experiment on rat and mice not available in India, if such, the breeder shall take the permission from Institutional Animal Ethics Committee (IAEC).

Power to suspend or revoke registration:

Rules made by the committee are not followed or not satisfied by the committee.

The Committee giving a reasonable opportunity for rectification, after that the registration may revoke for a specific period or indefinitely or grant the license on a special condition.

Failure of compliance of mule and regulation, the committee may impose pending or suspend the registration.

During suspension period, the breeder shall take care of animals, cease to perform any experiment or acquire or transfer of any animal is prohibited.

OFFENCE AND PENALTIES

S.NO.	OFFENCE	PENALTIES
1.	Treating animals cruelty	Fine up to 0-100 /3 month jail

2.	Contravention if any order made by or committing breach of any condition by the committee	Fine extending 200 with jail

NATIONAL PHARMACEUTICAL PRICING AUTHORITY

INTRODUCTION

- The drug (price control) order forms of a part of the new drug policy formed by government of India.
- **1987 → 1995 → 2013**

DPCO 1995	Passed on 6th Jan. 1995 by Ministry of Chemical and Fertilizer by virtue of section-3 of essential commodities act.
DPCO 2013	Passed by ministry of chemical and fertilizer (Department of Pharmaceutics).

IMPORTANT DATE

Essential commodities act	1955
National list of essential medicine	2011
National pharmaceutical pricing policy	2012
DPCO Came into force	15th may, 2013

OBJECTIVE

- Ensure equitable distribution of essential bulk drugs and to fix the maximum ret formulation in order to curb the exorbitant.

IMPORTANT POINTS

DPCO 2013 order does not cover patented drugs.

Power of govt. under DPCO 2013 - Any gazatted officer.

Power of entry, search, seize - Paragraph 30

Any new drug patented in India will be exempted from DPCO for 5 year

Power of review - Paragraph 30.

SCHEDULE OF DPCO

Schedule I	It contain the national list of medicines 2011 and divided into 27 section.
Schedule II	Various form for approval or revision of price of scheduled formulation.
Schedule III	Maximum par tax return as sales turnover of manufactured importer of formulation- A, B and C category.

DEFINITION

Ceiling price: It means a price fixed by govt for scheduled formulation in accordance with p of this order.

Margin to retailer: It means percentage of price to retailer.

Maximum retail price (MRP): It means the ceiling price or the retail price plus local taxes and duties as applicable, at which the drug.

National list of essential medicines: National list of essential medicines 2011 published by ministry of health and family welfare.

Non-scheduled formulation: It means formulation, the dosage form and strength of which are not specified in the first schedule.

Local taxes: It means any taxes or leavy (Except excise or import duty included in retail price)paid or payable to the govt or the state govt.

Price to retailer: It means the price of a drug at which it is sold to a retailer which include duties but does not include local taxes.

Retail price: It means price fixed by the govt. for a new drugs.

Schedule formulation: It means any formulation include in the first schedule whether referred to by generic version or brand name

SCHEDULE FORM

Form-III	Proforma for quarterly return in respect of production/import and sale of NLEM
Form-IV	Proforma for submission of the details in respect of discontinuation of the production and import of scheduled formulation
Form-V	Proforma for price list

Sale prices of Bulk Drugs:

- **First Schedule:** it contains the list of 74 bulk drugs.
- **Second Schedule:** it contains various forms for approval or revision of prices of Scheduled formulations.
- **Third Schedule:** it specifies the maximum pre-tax (of income or profits) considered or calculated before the deduction of taxes) return on sales turnover of manufacturer/importers of formulations under A, B & C categories.

SCHEDULED FORMULATION PRICE

(A) CALCULATION OF PRICE OF A SCHEDULE FORMULATION

Step 1: Calculation of average price of schedule formation i.e. P(s) to retailer

$$\text{Average price to retailer P(S)} = \frac{\text{Sum of price to retailer of all the brands and generic version of the medicine having market share more than or equal to 1\% of the total market turnover on the basis of moving annual turnover of the medicine.}}{\text{Total number of such brands and generic version of the medicine having market share more than or equal to 1 \% of total market turnover on the basis of moving annual turnover for that medicine.}}$$

Step 2: Calculation of ceiling price

$$P(C) = P(S)\left(1+\frac{m}{100}\right)$$

P(s) Average price to retailer for the same strength and dosage.

M= % of margin to retailer and its rule = 16

- Final MRP of the drug at retailer is increased with factor of 16%.

(B) CEILING PRICE OF A SCHEDULED FORMULATION IN CASE OF NO REDUCTION IN PRICE DUE TO ABSENCE OF COMPETITION.

- If there are less than 5 manufactures for that formulation having 1% or more market share.

Step 1: Calculation of average price of scheduled formulation i.e., P(s) to retailer

$$Ps = \frac{Pm(1-(Pi1+ Pi2 + ...}{(N\times100)}$$

Where,

Pm= Price to retailer of highest priced scheduled formulation under consideration.
Pi=% Reduction in average price to retailer of other strength and dosage forms
N = Number of such other strength or dosage forms or both in the list of schedule formulation.

Step2: Calculation of ceiling price

$$P(C) = P(S)\frac{1+M}{100}$$

Where,

P(s) = Average price to retailer for the same strength and dosage.
M =% of margin to retailer and its value = 16
Margin to retail: A margin of 16 % to retail shall be allowable

MAXIMUM RETAIL PRICE
MRP of schedule formation = Celling price + local taxes as applicable
MRP of new drug = Retail price + Local taxes as applicable

S. NO.	DPCO 1995	DPCO 2013
(a)	Governed by essential commodity act - 1995	It is governed by National Pharmaceutical Pricing Authorities (NPAA). (DPCO has enable NPPA regulate price of 348 drugs that come under national list of essential medicines)
(b)	They regulate price of only 74 drugs	They regulate price of 652 drugs
(c)	If once price is 3 fixed they cannot change according to act	Pricing is mainly based on simple average price be lowered dependency upon margin
(d)	Government fix price "industries cannot dominate" ↓ price were fixed accordingly to manufacture cost only	Price are fixed both by mutual agreement of government and industries
(e)	**Formula:** Calculation of Retail price	**New pricing in 2015 is MRP = Ceiling price + Local taxes**

	$R.P = (MC + CC + PM + PC) \times \frac{1+MAPE}{100} + ED$ **Where,** **R.P= Retail price** **M.C = Material cost** **C.C = Conversion price** **P.M= Packing material cost** **P.C = Packing charges** **MAPE = Maximum allowable post manufacturing expenses (NMT 100%)** **E.D= Excise duty**	**Celling price + Ps** $(\frac{1+M}{100})$

What is Essential Medicines?

- Essential medicines, as defined by the World Health Organization, are the medicines that "satisfy the priority health care needs of the population".
- These are the medications to which people should have access at all times in sufficient amounts. The prices should be at generally affordable levels.

National List of Essential Medicines (NLEM)

- The National List of Essential Medicines (NLEM) is a list released by the Ministry of Health and Family Welfare. The medicines listed in the NLEM are sold below a price ceiling fixed by the National Pharmaceutical Pricing Authority (NPPA).

National List of Essential Medicines 2015

(A) Anaesthetic Agents (Trick – HIK)

- ❑ **Halothane**
- ❑ **Isoflurane**
- ❑ **Ketamine**

(B) Analgesics, Antipyretics & NSAIDS (Trick – DIP)

- ❑ **Diclofenac**
- ❑ **Ibuprofen**
- ❑ **Paracetamol**

(C) Anti-Allergic & Anaphylaxis (Trick – ACP)

- ❑ **Adrenaline**
- ❑ **Cetirizine**
- ❑ **Prednisolone**

(D) Antidotes (Trick – NAN)

- ❑ **Atropine**
- ❑ **Naloxone**

- Neostigmine

(E) Anticonvulsants (Trick – CDC)

- Carbamazepine
- Diazepam
- Clobazam