DRUGS AND MAGIC REMEDIES ACT, 1954

Ms: Manisha K. Gavit
Assistant Professor
(Department of Pharmaceutical Chemistry)

JES's college of Pharmacy,Nandurbar

Introduction

- The Drugs and Magic Remedies (Objectionable Advertisements) Act, 1954 is an Act of the Parliament of India which controls advertising of drugs in India. It prohibits advertisements of drugs and remedies that claim to have magical properties, and makes doing so a cognizable offence.
- The Act came into force on 1st April, 1955.
- It is applicable to the whole of India (along with Jammu and Kashmir) after the removal of Article 370 in 2019.

Objectives of the Act

- To control certain kind of advertisements related to drugs.
- To control certain kind of advertisements related to magic remedies which falsely claimed and mislead public.

DEFINITIONS

- **Drug:** It includes –

i. A medicine for internal or external use of human beings or animals

ii. Any substance intended to be used for or in the diagnosis, cure, mitigation, treatment or prevention disease in human beings or animals,

iii. Any article other than food intended to effect or influence in anyway the. structure or any organic function of the body of human beings or animals,

iv. Any article intended for use as a component of any medicine, substance or article referred to in (i), (ii) (iii) as above.

- **Advertisement:** Advertisement includes any notice, circular, label, wrapper other document, and any announcement made orally or by any means of producing or transmitting light, sound or smoke;

- **Magic Remedy:** Magic remedy includes a talisman, mantra, kavacha, and any other charm of any kind which is alleged to possess miraculous powers for or in the diagnosis, cure, mitigation, treatment or prevention of any disease in human beings or animals or for affecting or influencing in any way the structure or any organic function of the body of human beings or animals;

- **Registered Medical Practitioner :**

i. A person who holds a qualification granted by an authority specified in or notified under section 3 of the Indian Medical Degrees Act, 1916 or specified in the Schedules to the Indian Medical Council Act, 1956

i. A person who is entitled to be registered as a medical practitioner under any law for the time being in force in any State to which this Act extends relating to the registration of medical practitioners.

SECTION 3 OF THE ACT

- Prohibition of advertisement of certain drugs for treatment of certain diseases and disorders:

  No person shall take any part in the publication of any advertisement that can lead to use of drug for –

a) the procurement of miscarriage in women or prevention of conception in women; or

b) the maintenance or improvement of the capacity of human beings for sexual pleasure; or

c) the correction of menstrual disorder in women; or

d) the diagnosis, cure, mitigation, treatment or prevention of any disease, disorder or condition specified in the Schedule, or any other disease, disorder or condition which may be specified in the rules made under this Act:

NAME OF THE DISEASE, DISORDER OR CONDITION SPECIFIED IN ORIGINAL SCHEDULE:

1. Appendicitis
2. Arteriosclerosis
3. Blindness
4. Blood poisoning
5. Bright's disease
6. Cancer
7. Cataract
8. Deafness
9. Diabetes
10. Diseases and Disorders of brain
11. Diseases and Disorders of the optical system
12. Diseases and Disorders of the uterus
13. Disorders of menstrual flow
14. Disorders of the nervous system
15. Disorders of the prostatic gland
16. Dropsy
17. Epilepsy
18. Female diseases (in general)
19. Fevers (in general)
20. Fits
21. Form and structure of the female bust
22. Gall stones, kidney stones and bladder stones
23. Gangrene
24. Glaucoma
25. Goitre
26. Heart diseases
27. High/low blood pressure
28. Hydrocele
29. Hysteria
30. Infantile paralysis
31. Insanity
32. Leprosy
33. Leucoderma
34. Lockjaw
35. Locomotor ataxia
36. Lupus
37. Nervous debility
38. Obesity
39. Paralysis
40. Plague
41. Pleurisy
42. Pneumonia
43. Rheumatism
44. Ruptures
45. Sexual impotence
46. Smallpox
47. Stature of persons
48. Sterility in women
49. Trachoma
50. Tuberculosis
51. Tumours
52. Typhoid fever
53. Ulcers of the gastro-intestinal tract
54. Venereal diseases, including syphilis, gonorrhoea, soft chancre, venereal granuloma and lympho granuloma.

