

# 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

# IMPORT OF DRUGS



# IMPORT OF DRUGS

- Classes of drugs prohibited to import
- Import of drug under license
  - 1) Specified in Schedule-C/C<sub>1</sub>
  - 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/C<sub>1</sub>) *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/C<sub>1</sub>)

## 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- Licensee must not sell drugs from which sample is withdrawn and he is advised *not to sale, and recall the batch* from the market.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 purpose*
- Drugs in Sch-C<sub>1</sub> 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	<ul style="list-style-type: none"><li>a) 3 years imprisonment and 5000 Rs. fine on first conviction</li><li>b) 5 years imprisonment OR 1000 Rs. fine OR both for subsequent conviction</li></ul>
Contravention of the provision	<ul style="list-style-type: none"><li>a) 6 months imprisonment OR 500 Rs. fine OR both for first conviction</li><li>b) 1 year imprisonment OR 1000 Rs. fine for subsequent offence</li></ul>

# 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

THANK  
YOU