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Drug and Cosmetics Act, 1940

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ABSTRACT

The drugs and Cosmetics Act 1940 is an act of the Parliament of India that regulates the import, manufacture and distribution of drugs in India. The main objective of this law is that drugs and cosmetics sold in India are safe, effective and meet state quality standards. The relevant drugs and cosmetic regulations of 1945 include regulations for the classification of drugs according to a specific program, with instructions for storage, sale, labelling and prescription for each program. . After obtaining approval from the Governor on April 10, 1940, the Ministry of Health The Ministry of Health came into effect on April 1, 1947.

Keywords: *Drug and Cosmetics Act*

THE SALIENT FEATURES OF THE DRUG & COSMETIC ACT, 1940 ARE AS FOLLOWS:

The main characteristics of the Drug and Cosmetics Act of 1940 were the following:

• The heaviest penalties are life imprisonment and a fine of 10 or 3 times the value of the property confiscated, whichever is greater.
• In addition to the Drug Enforcement Administration officers, the public authorities of other officers may prosecute. Act
• Certain crimes are identifiable and insoluble.
• A court specially appointed to try the crimes mentioned in the law.
• Provision of gross margin for minor defaults.

THE OBJECTIVES OF DRUG AND COSMETIC ACT, 1940 ARE AS FOLLOWS

- Regulate the import, manufacture, distribution and sale of drugs and cosmetic products through licenses.
- Only qualified personnel manufactures, distributes and sells drugs and cosmetics.
- Avoid preventing poor quality medications, perhaps to maintain high levels of treatment.
- Regulate the manufacture and sale of Ayurvedic, Siddha and Unani medicines.
- Establish a Drugs Technical Advisory Board (DTAB) and a Drugs Consultative Committees (DCC) for allopathy and allopathic medicines and cosmetics.

DEFINE "DRUG"

The definition of a drug is provided by law in the following explanatory clause:

• All drugs intended for internal or external use in humans or animals, and all substances used for diagnosis, treatment or the treatment. obstacle. In the human body or animals, including formulations applied to the human body to repel insects such as mosquitoes.
• A substance (not a food) used to affect the structure or function of other substances in the human body or to destroy insects. Insects that cause disease in humans or animals.
• All substances used as ingredients in pharmaceutical products, including empty capsules.
• These devices are intended for internal or external use in the diagnosis, treatment, relief or prevention of human diseases or disorders. Or animal

DEFINE "COSMETIC"

As described withinside the Act Cosmetic consists of any article meant to be rubbed, poured, sprinkled or sprayed on, or added into, or in any other case carried out to, the human frame or any component thereof for cleansing, beautifying, selling attractiveness, or changing the appearance, and consists of any article meant to be used as a factor of cosmetic.

Drugs type

- ***Misbranded drugs:*** (a) if it's so coloured, coated, powdered or polished that harm is hid or if it's far made to seem of higher or more healing cost than it certainly is; or (b) if it isn't labelled withinside the prescribed form.
- ***Adulterated drug :*** (a) if it consists, in complete or in part, of any filthy, putrid or decomposed substance; or (b) if it's been prepared, packed or saved beneathneath insanitary situations wherein it is able to had been infected with grime or wherein it is able to had been rendered injurious to health; or (c) if its field consists in complete or in part, of any toxic or deleterious substance which might also additionally render the contents injurious to health.
- ***Spurious drugs :*** (a) if it's far imported below a call which belongs to every other drug; or (b) if it's far an imitation of, or a alternative for, every other drug or resembles every other drug in a way probable to lie to or bears upon it or upon its label or field the call of every other drug.

MANUFATURING OF DRUG AND COSMETIC:

In relation to any drug or beauty, it consists of any system or a part of a system for making, altering, ornamenting, finishing, percent king, labelling, breaking apart or in any other case treating or adopting any drug or beauty for you to its sale or distribution however does now no longer encompass the compounding or shelling out of any drug, or the packing of any drug or beauty, withinside the normal route of retail business.

DEFINE CENTRAL DRUG LABORATORY(CDL) UNDER DRUG & COSMETIC ACT

Central Drug Laboratory(CDL), Established in Calcutta, below the manage of a director appointed through the Central Government.

Functions:

- Analysis or check of samples of drugs/cosmetics despatched through the custom creditors or courts.
- Analytical Q.C. of the samples that are imported.
- Collection, garage and distribution of inner requirements.
- Preparation of reference requirements and their maintenance.
- microbial cultures maintenance.
- Any different responsibilities entrusted through Central Government.
- Acting as an appellate authority in remember of disputes.

DEFINE "LOAN LICENSE"

A person(applicant) who does now no longer have his personal arrangements(factory) for manufacture however who desire to production centers owned via way of means of every other licensee. Such licenses are referred to as Loan licenses.

LOAN LICENSES ARE ISSUED FOR

1) Drugs aside from laid out in C/C1 & X.
2) Drugs laid out in Schedule-C/C1 SJTPC 48

PROCEDURE: Licence is acquired from licensing authority on utility in prescribed forms (24-A , 27-A) with prescribed fees is (Rs. 6000, 1500).

