Unit-4

Study of Salient features of Drugs and magic Remedies Act and its rules:—

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Introduction:— Advertisement have become a part of our life and advertising has undergone revolutionary changes due to explosion in Communication technology.

Modern methods of advertising like television, internet, cellphones (mobiles) etc have proved to be very effective.

Advertisements for drugs are not meant for the public directly but through qualified persons like physicians, Pharmacists and nurses etc However advertisements for OTC drug products and cosmetics are meant for general public.

In recent years there has been a grant increase in the number of objectionable advertisements published in newspapers and magazines etc relating to alleged cures for venereal disease, sexual stimulants and about disease and conditions Peculiar to women.

Objectives:— The main objective of DMR act is to Control the advertisement of drugs in certain Cases and to prohibit the advertisement Connected with remedies alleged to passes magic qualities and to provide for matters connected therewith.

Advertisement:— Advertisement includes any notice, circular label, wrapper, or other documents, and any announcement made orally or by 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.

Prohibited Advertisements:— 1) No person can take part in the publication of any advertisement referring to any drug in terms which suggest or are calculated to lead to use of that drug for.

a) Procurement of miscarriage in women, or prevention of conception in women.

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

c) Correction of menstrual disorder in woman

d) diagnosis, cure, mitigation, treatment or prevention of any disease, disorder or condition specified in Schedule J of the Drug & Cosmetic Rules 1945.

2. No person shall take part in the publication of any advertisement relating to a drug if the advertisement contains any matter which

a) directly gives a false impression regarding the true character of the drug

b) makes a false claim for the drug

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

3] No person carrying or purporting to carry on the profession of advertising magic remedies should take part in the publication of any advertisement referring to any magic remedy.

4] No person shall take part in the publication of any advertisement referring to any drug in terms which suggest or calculated to lead to the use of that drug for diagnosis, cure, mitigation, treatment or prevention of any disease, disorder or condition in Asthma and AIDS.

Import and export of all the above mentioned advertisements is prohibited.

Exempted Advertisements:— Advertisements are permitted if made in the manner mentioned below.

a) Any sign board or notice displayed by a RMP (Rural medical practitioners) on his premises indicating that the treatment for any disease, disorder or condition is undertaken relating to which advertisements are otherwise prohibited.

b) Any treatise or book dealing with any of the matters relating to the diseases or conditions which are otherwise prohibited to be advertised, provided they are published from a bona fide

scientific or social standing.

d) Any advertisement relating to any drug sent confidentially to a RMP.

e) Any advertisement relating to a drug printed or published by the Government, or by any person with the prior permission of the Government

f) Any advertisement, labels or sets of instructions which are permited under the Drugs and Cosmetics Act or Rules.

Offence and Penalties:— Contravention of any provision of the Act is punishable with imprisonment up to 6months or fine or both on first Conviction, and imprisonment up to 1years or fine or both on any subsequent Conviction. Any document, article or thing in respect of which the Contravention is made, can also be farfoited.

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① Sobhita.
② Sunil Kan or Gond
③ Ravi

Prevention of Cruelty to Animal Act-1960

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The Prevention of Cruelty to Animals Act, 1960 (which ~~reports~~ repeals the Act of 1890 has been enacted to prevent the infliction of unnecessary pain or suffering on animals. As recognition of the general awareness about animal welfare, the breeding of and experiment on animals (control and supervision) Rules 1998 have been recently incorporated.

Objectives:—

① To prevent the infliction of unnecessary pain or suffering on animals as well to prevent cruelty to animals.

② To promote animal welfare generally

③ To protect animals from unnessary pain and suffering by chairman, vice chairman, secretary and other members.

④ To Provide guideline for-housing, care breeding and maintenance source of experimental animals and acceptable experimental procedures for anaesthesia and euthanasia.

⑤ The goal of these guidelines is to promote the human care of animals use in biomedical and behavioral research & testing.

Definitions

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Experiment :- Experiment means any programme/project involving use of an animal / animals for the acquisition of knowledge of a biological, psychological, ethological, physical or chemical nature and includes the use of animals in the production of reagents and products such as antigens and antibodies, routine diagnostics, testing activity and establishment of transgenic stocks, for the purpose of saving or prolonging life or alleviating suffering or for combating any disease whether on human beings or animals.

Institutional Animals Ethics Committee :- Institutional Animals Ethics Committee means a body comprising of a group of person recognised 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.

Institutional Animals Ethics (IAE) Committee

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Objective:— To Contribute to effective functioning of Institutional Animal Ethics Committee (IAEC)

⇒ Experiment shall be performed in every case by or under the supervision of a person duly qualified.

