# Clinical Trial Regulations in India

## The Drugs And Cosmetics Act And Rules


Module 5 Topic 3_2

# Drug and Cosmetic (D&C) Act

- **History:**
  - Government of India Ministry of Health and Family Welfare introduced the drugs and cosmetics act (1940) and rules (1945)
  - Originally act was passed in 1940 and was known as the Drug Act
  - The original act was prepared in accordance to the recommendations of the Chopra Committee formed in 1930
  - Since 1940, the act has been amended several times and is now known as the Drugs and Cosmetics Act, 1940

# D&C Act: Objectives

**Objective:**

- To regulate the
  - IMPORT
  - MANUFACTURE
  - DISTRIBUTION
  - SALE

  of drugs and cosmetics

# D&C Act: Objectives (contd)

- To regulate the import of drugs in India, to prevent substandard or spurious drug entry in India
- To prohibits the manufacturing of substandard or spurious drug in the country
- To control the sale & distribution of drugs by only trained & qualified persons
- To control the manufacturing, sale & distribution of Ayurvedic, Siddha, Unani & Homeopathic drugs
- To regulates the import, manufacture, sale & distribution of cosmetics
- To have regular inspection of licensed premises by drug inspectors

# D&C Act: Objectives (contd)

- To have control over the standards of drugs & cosmetics by taking samples & analyzing them at approved laboratories
- To provide special provisions to regulate the preparation, standardization & storage of biological & special products
- To prescribe the manner of labeling & packing of the various classes of drugs & cosmetics

# D&C Act: Definitions

**Drug**

- All medicines for internal or external use of human beings or animals and all substances intended to be used for or in the diagnosis, treatment, mitigation or prevention of any disease or disorder in human beings or animals, including preparations applied on human body for the purpose of repelling insects like mosquitoes
- Such substances (other than food) intended to affect the structure or any function of human body or intended to be used for the destruction of (vermin) or insects which cause disease in human beings or animal

# D&C Act: Definitions

**Drug (contd)**

- All substances intended for use as components of a drug including empty gelatin capsules
- Such devices intended for internal or external use in the diagnosis, treatment, mitigation or prevention of disease or disorder in human beings or animals

# D & C Act: Definitions

**Cosmetics**

- Cosmetic means any article intended to be rubbed, poured, sprinkled or sprayed on, or introduced into, or otherwise applied to, the human body or any part thereof for cleansing, beautifying, promoting attractiveness, or altering the appearance, and includes any article intended for use as a component of cosmetic

# D & C Act: Definitions

**Ayurvedic, Siddha, or Unani drug**

- Includes all medicines intended for internal or external use for or in the diagnosis, treatment, mitigation or prevention of disease or disorder in human beings or animals, and manufactured exclusively in accordance with the formulae described in, the authoritative books of Ayurvedic, Siddha and Unani systems of medicine, specified in the First Schedule

# D&C Act: Definitions

**Standards of quality**

- Standards of quality in relation to a drug means that the drug complies with the standard set out in the Second Schedule and in relation to a cosmetic that the cosmetic complies with such standards as may be prescribed

# D&C Act: Definitions

**Misbranded drugs**

- A drug shall be deemed to be misbranded
  - If it is so coloured, coated, powdered or polished that damage is concealed or if it is made to appear of better or greater therapeutic value than it really is; **or**
  - If it is not labelled in the prescribed manner; **or**
  - If its label or container or anything accompanying the drug bears any statement, design or device which makes any false claim for the drug or which is false or misleading in any particular

# D&C Act: Definitions

**Adulterated drugs**

- A drug shall be deemed to be adulterated
- If it consists, in whole or in part, of any filthy, putrid or decomposed substance; or
- If it has been prepared, packed or stored under insanitary conditions whereby it may have been contaminated with filth or whereby it may have been rendered injurious to health; or
- If its container is composed in whole or in part, of any poisonous or deleterious substance which may render the contents injurious to health; or

# D&C Act: Chapters

D&C act is divided in following 5 major chapters

| | |
|---|---|
| I | • Introductory |
| II | • The Drugs Technical Advisory Board (DTAB),<br>• The Central Drugs Laboratory (CDL) &<br>• The Drugs Consultative Committee (DCC) |
| III | • Import of Drugs and Cosmetics |
| IV | • Manufacture, sale and distribution of Drugs and Cosmetics<br>• Provisions Relating to Ayurvedic Siddha And Unani Drugs |
| V | • Miscellaneous |

# D&C Act: Schedule

## Schedule A

- Contains number of forms for various purposes

## Schedule B

- Fees for test or analysis by the Central Drugs Laboratories or State Drugs Laboratories requiring use of animals

## Schedule C

- Biological and Special Products Sera. Solution of serum proteins intended for injection

## Schedule D

- Class of drugs Extent and conditions of exemption Substances not intended for medicinal use

# D&C Act: Schedule (contd)

**Schedule E**

- List of poisonous substances under the Ayurvedic (including Siddha) and Unani Systems of Medicine

**Schedule F**

- Requirements for the functioning and operation of a blood bank and / or for preparation of blood components

**Schedule G**

- Details the drugs to be labeled with the words “Caution”

**Schedule H**

- Prescription drugs

# D&C Act: Schedule (contd)

## Schedule I

- Omitted

## Schedule J

- Diseases and ailments (by whatever name described) which a drug may not purport to prevent or cure or make claims to prevent or cure

## Schedule K

- Class of Drugs is not sold for medicinal use or for use in the manufacture of medicines and that each container is labeled conspicuously with the words “NOT FOR MEDICINAL USE”

## Schedule L

- Omitted

# D&C Act: Schedule (contd)

**Schedule M**

- Good manufacturing practices (GMP) and requirements of premises, plant and equipment for pharmaceutical products

**Schedule N**

- List of minimum equipment for the efficient running of a pharmacy

**Schedule O**

- Standard for disinfectant fluids

**Schedule P**

- Life period of drugs

# D&C Act: Schedule (contd)

**Schedule Q**

- List of Dyes, colours and Pigments permitted to be used in Cosmetics and Soaps

**Schedule R**

- Standards for condoms made of rubber latex intended for single use and other mechanical contraceptives

**Schedule S**

- Standards for cosmetics

**Schedule T**

- Good manufacturing practices for Ayurvedic, Siddha and Unani medicines

# D&C Act: Schedule (contd)

**Schedule U**

- Particulars to be shown in manufacturing records

**Schedule V**

- Patent or proprietary medicines

**Schedule W**

- Gives the names of the drugs which shall be marketed under generic names only

**Schedule X**

- Gives the names of psychotropic drugs requiring special licenses for manufacture and sale

**Schedule Y**

- Requirement and guidelines on clinical trials of import and/ or manufacture of new drug