DEFINE "REPACKAGING LICENSE"

Process of breaking apart any drug from a bulk field into small programs and labelling so as to their sale and distribution. Repackaging of medication is granted of medication aside from Schedule-C/C1 and X.

PROCEDURE:

Licence is received from licensing authority (FDA) on utility in prescribed forms (24-B) with prescribed fees (Rs. 500, 200).

CLASS OF DRUGS PROHIBITED FROM BEING SOLD:

Class of drug prohibited to sale are:

- Misbranded, spurious, adulterated and pills now no longer of widespread quality.
- Patent/Proprietary pills with undisclosed formula.
- Sch-J pills.
- Expired pills.

SHORT NOTE ON "DRUGS CONSULTATIVE COMMITTEE"(DCC):

It is likewise an advisory frame constituted with the aid of using principal government.

CONSTITUTION:

- Two representatives of the Central Government One consultant of every State Government.

FUNCTIONS:

- To propose the Central Government, the State Governments and the Drugs Technical Advisory Board on another count tending to stable uniformity in the course of India withinside the administration of this Act.
- The Drugs Consultative Committee shall meet while required
- Has strength to alter its personal procedure.

SHORT NOTE ON "GOVERNMENT ANALYST"

These officials are appointed via way of means of the vital or country authorities and carry out the duties.

Qualification of presidency analysist:
• Persons having qualification for appointment as authorities as govermental Analysis for allopathic pills.
• having a diploma in medicine, ayurved, sidha or unani machine and now no longer much less than 3 12 months publish graduate revel in withinside the evaluation of medication in a laboratory below manage of a central authority analyst.

Duties:
• The Government Analyst shall purpose to be analysed or examined such samples or pills and cosmetics as can be despatched to him via way of means of Inspectors.
• A Government Analyst shall on occasion ahead reviews to the Government giving the end result of analytical paintings and studies so that it will their publication.

SHORT NOTE ON "LICENCING AUTHORITY":

Qualification
• Graduate in Pharmacy on Pharmaceutical Chemistry or in Medicine with specialization in scientific pharmacology or microbiology from a University mounted in India through constitution.
• Experience withinside the manufacture or trying out of medication a minimal length of 5 years, Provided that the necessities as to the instructional qualification shall now no longer follow to the inspectors .

Duties
• to look at all institutions certified for the sale of medication in the location assigned to him.
• to meet himself that the situations of the licences are being observed.
• you acquire and ship for check or analysis, if vital, imported packages.
• to research any complaint.
• to keep a report of all inspections made and movement taken through him withinside the overall performance of his duties.
• to make such enquiries and inspections as can be vital to discover the sale of medication in contravention to the Act.

IMPORTING OF DRUGS AND COSMETICS:

➢ ***Drugs Imported for examination, take a look at or evaluation Conditions to be fulfilled:***
• License is essential below form-11.
• Must use imported capsules best for stated cause and on the vicinity distinctive withinside the license.
• Must hold the document with appreciate to quantities, call of the producer and date of import.
• Must permit an inspector to check out the premises and take a look at the records.

➢ ***Drugs imported for non-public use Conditions to be fulfilled:***
• Up to one hundred common doses can be imported with none permit, supplied it's far a part of passenger's luggage.
• More than one hundred doses imported with license. Apply on form no.-12-A,12-B
• Drugs ought to be bonafide non-public use.
• Drugs ought to be declared to the custom creditors in that case directed.

➢ ***Import of medicine without license:***
• Substances now no longer used for medicinal cause
• Drugs in Sch-C1 required for production and now no longer for medicinal use.
• Substances that are each capsules and meals such as: Condensed/Powdered Milk Malt Lactose Farex/Cereal Oats
• Pre-digested meals
• Ginger, Pepper, Cumin, Cinnamon

➢ ***Cosmetics prohibited to import***
• Misbranded cosmetics
• Spurious cosmetics
• Cosmetic containing dangerous ingredients
• Cosmetics now no longer of well-known quality
• which includes greater than-2 ppm Arsenic, 20 ppm lead, one hundred ppm heavy metals

PENALTY FOR OBSTRUCTING INSPECTOR:

If any man or woman wilfully impede an Inspector withinside the workout of the powers conformed upon him or refuse to provide any record, sign in or every other report while required or any report while required, he will be punishable with imprisonment (jail) up to three 12 months with fine or with both.

THE APPLICATION OF LAW RELATING TO SEA AND CUSTOMS:

The Customs Collector and different officials legal on this behalf through the Central Government can also additionally detain any imported programs which he suspects to incorporate any drug or beauty the import of that is prohibited through this Act and document such detention to the Drugs Controller, India and if determined vital can ahead any bundle or pattern to CDL for analysis.

DEFINE "REGISTRATION CERTIFICATE":

It approach a certificates issued via way of means of the License Authority for the registration of premises and pills synthetic via way of means of the producer intended for import into and use in India. An software for the difficulty of a registration certificates must be made to License Authority at the side of the records and project laid out in time table DI and DII. This certificates is legitimate for a duration of three years.

