PHARMACEUTICAL JURISPRUDENCE

UNIT 4 NOTES

- DRUGS & MAGIC REMEDIES ACT
- PREVENTION OF CRUELTY TO ANIMAL ACT
- NATIONAL PHARMACEUTICAL PRICING AUTHORITY

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Study Of Salient Features Of Drugs And Remedies Act And It's Rules

Introduction

- The drugs & Magic Remedies Act was enacted in 1954 to manage and prevent these problems.
- In India, ads promoting magic solutions like Kavachas, Mantras & Talismans as healing methods for incurable illness.
- The act started on April 1, 1955 and was put into action in 1963
- The act, known as the objectionable Advertisement Act, applies to all of India except Jammu & Kashmir.

Objectives

- To ban specific types of ads about magic cures that make false statements & can mislead people.
- To manage certain drug adjustments that may confuse the public.

DEFINITIONS

① ADVERTISEMENTS

It includes all notices, labels, circulas, wrappers, documents & verbal or visual announcements.

② DRUGS

A substance used to diagnose, treat or prevent diseases in humans or animals, excluding food.

③ MAGIC REMEDIES

It includes talismans, mantras, kavachas & charms believed to have magical powers for diagnosing, treating or preventing diseases in humans or animals.

PROHIBITION OF CERTAIN ADVERTISEMENTS

The Act bans following types of Advertisements :

- **ADVERTISEMENT OF DRUGS**
  - For preventing pregnancy or dealing with miscarriage in women.
  - To address menstrual issues in woman.
  - To enhance human sexual pleasure / activity.
  - The identification, healing, reduction, management or avoidance of any condition in Schedule J.

- Mispresents the drug's true nature, making false or deceptive claims.
- Ads for magical rules, cures claims to work in any situation, created by sellers of these remedies.

Classes Of Exempted Advertisements

The categories of Adverstisments have been taken out of the rules in this ACT including:

Advertisements	Conditions
Drug packaging without inserts or ads in medical & scientific magzines.	Advertisements includes only essential information for registered medical pratictioners on: Uses of medication for treatment. side effects of drugs. Safety measures of medication use. Guidelines for using & dosing the medication.
Advertisements of drugs in medical pharmaceutical, scientific & technical journals.	The Advertiser must prove that drug advertisement claim is not false or not misleading.
Price list or therapeutic indexes from licensed drug manufactures or distributors.	The adverstisements offer essential information for RMP on drug uses, dosage, administration, side effects & treatment precautions. The advertiser must prove that any claim is the advertisement is true & not misleading.

ADVERTISEMENT	CONDITIONS
Medical literature provided by health-care professionals or drug distributors.	This literature is distributed drug only to RMP, hospitals, dispanceries, medical institutions, & licensed pharmacies.

OFFENCES AND PENALTIES

- If any part of the Act & Rules is violated then the first offence may result in upto six month in prison or fine, while the second offence can lead to upto one year prison or a fine.

Prevention Of Cruelty To Animals Act - 1960

Introduction

- The prevention of Cruelty to Animals Act of 1960 replaced the 1890 Act.
- It covers of Indian except for the state Jammu & Kashmir.

Definitions

- **Animal** Any living creature other than a human being.
- **Board** The Animal Welfare Board was created under section 4 of the Act.
- **Breeder** An indivisual or organization that rises animals for research Facilities.
- **Committee** The committee under section 15 of the Act oversees animal management.
- **Establishment** Any person, bussiness or organization, excluding schools, upto higher secondary level, that conducts animal experiments.
- **Experiments** A program that conducts animal experiments to gain knowledge about physiology to save or extend life or combat disease.
- **Contract Research** Contract research done by a person, bussiness or organization for a Foriegn person or entity.

- **Collaborative Research** Collaboration begins b/w research institutions on equal items, aimed to advance scientific research for humanity's benefit.

- **Institutional Animal Ethics Committee** A body is group of people registered with the committee for Animal control, operating in a Facility run according to the Committees procedures.

Institutional Animal Ethics Committee

- IAEC is a committee of indivisuals registered with the CPSCEA, with the expert consultant in Chennai & the member Secretary for Animal Welfare in New Delhi, under the Ministry of Environment & Forests.