⇒ Experiment should performed with due care and humanity.

⇒ Committee was prescribed by the CPCSEA under PCA Act (Prevention of Cruelty to Animal Act) 1960 and Breeding and Experimentation Rules 1998.

every Institutional Animals 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-scientific ~~society~~ socially aware member

vii] A representative as nominee of the Committee.

viii] A specialist may be co-opted while reviewing special projects using hazardous agents such as radioactive substances and deadly microorganisms.

Breeding and Stocking of Animals:— Animal breeding is a branch of animal science that addresses the evaluation of the genetic value of livestock.

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Selecting for breeding animals with superior EBV in growth rate, egg, meat, milk, or wool production, or with other desirable traits has revolutionized livestock production throughout the entire world.

The scientific theory of animals breeding incorporates population genetics, quantitative genetics, statistics and recently molecular genetics, ~~statistics and is based on the pioneering work of sewell~~.

Animal breeding is the process of selective mating of animals with desirable genetic traits to maintain or enhance these traits in future generation.

⇒ Only registered establishment can carry on the business of breeding of animals or trade of animals for the purpose of experiment, every breeder establishment carrying on the business of breeding animals or trade of animals for the purpose of experiments shall apply for registration with in sixty days from the date of commencement of the breeding of and Experiment on Animals.

Performance of Experiments:— Performing experiments on Animals for the purpose of advancement by new discovery of knowledge, which will be useful for saving or prolonging life or alleviating suffering or for combating any disease in human beings, animals or plants, is lawful.

The experiment shall neither be performed for the purpose of attaining or retaining manual skill except in schools, colleges and recognised training institutions, nor by way of an illustration or as a public demonstration.

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Transfer and Acquisition of Animals for Experiment:—

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Transfer of any animal by way of sale or otherwise by a breeder to an unregistered establishment is not permitted. A breeder shall not acquire any animal by sale or otherwise except from a registered breeder.

⇒ Potential vendors should be evaluated for the quality of animals to be supplied by them. A registered veterinarian should properly evaluate animals to be used in research.

⇒ All animals must be acquired lawfully and the receiving institution should make reasonable attempts to ensure that all transactions involving animal procurement are conducted in a lawful manner.

⇒ Animals not bred in a research facility are to be acquired lawfully as per the prevailing laws. A health certificate should be obtained from a registered veterinarian.

⇒ Researchers should make every effort to ensure that those responsible for transporting the animals to the facility provide adequate food, water, ventilation, space and impose no unnecessary stress on the animals.

~~Power to suspend or revoke registration:—~~

Records:— Every establishment / Institutional Animals Ethics Committee shall maintain a record of the animals under its control and custody and furnish such information as the Committee may from time to time require, in the specific format. All laboratories shall inform the exact number / species of animals to the secretary or any other officer authorised in this regard by the Committee as per the specific format.

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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 / Institutional Animals Ethics Committee, the Committee may, after giving reasonable opportunity of being heard in the matter, revoke the same either for a specified period or indefinitely or may allow the Institutional Animals Ethics Committee to carry on subject to such special condition as the Committee may impose.

NK Jain - Page No- 305

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Penalties:— Contravention of any order made by or committing of any condition imposed by the Committee is punishable with fine extending to Rs. 200, when the contravention or breach of condition takes place in any institution, the person in charge of the institution shall be guilty of the offence and shall be punishable accordingly.

National Pharmaceutical Pricing Authority

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The National Pharmaceutical Pricing Authority is a government regulatory agency that controls the prices of Pharmaceutical drugs in India.

The National Pharmaceutical Pricing Authority (NPPA) was constituted vide Government of India resolution dated 29th August 1997 as an ~~independent regular for pricing of drugs and to ensure~~ attached office of the Department of Pharmaceuticals.

Functions of National Pharmaceutical Pricing Authority:—

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⇒ To implement and enforce the provisions of the Drugs (Prices Control) order.

⇒ To deal with all legal matters arising out of the decisions of the Authority.

⇒ To undertake or sponsor relevant studies in respect of pricing of Pharmaceuticals.

⇒ To render advice to the Central Government on changes in the drug policy.

⇒ To render assistance to the Central Government in the parliamentary matters relating to the drug pricing.

Sale prices of bulk drugs:— In Control of sale prices of bulk drugs and formulations, No Person shall sell any bulk drug or formulation to any consumer at a price exceeding the price specified in the current price list or price indicated on the label of the container or pack thereoff whichever is less, plus all local taxes if any payable.

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Retail price of formulations:—