

Drugs and Cosmetics Act 1940 and Rules 1945

EBC's Bare Act

DRUGS AND COSMETICS ACT, 1940

along with

DRUGS AND COSMETICS RULES, 1945

together with

**State Amendments
Subject and Product Index**



Third Edition

CONTENTS

- *Administration of the act and rules*
- *Provisions related to Import*

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

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

DRUGS TECHNICAL ADVISORY BOARD (DTAB)

Nominated:

- 1) Two persons by the Central Government from among persons who are in charge of drugs control in the **States**
- 2) One person by the Central Government from the **pharmaceutical industry**
- 3) Two persons holding the appointment of **Government Analyst** under this Act, to be nominated by the Central Government

DRUGS TECHNICAL ADVISORY BOARD (DTAB)

Elected:

- 1) one person, to be elected by the Executive Committee of the **Pharmacy Council of India**, from among **teachers** in pharmacy or pharmaceutical chemistry or pharmacognosy on the staff of an Indian university or a college affiliated thereto;
- 2) one person, to be elected by the Executive Committee of the **Medical Council of India**, from among **teachers** in medicine or therapeutics on the staff of an Indian university or a college affiliated thereto;
- 3) one **pharmacologist** to be elected by the Governing Body of the Indian Council of Medical Research;
- 4) one person to be elected by the Central Council of the **Indian Medical Association**;
- 5) one person to be elected by the Council of the **Indian Pharmaceutical Association**;

DRUGS TECHNICAL ADVISORY BOARD (DTAB)

Functions:

To **advise** the Central Government and the State Governments on technical matters arising out of the administration of this Act.

To carry out the other functions assigned to it by this Act.

(The nominated and elected members of the Board shall **hold office for three years**, but shall be eligible for re-nomination and re-election)

DRUGS CONSULTATIVE COMMITTEE(DCC)

- It is also an **advisory body** constituted by central government.

- Constitution:

Two representatives of the **Central Government**

One representative of each **State Government**

DRUGS CONSULTATIVE COMMITTEE(DCC)

Functions:

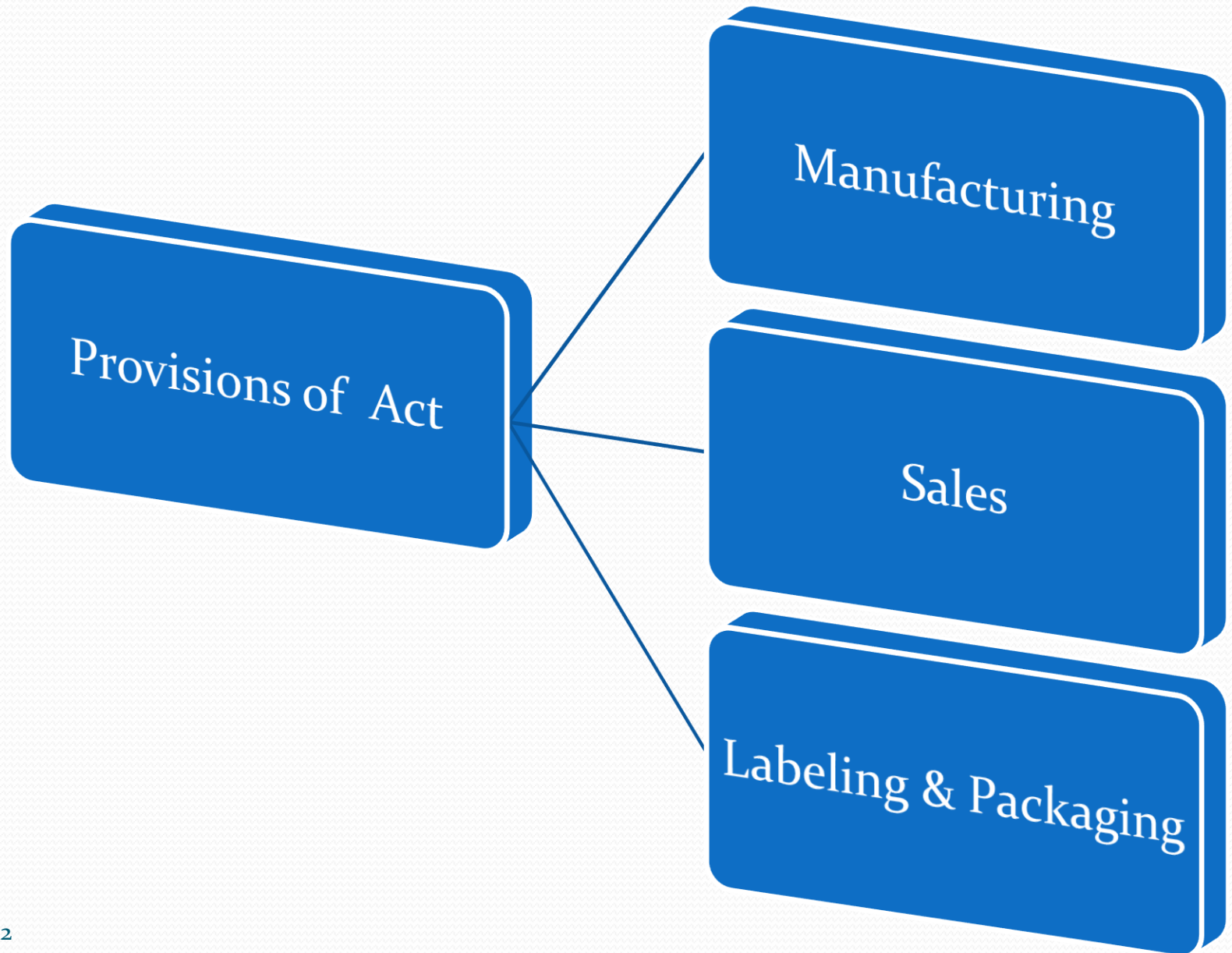
- To advise the Central Government, the State Governments and the Drugs Technical Advisory Board on any other matter tending to secure **uniformity throughout India** in the administration of this Act.
- The Drugs Consultative Committee shall **meet when required**
- Has power to regulate its own procedure.