The IAEC Constitution at the NIB includes 8 Members:

- The leader of the group
- Two researchers from different fields of biology
- A researcher from an external institute
- A socially consicious non-scientist member
- A representative from CPSCEA
- A scientist responsible for the animal facility at establishment.
- A Veterinarism for animal matters.
- An addition in-house scientist (either a microbiologist or pathologist).

CPCSEA Guidelines For Bredding And Stocking Of Animals

- Apply for registration within 60 days from the date of commecement of breeding & experiments on animals & breeding should be stopped if the committee refuses registration.
- When registration within 60 days is denied, cease all breeding activities.
- The application must be submitted in the required format to the committee's member secratory.
- The Government of India has formed a committee under the Ministry of Social Justice & Empowement to oversee animal experiments & register breeders.
- The committee's secratory requested details on experiment locations, animal housing, breeding, trade, infrastructure, staff availability & registration verification.
- The committee or authorized personnel can review the register & act if improvements are lacking.
- The breeder & the establishment must stock the animals in a specific way.
- Animal shelters should be located in calm, clean & safe areas, away from traffic & extreme weather.
- Animal cages & stables for large animals should be designed for comfort to avoid overcrowding.
- The registered breeder must adhere to the committees guidelines for housing, feeding & caring for various research species.
- The Indian Standards Institution (ISI) has set standards for cages & stables, requiring staff to be trained & experienced in animal care.

PERFORMANCE OF EXPERIMENTS

- Animal experiments are acceptable when they help, save or extend life or combat diseases in humans, animals or plants.
- Experiments should only occur in schools, colleges & approved training centers, not for skill retention or public demonstrations.
- When experiments are conducted at any institution, the person in-charge is held responsible.
- Test conducted with guidance from a trained professional.
- A qualified indivisual must have a degree or diploma in veterinary science, veterinary medicine or Laboratory animal science.
- Experiments should be conducted with care & respect.
- Animals should not endure unneccessary pain or suffering in experiments.
- Major surgeries must be performed in an anaesthetic setting by a qualified indivisual to prevent animal pain.
- If an animal is severaly injured & recovery would cause pain, it's humanely euthanized after anaesthesia.

TRANSFER AND AQUISITION OF ANIMALS FOR EXPERIMENTS

- Selling or transefering an animal to an unregisered place is illegal under this law.
- Also, once an establishment buys an animal, it can't sell it to another unregistered breeder or place.
- Breeders or Organizations must provide animals from breeding experiments for domestic use.
- The breeder or organizations must follow the committees rules for overseeing & animal experiments.
- Breeder or organizations can't bring in animals already in the country.

RECORDS

- Each establishments must maintain records of managed animals & provide this information in the required format upon the Committee's request.
- All labs must report the number & species of animals to the secratory or authorized committee officer in the required format.

POWER TO SUSPEND OR REVOKE REGISTRATION

- The committee will take action if it finds any establishment, breeder or IAEC is not following its rules.
- The committee can temporarily or permanently suspend or cancel registration after allowing the involved party to present their case.
- It may allow the establishment, breeder or IAEC to continue if they meet committee's special conditions.

OFFENCES AND PENALTIES

- A person is accountable for an offense under this Act if they :
  - Trains any unregistered animal.
  - Shows or trains any animal that he/she is not registered for.
  - No person or officer may enter the experiment location.
  - Conceals any animal to escape examination.
  - Despite being registered under this Act, it wouldn't issue the certificate without a valid person.
  - Seeks registration under this Act despite ineligibility.
  - If a person found to lie or to be guilty in any of these offences, he/she is punished with fine of ₹ 500 or is imprisoned for 3 months or both.

National Pharmaceutical Pricing Authority - DPCO

Introduction

- Drug Price Control Orders (DPCO) are issued by the Goverment under Section 3 of the essential Commodities Act, 1955.
- Drugs are essential & should be available at fair prices. The latest DPCO 2013 was released on May 15, 2013.