SECTION 4 OF THE ACT

- Prohibition of misleading advertisements relating to drugs:

  No person shall take any part in the publication of any advertisement relating to a drug if the advertisement contains any matters which—

(a) directly or indirectly gives a false impression regarding the true character of the drug; or

(b) makes a false claim for the drug; or

(c) is otherwise false or misleading in any material particular

SECTION 5 OF THE ACT

- Prohibition of advertisement of magic remedies for treatment of certain diseases and disorders: No person carrying on or purporting to carry on the profession of administering magic remedies shall take any part in the publication of any advertisement referring to any magic remedy which directly or indirectly claims to be efficacious for any of the purposes specified in conditions (a), (b), (c) or (d) of section 3.

Classes of Advertisement

S.No	Class of Advertisement	Condition
1.	Leaf-let or literature accompanying packaging of drug and 2. Advertisement in Journals	Advertisement contain only formulation for RMP following. - Therapeutic Indication of drug - Administration - Dosage - Side effect - Precaution Responsibility to Prove the any claim of Advertisement in respect to the not false.
3.	Price list of Manufacturer, distributer, importer of drug and 4. Advertisement of chemical Contraceptive for Oral use	Advertisement only contain technical information for guideline to RMP - Therapeutic action - Administration etc Advertisement to the chemical contraceptive.

OFFENCES AND PENALTIES

- Whoever contravenes any of the provisions of this Act or the rules made there under shall, on conviction, be punishable –

OFFENCE	PENALTY
First Conviction	Imprisonment which may extend to six months, or fine, or both
Subsequent Conviction	Imprisonment which may extend to one year, or fine, or both

Thank you

THE PREVENTION OF CRUELTY TO ANIMALS ACT 1960

Ms: Manisha K. Gavit
Assistant Professor
(Department of Pharmaceutical Chemistry)

JES's college of Pharmacy,Nandurbar

OBJECTIVE

- In modern day research animals are – important experimental subjects because of physiological similarity to human beings.
- To establish safety and efficacy of drugs experiments on animal unavoidable.
- Clinical trails under D&C act preceded by data generation on animal toxicology and pharmacology.
- Implies that animals may be subjected to pain/injury is unethical.
- The prevention of cruelty to animals act 1960 has been entacted to prevent unnecessary pain on suffering on animals.
- Breeding of and experiments on animals rules, 1998 have been incorporated in this act.
- This act extends to whole India except Jammu & Kashmir.

DEFINITIONS

- **Animal:** Any living creature other than a human being
- **Breeder:** Person including institution, which breeds animals for the purpose of transfer to the authorized institution for performing experiments.
- **Committee :** Any individual, company, firm, corporation, institution other than schools up to higher secondary level, which performs experiments on animals.
- **Experiment:** Any program/project involving experiments on animal/animals for the purpose of advancement by new discovery of physiological knowledge which will be useful for saving or prolonging life or alleviating suffering or for combating any disease whether on human beings or animals.

- **Institutional Animal Ethics Committee** : A body comprising of a group of persons recognized and registered by the committee for the purpose of control and supervision on animals performed in an establishment which is constituted and operated in accordance with procedures specified for the purpose by the committee.

- **Contract Research**: Any research undertaken by an individual, company, firm, corporation or institution on behalf of a foreign individual, company, corporation or institution for any consideration.

- **Collaborative Research :** Any research undertaken between two or more research institutions on an equal footing which does not involve any financial or monetary considerations and is undertaken solely for the purpose of advancement of scientific research and human welfare.

- **Cruelty to animals :**

  Includes

a) subjecting any animal to unnecessary pain or suffering or treatment, or

b) Employing any unfit animal for work or labour, or

c) Willfully and unreasonably administering any injurious drug or substance to any domestic or captive animal, or

d) Keeping or confining any animal in any cage of insufficient size not permitting it reasonable movement, or

e) Failure to provide any animal with sufficient food, drink or shelter by its owner, or

f) Needlessly mutilating any animal or killing any animal in an unnecessarily cruel manner.

