Drug & Cosmetic, 1940 and its Rules 1945

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Objective

- The D&C Act was passed in 1940 (10th April 1940), with the main object to-
- Import,
- Manufacture,
- Distribution &
- Sale of drug & cosmetics.

The act regulates the import of drugs in India, so that no substandard or spurious drug will enter into our country.

The act prohibits the manufacture of substandard or spurious drug in the country.

The act provide for the control over the sale & distribution of drugs by only trained & qualified persons.

The act also provide for the control over the manufacture, sale & distribution of Ayurvedic, Siddha, Unani & Homeopathic drugs.

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- To regulate the import, manufacture, distribution and sale of drugs & cosmetics through licensing.
- Manufacture, distribution and sale of drugs and cosmetics by qualified persons only.
- To prevent substandard in drugs, presumably for maintaining high standards of medical treatment. • To regulate the manufacture and sale of Ayurvedic, Siddha and Unani drugs.
- To establish Drugs Technical Advisory Board(DTAB) and Drugs Consultative Committees(DCC) for Allopathic and allied drugs and cosmetics.

Salient features

The salient features of the Drugs & Cosmetics Act, 1940 are as follows:

- a) Maximum penalty life imprisonment and fine of Rs. 10 lakhs or 3 times the value of the confiscated goods, whichever is more.
- b) Some of the offences cognizable and non-bailable. c) Besides officers from the Drug Controller's Office, other gazette officers also authorized to launch prosecution under the Act;
- d) Specially designated courts for trial of offences covered under the Act;
- e) Provision for compounding of minor offences

Definitions

- **Drugs** : 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.
- **Cosmetic** : Any article intended to be rubbed, poured, sprinkled or sprayed on, 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.

Misbranded drugs :

- if it is so coloured, coated, powdered or polished that damage is concealed.
- 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.

Adulterated drug :

- 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.

Spurious drugs :

- if it is imported under a name which belongs to another drug; or
- if it is an imitation of, or a substitute for, another drug or resembles another drug in a manner likely to deceive or bears upon it or upon its label or container the name of another drug. or
- if it has been substituted wholly or in part by another drug or substance

Manufacture

In relation to any drug or cosmetic, it includes any process or part of a process for making, altering, ornamenting, finishing, packing, labeling, breaking up or otherwise treating or adopting any drug or cosmetic with a view to its sale or distribution but does not include the compounding or dispensing of any drug.

Patent or Proprietary medicine :

A drug which is a remedy or prescription presented in a form ready for internal or external administration of human beings or animals and which is not included in the edition of the Indian Pharmacopoeia for the time being or any other Pharmacopoeia authorized in this behalf by the Central Government.

Administration of the act and rules:

A) Advisory : 1)Drugs Technical Advisory Board-DTAB

2)Drugs Consultative Committee-D.C.C.

B) Analytical :

1)Central Drugs Laboratory - CDL

2)Drug Control Laboratory in states 3)Government Analysts

C) Executives :

1)Licensing authorities

2)Controlling authorities

3)Drug Inspectors

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Drugs Technical Advisory Board(DTAB) Ex-Officio:

(i) Director General of Health Services (Chairman)

(ii) Drugs Controller, India

(iii)Director of the Central Drugs Laboratory, Calcutta

(iv) Director of the Central Research Institute, Kasauli

(v)Director of Indian Veterinary Research Institute, Izatnagar

(vi) President of Medical Council of India

(vii) President of the Pharmacy Council of India

(viii)Director of Central Drug Research Institute, Lucknow

Certain provisions of the act regulates the import, manufacture, sale & distribution of cosmetics.

- To have regular inspection of licensed premises by drug inspectors.
- 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.

COSMETIC

COSMETIC" means any article intended to be rubbed, poured, sprinkled or sprayed on, or introduced into, or otherwise applicated 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.

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 animals, as may be specified from time to time by the Central Government by notification in the Official Gazette .
- All substances intended for use as components of a drug including empty gelatin capsules;

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- Such devices intended for internal or external use in the diagnosis, treatment, mitigation or prevention of disease or disorder in human beings or animals, as may be specified from time to time by the Central Government by notification in the Official Gazette, after consultation with the Board Misbranded drugs :
- (a) if it is so colored, 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
- (b) if it is not labeled in the prescribed manner; or
- (c) 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.

Inspectors.

(1) The Central Government or a State Government may, by notification in the Official Gazette, appoint such person as it thinks fit, having the prescribed qualification, to be Inspectors for such areas as may be assigned to them by the Central Government or State Government, as the case may be.

(2) The powers which may be exercised by an Inspector and the duties which may be performed by him, the drugs or [classes of drugs or cosmetics or classes of cosmetics] in relation to which and the conditions, limitations or restrictions subject to which, such powers and duties may be exercised or performed shall be such as may be prescribed.

(3) No person who has any financial interest [in the import, manufacture or sale of drugs or cosmetics] shall be appointed to be an Inspector under this section.

(4) Every Inspector shall be deemed to be public servant within the meaning of section 21 of the Indian Penal Code (45 of 1860), and shall be officially subordinate to such authority [having the prescribed qualification] as the Government appointing him may specify in this behalf.

THANK YOU