CENTRAL DRUG LABORATORY(CDL)

- Established in **Calcutta**, under the control of a director appointed by the Central Government

Functions:

- **Analysis or test** of samples of drugs/cosmetics sent by the custom collectors or courts.
- Analytical **Q.C.** of the imported samples.
- Collection, storage and distribution of **internal standards**.
- Preparation of **reference standards** and their maintenance.
- Maintenance of **microbial cultures**.
- **Any other duties** entrusted by Central Government.
- Acting as an **appellate authority** in matter of disputes.



IMPORT



IMPORT OF DRUGS

- *Classes of drugs prohibited to import*
- *Import of drug under license*
 - 1) Specified in Schedule-C/C₁
 - 2) Specified in Schedule-X
 - 3) Imported for Test/Analysis
 - 4) Imported for personal use
 - 5) Any new drugs
- *Drugs exempted from provisions of import*
- *Offences and Penalties*

CLASSES OF DRUGS PROHIBITED TO IMPORT

- **Misbranded** drugs
- Drugs of **substandard quality**
- Drugs claiming to cure diseases specified in **Sch-J**
- **Adulterated** drugs
- **Spurious** drugs
- Drugs whose manufacture, sale/distribution are **prohibited in original country**, except for the purpose of test, examination and analysis.
- **Patent/Proprietary** medicines whose true formula is not disclosed.

CLASSES OF DRUGS PROHIBITED TO IMPORT

- Drugs not **labelled/packed** in prescribed manner.
- Drugs of biological products(C/C₁) **after the date of expiry**
- Drugs not claiming therapeutic values.
- Drugs which is **risky** to human beings or animals.
- Any **new drug** except with express permission of Lic.authority.

IMPORT OF THE BIOLOGICAL DRUGS(C/C₁)

Conditions to be fulfilled:

- Licensee must have adequate **facility for the storage**.
- Licensee must maintain a **record of the sale**, showing the particulars of the names of drugs and of the persons to whom they have been sold.
- Licensee must **allow an inspector to inspect** premises and to check the records.
- Licensee must **furnish the sample** to the authority.
- Licensee must not sell drugs from which sample is withdrawn and he is advised **not to sale, and recall the batch** from the market.

IMPORT OF THE **SCHEDULE-X** DRUGS (NARCOTIC & PSYCHOTROPIC DRUGS)

Conditions to be fulfilled:

- Licensee must have adequate **storage facility**.
- Applicant must be **reputable** in the occupation, trade or business.
- The license **granted ever** before should **not be suspended or cancelled**.
- The licensee has **not been convicted any offence** under the Drugs and Cosmetics Act or Narcotic and Psychotropic Substances Act.

DRUGS IMPORTED FOR EXAMINATION, TEST OR ANALYSIS

Conditions to be fulfilled:

- License is necessary under form-11
- Must use imported drugs **only for said purpose** and at the place specified in the license.
- Must keep the **record** with respect to quantities, name of the manufacturer and date of import.
- Must **allow an inspector** to inspect the premises and check the records.



DRUGS IMPORTED FOR PERSONAL USE

Conditions to be fulfilled:

- **Up to 100 average doses** may be imported **without any permit**, provided it is part of passenger's luggage.
- More than 100 doses imported with license. Apply on form no.-12-A,12-B
- Drugs must be **bonafide personal use**.
- Drugs must be **declared** to the custom collectors if so directed.

IMPORT OF DRUGS WITHOUT LICENSE

- Substances **not used for medicinal pupose**
- Drugs in Sch-C₁ required for manufacturing and not for medicinal use.
- Substances which are **both drugs and foods** such as:

Condensed/Powdered Milk

Malt

Lactose

Farex/Cereal

Oats

- Predigested foods
- Ginger, Pepper, Cumin, Cinnamon



PENALTIES RELATED TO IMPORT

OFFENCES	PENALTIES
Import of spurious OR adulterated drug OR drug which involves risk to human beings or animals OR drug not having therapeutic values	a) 3 years imprisonment and 5000 Rs. fine on first conviction b) 5 years imprisonment OR 1000 Rs. fine OR both for subsequent conviction
Contravention of the provision	a) 6 months imprisonment OR 500 Rs. fine OR both for first conviction b) 1 year imprisonment OR 1000 Rs. fine for subsequent offence

IMPORT OF COSMETICS

Cosmetics prohibited to import:

- **Misbranded** cosmetics
- **Spurious** cosmetics
- Cosmetic containing **harmful** ingredients
- Cosmetics **not of standard quality**
- which contains more than-2 ppm **Arsenic**, 20 ppm **lead**, 100 ppm **heavy metals**

CONT....

- Cosmetics meant for eye and containing **coal tar dyes**
- Cosmetics coloured with lead **OR** arsenic compounds
- Cosmetics containing **Hexachlorophene OR Mercury**
- **Risky** to user

References

- Available on www.cdsco.nic.in
- “Pharmaceutical Jurisprudence” by Dr.G.K.Jani; Atul prakashan; Fifth edition(2005-06); 28-133.
- Forensic Pharmacy by C.K. Kokate and S.B. Gokhle; Published by Pharma Book Syndicate; 152.

THANK YOU