- Treating animal cruelly is an offence punishable with fine up to Rs. 50 in the first instance and if a **second offence** is committed within three years of the previous offence, the fine may extend to Rs. 100, or with imprisonment up to three months, or with both.

- **Institutional Animal Ethics Committee :**
- Every Institutional Animal Ethics Committee shall include

i) A biological scientist,

ii) Two scientists from different biological disciplines,

iii) A veterinarian invited in the case of animals,

iv) The scientist in charge of animals facility of the establishment concerned,

v) A scientist from outside the institution,

vi) A non-scientist socially aware member.

BREEDING AND STOCKING OF ANIMALS

- Only registered establishments can carry on business of breeding of animals for the purpose of experiments.
- Every breeder shall apply for registration with in 60 days from the date of commencement of breeding of and experiments on animals and stop breeding should be stopped if the committee refuses registration.
- The application should be made in specified format to the member secretary by the committee in this regard.
- For registration of establishments/breeders the Govt. of India has setup the **“committee for the purpose control and supervision of experiments on animals”(CPCSEA)** under the ministry of social justice and empowerment, shastri Bhavan, New Delhi.

- The secretary of the committee may ask for the information relating to the premises where the experiments are to be conducted, animal house facilities, details of breeding of animals and its trade, other infrastructure including availability of manpower trained in handling animals and for verification of facts mentioned in the application for registration.
- And if satisfied, shall register such establishment or the breeder.
- A breeder shall comply with all the conditions specified at the time of registration.
- Every registered establishment shall maintain a register as per the specified format and keep complete particulars about
- the kind of animal to be used for conducting experiment,
- the health of the animal, nature of the experiment,
- the reasons to perform such experiment on particular species

- The member secretary/officer authorized by the committee may examine the register so maintained, and if he is not satisfied irrespective of the opportunity given for improvement, he may bring the same to the notice of the committee seeking directions in this regard.
- The animals shall be stocked by the breeder and the establishment in the prescribed manner.
- Animal houses shall be located in a quiet atmosphere undisturbed by traffic and the premises kept tidy, hygienic and protected from drought and extremes of weather.
- Animal cages for small animals stables for large animals so that it may be comfort and overcrowding avoided.
- Standards have been laid down by the Indian standards institution (ISI) for the cage and stables.

- Animal attendants must be trained and experienced in duties.
- Before acquiring an animal or conducting any experiment on an animal every registered establishment shall apply for permission of the committee/IAEC.
- The secretary of the committee shall cause the application for permission to be brought before the committee/IAEC after scrutinizing if satisfied, may grant the permission to establishment stating the name of the species and the number of
- animals that can be acquired for carrying out the experiments.
- While granting permission for conducting experiments on animals they may put conditions as it may deem fit to ensure that animals are not subjected to unnecessary pain or suffering before, during or after the performance of experiments on them.

PERFORMANCE OF EXPERIMENTS

- Performing experiments on animals
- For the advancement by new discovery of knowledge, which will be useful for saving or prolonging life or for combating any disease in human beings, animals, plants is lawful.
- The experiment shall neither be performed for the purpose of attaining or retaining manual skill except in schools, colleges and recognized training institutions, nor by way of an illustration or as a public demonstration.
- When experiments are performed in any institution the responsibility is placed on the person in charge of the institution and incase of outside responsibility will be his own.

- Experiments performed under the supervision of a qualified person.
- The qualified person shall hold a degree or diploma in Veterinary science or medicine or Laboratory animal science of a university or an institution recognized by the government for the purpose.
- Experiments shall be performed with due care and humanity.
- Animals must not subjected to unnecessary pain or suffering before, during or after the performance of experiments on them.
- Experiments with severe operations shall be done under anesthetic environment by a trained person to prevent the animal feeling pain.

- In the experiment under anesthesia if animal injures severely that recovery involve pain and suffering then they shall be destroyed humanely.
- No experiment shall be repeated without previous justification if the result of such experiment is already known.

Transfer and Acquisition of animals for Experiment

- Transfer of any animal by way of sale by a breeder to an unregistered establishment is not permitted.
- After acquisition animals shall not be transferred to any person except to a registered breeder.
- However the animals used for experimentation in a breed improvement program may be given out by the breeder institution for domestic use.

Records

- Every establishment/IAEC shall maintain a record of the animals in its control and custody and furnish such information as the committee may from time to time require in the specified format.
- All laboratories shall inform the exact number/species of animals to the secretary or any other officer in this regards by the committee as per the specified format.

Power to suspend or revoke registration

- If the committee is satisfied that the rules made by it are not being followed by any establishment/Breeder/IAEC the committee may after giving reasonable opportunity of being heard the matter revoke the same either for a specified period or indefinitely or may allow the establishment to such special conditions as the committee may impose.

- A breeder shall comply with the directions given by the committee for the purpose of controlling and suspending experiments on animals.
- Import of any animal in the country by a breeder is also not allowed.
- The committee may pending the final determination but prima facie failure to comply with the provisions of these rules, suspend the registration of such establishment/ breeder.
- In the event of revocation or suspension of registration of an establishment the committee may issue direction for the care and protection of the animals, which are under the custody of such establishment.

Penalties

- Breaching of any condition is punishable with fine extending to Rs 200.

- When the contravention takes place in institution the person in charge shall be guilty of the offence and shall be punishable accordingly.

THANK YOU

National Pharmaceutical Pricing Authority

Ms: Manisha K. Gavit
Assistant Professor
(Department of Pharmaceutical Chemistry)

JES's college of Pharmacy,Nandurbar

Objectives

- To Achieve Adequate Production
- To regulate Equal Distribution
- To Maintain and Increase Supply Of Bulk Drugs
- To make at Fair Prices.

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.

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

Definitions

- **BULK DRUGS** :- It means any pharmaceutical, chemical and biological or plant product conform to pharmacopoeial standards specified in D And 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.

A) 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.

✓ For new plant, return of 12% based on long term marginal cost.

✓ On the basic stage of production, post tax return of 18% on net worth or 26% on capital employed.

Prices of bulk drugs

B) At the time of production of drug, manufacturer fill detail in FORM-I and give necessary information to government within 15 days.

C) Make necessary inquiry and then government fix maximum sale price of bulk drug and noted in official gazette.

D) Gov. Also fix or revise the price of non-scheduled bulk drugs.

Retail price of formulation

- CALCULATION :-

FORMULA :

$$R.P. = (M.C. + C.C. + P.M. + P.C.) \times (1 + MAPE / 100) + ED.$$

Where,

R.P. = Retail Price

M.C.= Material Cost

C.C.= Conversion Cost

P.M.= Packaging Material Cost

P.C.= Packing Charges

MAPE= Maximum Allowable Post Manufacturing Expenses

ED = Excise Duty

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 Govr. 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 with formula given in the Paragraph 7 keep cost and efficiency or both.
- 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.

New Drug / New Formulation

A) NLEM (National List of Essential Medicines) Formulations with same specified dosage and strength as combined with another NLEM Formulations with same specified dosage and strength.

Example I:

- Paracetamol 500mg Tablet is Scheduled Formulation
- Diclofenac 50mg Tablet is Scheduled Formulation New Drug = Paracetamol 500mg + Diclofenac 50mg Tablet is New Drug/Formulation.

B) NLEM Formulations with same specified dosage and strength as combined with another Non - NLEM Formulations

Example II:

- Paracetamol 500mg Tablet is Scheduled Formulation
- Aceclofenac 100mg Tablet is Non - Scheduled Formulation
- Paracetamol 500mg + Aceclofenac 100mg Tablet is New Drug \

C) NLEM Formulations by changing its strength

Example I:

- Paracetamol 500mg Tablet is a Scheduled Drug
- Paracetamol 325mg Tablet is a New Drug

D) NLEM Formulations by changing its dosage

Example I:

- Diclofenac 50mg Tablet is a Scheduled Drug.
- Diclofenac 50mg Ointment is a New Drug.

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.

Thank you