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ABOUT US

LexForti is a free open access peer-reviewed journal, which gives insight upon broad and dynamic legal issues. The very objective of the LexForti is to provide open and free access to knowledge to everyone. LexForti is highly committed to helping law students to get their research articles published and an avenue to the aspiring students, teachers and scholars to make a contribution in the legal sphere. LexForti revolves around the firmament of legal issues; consisting of corporate law, family law, contract law, taxation, alternative dispute resolution, IP Laws, Criminal Laws and various other Civil issues.

Drugs and Cosmetics in Law

Divya Chellam. P.

DRUGS AND COSMETICS

A drug is a medicine used for the internal and external purpose of human beings, including animals, used for the purpose of diagnosis, mitigation, pleasure, disease control, also used for the purpose of repelling.

Drugs can be excluded from foods, but not safe when mixed with foods, intended to affect the function of the human body, also in the destruction of insects which cause diseases in humans. The drugs also contained varieties of remedial substances and medical implementations as a whole.

Cosmetics is applied to the human body for the purpose of cleansing, beautifying, bringing attractiveness, altering the appearance by the way of rubbing, pouring, sprinkling, spraying, etc. The Act of 1964 proclaimed to introduce Ayurvedic, Siddha and Unani drugs as cosmetics, but excluded soaps.

DRUGS AND COSMETICS ACT,1940

This Act brought in India regulates the process of import, sale, manufacture, and distribution[1] of drugs in India. This law has initiated drugs to be labeled with directions of safety use, effectiveness with quality standards, and checks. This Act provides regulations for storage, display, sale, dispensing, leveling, prescribing, etc of the drugs and cosmetics. This Act was bought forth on 25 June 1938. This Act was enacted by the Department of Health under the Ministry of Health and Family Welfare.

Features of the Act

1. To regulate drugs and cosmetics through licensing.
2. The process of manufacture, distribution, and sale of drugs and cosmetics to be done only by qualified persons.
3. To maintain the high standards in medical treatments.[2] To establish the Drugs Technical Advisory Board, Drugs Consultative Committees for Allopathic and allied drugs, and cosmetics.
4. The punishment ranges with the penalty of life imprisonment and a fine of Rs. 10 Lakhs, or 3 times the value of the confiscated goods. Some offenses can be considered cognizable and non-bailable.
5. The prosecution can be done by Drug Controller's officers, also gazette officers.
6. There are designated courts for the offences covered under this Act.

[1] Malik, Vijay (2014). Law Relating to Drugs and Cosmetics (24th ed.).
[2] Malik, Surendra (2016). Supreme Court on Narcotics and Drugs (2nd ed.).

7. **Drug Types**

1. Misbranded Drugs

   If a particular drug is not labeled, if it is colored, coated, polished, powdered, with its damage concealed, it is misbranded drugs.

2. Adulterated Drug

   If it contains filthy, decomposed, harmful, toxic substances, which is poisonous, low quality, and standard, causes harm to health, they are adulterated drugs.

3. Spurious Drugs

   It is an imitation or substitute for another drug, with a false name, tends to be spurious drugs.

Drug Inspector

A person appointed as Governmental Analysis for allopathy drugs, having a degree in Ayurveda, Siddha, Unani systems, having not less than 3 years post-graduate experience, appointed as Government analyst, chemical examiner, head of the institution appointed for this purpose.

List of Amendments and Adaptation Order

1. The Repealing and Amending Act, 1949.
2. The Adaptation of Laws Order, 1950.
3. The Part B States Act, 1951.
4. The Drugs Amendment Act, 1955.
5. The Drugs Amendment Act, 1960.
6. The Drugs Amendment Act, 1962.
7. The Drugs and Cosmetics Amendment Act, 1964.
8. The Drugs and Cosmetics Amendment Act, 1972.
9. The Drugs and Cosmetics Amendment Act, 1982.
10. The Drugs and Cosmetics Amendment Act, 1986.
11. The Drugs and Cosmetics Amendment Act, 1995.
12. The Drugs and Cosmetics Amendment Act, 2008.

Schedules to the Act

1. Schedule 1

The name of books under the Ayurvedic and Siddha system.

2. Schedule 2

The standard of the drugs imported, for sale, manufacture, distribution.

3. Schedule 3

Deals with the categories of drugs in central licensing authority to issue the license.[3]

Administration of the Act

1. Advisory

- Drugs Technical Advisory Board
- Drugs Consultative Committee.

2. Analytical

- Central Drugs Laboratory
- Drug control Laboratory in states
- Government Analyst.

3. Executives

- Licensing authorities
- Controlling authorities
- Drug Inspectors.

4. Schedule N
5. Schedule M
6. Schedule Y

Drug Control Laboratory

It analyses all the test samples of drugs, cosmetics, (Q.C. of imported samples) sent by the custom collectors or courts, which acts as an appellate authority in disputes.

It maintains microbial cultures.

Includes divisions like Pharmaceutical, Pharmacology, Pharmacognosy divisions, food division, ayurvedic division, immunology division.

Government Analyst

3 persons appointed (1- government analyst for allopathic drugs), (2- degree in medicine, Ayurveda, Siddha)

Loan License

An applicant who does not have the manufacturing unit of his own, but wish to avail the facilities owned by another licensee, gets a license, termed loan license.

Such licenses should be obtained from authorities by application forms, 24-A, 27-A, with a prescribed fee amount.

Loan licenses are mainly issued for drugs specified in schedule C/C1.

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[3] Malik, Surendra (2014). