

4. a. study of salient features of drugs & Magic Remedies act & its Rules

objectives :-

1. To control drug Advertisement :-

- drug Advertisement should be made to medical [pharmacy] Nursing Profession and not directly to the patient
- As drug is a toxic substance & Advertisement provokes self medication

2) To prohibit Advertisement of Remedies that say to Have Magic Qualities.

- Mainly for sexually transmitted disease there is a problem in India regarding churm & Magic Remedies
- such Advertisement with false claims are prohibited that would prevent people from misleading.

Prohibited Advertisements:-

The following classes of Advertisements are prohibited under drug & Magic Remedies act :-

① Advertisement for drugs used in following conditions:

- drugs that claim to "improve sex drive"
- drugs that claim to cause miscarriage
- and prevent conception in females.
- drugs that claim to cure menstruation disorders in women
- drugs that claim to diagnose, treat, mitigation & prevent schedule 'I' diseases.

② A misleading Advertisement:-

- Advertisement having statement that false claims the use illustrates or drug is prohibited

- ③ Advertisement for remedies that say to be magical for schedule I disease are prohibited

Exempted Advertisement :-

without ↗ ↘ condition

- The following classes of Advertisements are exempted from the provisions of Prohibition (means they are not prohibited)

- ① Notice Board / sign Board displayed by RMP at the premises that give information regarding treatment of certain disease.

- ② Books that deal with diseases & treatment and were published from scientific pov.

- If the Advertisement has any statement that creates fear among people e.g. forces them to use product.

- ③ certain drugs are sent confidentially to RMP and Advertisement of such drug have no statement "only for RMP".

- If Advertisement has any statement that suggested reward and leads to excessive use of by people.

- If Advertisement has statement that claims universal uncuring, guaranteed treatment cure cure.

- If Advertisement of vitamin prep has a statement that it could replace balanced diet.

(4) Advertisment for certain drug done by Govt.

(5) Advertisment for certain drug done by products permitted under drugs & cosmetics Act.

(6) Labels & Instruction set that come along with certain drugs & cosmetics Act.

Exempted Advertisment with conditions :-
Advertisment conditions
Advertisment of drug
Medical scientific pharmaceutical Journal RMP

Advertiser

- ① Advertisment has info that provides guideline only for RMP
- ② Advertisment ensures that no statement in Ad. gives false claim or is misleading.

(3) Advertisment of chemical & medical contraceptives

same cond'n
(2)

If any person 1st conviction :-
controversy to this 6 months imprisonment
Act provisions, e.g. -> & fine
displays an ad. i.e. to be prohibited 2nd conviction
& yr imprisonment & fines

(2) Advertisment on medical & some condition
of product distributed by medical representatives

b. Reservation to cruelty at Animals Act 1985

objectives → Novocain, in modern pharmaceutical science, animals are used for testing safety & efficacy of drug as they have system similar to human body.

- But this purpose can lead to pain, injury & death of animals.

- This act prevents cruel behaviour of man towards animal & also prevents animals from unnecessary pain.

Provision to perform experiments :-

1. Before performing experiment it is necessary to get permission from institute animal ethics committee and if found satisfactory permission will be granted.
2. Experiment on animals must be performed under supervision of qualified person like,
 - ① degree, diploma in Veterinary science.
 - ② degree in medicine

(2) Laboratory Animal Science from Recognised Institute.

- ③ Experiment cannot be performed until the animal is registered.
- ④ Animal should be properly cured before & after performing experiment.

- ⑤ If the experiment is an operative procedure the animal must be given anaesthesia prior experiment.
- ⑥ This should be done by veterinary surgeon or any person trained to do so & he should remain near the animal throughout procedure.

- ⑦ If during operative procedure animal is injured such that suffers anaesthesia effect would feel pain to recover in such situation animal must be destroyed humanely under anaesthetic effect.
- ⑧ If possible avoid use of animals and use models and films for experiments.
- ⑨ Prefer use of small animals & avoid using larger animals.

9. Experiments should be performed for Research purpose & to get information about the details. Regarding, not too demonstration to public.

10. If an experiment is having conclusive result, it should not be repeated on Animals.

11. Records should be maintained for every experiment as given,

- Type of Animal used
- Health of Animal
- Nature of experiment
- Purpose of experiment

CPCSEA guidelines for breeding & stocking of Animals,

CPCSEA - Committee for the purpose of Control and Supervision of Experiments on Animals

Breeding :-

→ Before conducting Breeding Registration must be done to the numbers secretary of committee as any others Authorised number of committee.

Breeder.

- To Registration Application is to be given with all the details. Regarding,

• Registers where experiment & breeding is conducted.

- Animal Housing facilities
- Availability of man trained to handle animals

• Application must be given two months before commencement of breeding.

- If found satisfactory the committee would register for breeding.

- A Register should be maintained having details of animals used day to day for breeding.

- Following details should be mentioned.

- No of Animals used
- Species of animals
- Age

The Register may be examined by authorised person of committee & if something found unacceptable a chance of improvement is given or Action is taken against

Stocking :-

- The premises for Housing of Animals should be in quiet atmosphere.

- The premises should be Maintained clean & hygienic.

- The cage for small Animals & Stable of large Animals should have sufficient area.

to Avoid overcrowding

- The cage and stable should be as per standards of ISI i.e. Indian Standard Institute.

- Proper care of Animals should be maintained even during off hours & Holidays.

- The Establishment Registered must be following the Rules by Committee for Housing, feeding & Nursing Animals.

offences & Penalties

offences Penalties.