Drug Price Control Order (DPCO - 2013)

- The latest DPCO - 2013 was issued on May 15, 2013 by the ministry of Chemicals & Fertilizers, Following the National Pharmaceutical Pricing Authority policy of 2012.
- The NPPA was released on December 7, 2012, to regulate medicine prices in the National List of Essential Medicines - 2011 by the Ministry of Health and Family Welfare.
- The National Pharmaceutical Pricing Authority (NPPA) regulates drug prices with goverment authority under the Essential Commodities Act.

Objectives

- Ensure all essential medicines are available at a fair price.
- To ensure that drug quality remains high even with price controls.
- To encourage the smart & affordable use of prescribed medications.

DEFINITIONS

- **CEILING PRICE** A price set by the Government for scheduled formulations.
- **DISTRIBUTOR** A distributor or stockiest selected by a manufacturer or importer to sell their drugs to a dealer.
- **BULK DRUG** A pharmaceutical, chemical, biological or plant product, including its derivating, that complies with the second schedule of the D & C Acts 1940, and is used alone or in formulations.
- **DEALER** A person involved in buying or selling drugs, whether as a whole saler or retailer, including their agent.
- **FREE RESERVE** A reserve from profit allocation, excluding those for liabilities, treat, relieve or prevent diseases in humans & animals.
- **FORMULATION** A medicine containing APIs, used to diagnose, treat, relieve, or prevent diseases in humans or animals.
- **BRAND** A brand is a name, term, design, symbol or trademark that distinguishes one sellers drug from others.
- **PRICE LIST** The price list mentioned in paragraphs 24 & 25 also includes an additional price list.
- **WHOLESALER PRICE INDEX** The wholesale price index is an annual measure of wholesale price for all goods, released periodically by India's Department of Industrial Policy and Promotion.
- **RETAILER** A seller who runs a retail shop selling drugs to customers.
- **WHOLESALER** A dealer agent, stockiest selected by a manufacturer or importer sell drugs to retailers, hospitals & institutions that purchase in bulks.

SALE PRICE OF BULK DRUGS

- The Government can set a maximum price for drugs in the First schedule, prohibiting sales above this price, including local taxes.
- Manufactures starting drug production in the First sechedule must complete form I within 15 days.
- Manufactures must use form I to apply to the government to change the maximum sale price of a bulk drug.
- The goverment will set a new bulk drug price within 4 months of recieving all required information.
- A list of scheduled & non-scheduled bulk drugs & their costs will be provided within 30 days & by Semptember 30 each year.
- The government can set or change the price of any non-scheduled bulk drug for the public good.
- The manufacturer or importer must cell the drug at the set price within 15 days of recieving the orders.

RETAIL PRICES OF FORMULATIONS

- Use this formula to find the retail price of a formulation –

$$RP = MC + CC + PM + PC = (1 + MAPE/100) + ED$$

Where, RP = Retail Price
MC = Material Cost
CC = Conversion Cost
PM = Cost of Packeging Material
PC = Packaging Charges
MAPE = Maximum Allowing Post Manufacturing Expenses
ED = Excise Duty

RETAIL PRICING AND CEILING PRICE OF SCHEDULE FORMULATIONS

- The Government sets or updates the bulk drug price, which manufacturers use in their formulations.
- He must submit Form-III to the government within 30 days to request a review of the price for all formulations.
- The Government will set or adjust the price upon recieving a status with a satisfaction of application.
- A manufacturer must submit form III or IV to the government to change a formulation's retail price.
- The government should review the applicaction & within 2 months, set a new price or reject it if the records are unsatisfactory.
- Bulk drugs prices should remain at their previous level until the Gov. set a fixed price.
- The drug maker should not change more than the Pre-order price.
- No manufacturer or importer can sell a new scheduled product without prior government price approval.

CEILING PRICE OF SCHEDULE FORMULATION

The celing price for a scheduled formulation with specific strength & dosage can be determined as follows:

① **STEP-I** The typical cost to share the retailer for the planned formulation [PCs] is determined in the way -

Average price to Retailer [Pcs] = (Total prices of brands & generics with ≥ 1% market shares) / (count of those brands & generics).

② **STEP-2** The maximum price for the planned formulation [PCs] can be determined

$$P(c) = P(s) \cdot (1 + M/100)$$

Where, P(s) = The typical cost to the retailer for the same strength & dosage of medicine.

M = Retailer's margin percentage & it's value equals 16.

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