But Injurious to Animal Health

① Behaviour cruelly conviction → 3000/- 6 months imprisonment

and conviction → 6 months jail.

② Co-Convention with 2st conv. → 10000/- 6M Jeal
the Rules of and → 20,000/- Committee conv

③ Performing experiment it → 20,000 on Animals without conv on Registration

Performing Experiment 2nd { → 50,000/- on Animals which c are not for the purpose

④ If experiment performed 1st c → 20,000/- on cow or any others 4 M Jeal

milk giving Animal 4 M Jeal

whose something is 2nd c → 50,000/- injected to improve 4 M Jeal lactating.

C. National Pharmaceutical Pricing Authority (NPPA)

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- NPPA is an independent body under pharmaceuticals, fertilizers & chemicals.
- Its main role is to fix prices of bulk drug and formulation.
- also receives amounts overcharged by the manufacturer.

DPCO - Drug Pricing control order : 1966
- 2013

$$RP = (MC + CC + PM + PC) \times (1 + M&EE) + ED$$

RP → Retail Price.
MC → Material cost, includes cost of drugs

- DPCO is made under sec-3 of Essential Commodities Act.

- It was issued in 1966 & the latest in 2013

PM → Packaging material cost, that is used to pack the formulation.

Objectives :-

- (1) To ensure equitable distribution of Bulk drug
- (2) To fix MRP of drugs to check profiteering tendencies
- (3) To impose control at govt. overs' prices of Bulk drug and formulated drug.
- (4) To increase no. of drugs from auto 659 whose price is regulated by DPCO.
- (5) To regulate price of 384 drugs mentioned in the national list of drugs at or below the price set by DPCO.

CC → Commission cost, includes labour cost and manufacturing cost

PC → Packaging charges, includes labour cost to pack the formulations

NARE → Max allowable post-marketing expenses

- includes all cost incurred by manufacturer from ex-factory to retail selling also includes trade margin

ED → Excise duty.

- To permit sale of drugs at or below the price set by DPCO.

Provision under U.P.C.O.-2013

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- for formulations of category 3, MOPR should not exceed 30% and for schedule 3 of category 2 as per schedule 3 should not exceed by 100%.
- if the formulation belongs to both category 1 & 2 it is considered to be category 1 formulation.
- for imported formulations the pricing is done. Based on landed cost + original price + transportation fee + insurance + taxes + R.P. currency conversion + R.P.
- for new formulation or new packaging the retail price needs to be revised by the govt. for this application is given to govt.
- if you does not revised the R.P even after 4 months of application, the formulation should be sold at R.P mentioned in Application.
- the manufacturer, importer or distributor can sell the formulation to whole seller at R.P (minus) 20% & retails at R.P (minus) 15%.

1. Prices of Bulk drugs

1. Retail prices of formulations
2. Price to Wholesaler & Retailer
3. Schedules

2. Prices of bulk drug

- Govt fixes time to time a base sale price at which bulk drug is to be sold.

- This is done to perform equitable distribution of bulk drug at fair price from different manufacturers.

- If any manufacturer wants to revise the base sale price of drug fixed by govt, an application is made to govt.

- Govt will revise the into 4 months of receipt of Application would either fix the price as reject the Application. Reason will be given in writing.

3. Retail prices of formulation

1. Calculated before
2. Prices to wholesaler & retailers

for scheduled products.

→ Prices of Purchase for whole seller \rightarrow MRP 20%
" " Retailer \rightarrow RP 15%
Prices of "

④ Schedules :- Three schedules to exist,

DPCO ① I :- List of Bulk drugs (745) listed
in Schedule formulation

② II :- List of forms

③ III :- Comprise Pose-huge Returm.ans.
Sale turnover or formulation
at diff category

\Rightarrow National List of Essential Medicines :- NLEM

Executive Medicines \rightarrow As per WHO, the
Medicines that satisfy the priority
of health care needs of population are
called as Executive Medicines.

Medicine	level of Healthcare	dosage form
1. Halothane	P, S, T	Inhalation
2. Isotyrosine	P, S, T	"
3. Ketamine		Injection

(Section 2) Analgesic Agent

① Diclofenac	Tablet Injection
② Ibuprofen	Tablet, oral suspension

(Section 2) Analgesic Agent

(Section 2) Analgesic Agent

NLEM :- Ministry of Health & family welfare.
Has formulated a list of Medicine
on Basis of Essentiality i.e.,
NLEM.

③ Metformin Acid	P, S, T	capsules
④ Ketorolac		cream
⑤ PGM		cream

- This list of Medicines is now included in

Schedule I of DPCO-2013. MPPA will now

Regulate prices of these medicines.

A brief view of NLEM is given below
full medicines are not included)

Symbol P, S, T denote level of
Healthcare primary, secondary & tertiary

Section 6: - Anticonvulsants

Medicines

Healthcare Level

degree: form

① carbamazepines

P.S.I.T

Tub, oral

elixir

② Diclofenac

Injection,
osol,

③ fosfrenazepam

Tub, injectio

function of DPCO :-

- (1) To Monitor Availability of drugs,
Identify shortages & take Remedial steps.
- (2) collects data for Bulk drug & formulation
regarding its production, export -
import Market Share of company,
profitability company etc.,
- (3) performs Relevant studies in respect
of pricing of drugs.
- (4) will implement & Enforce the
provisions within it.
- (5) To Advice central govt for changes in
drug Policy.
- (6) To Assist central govt in Implementing
Matters. Affecting to drug pricing.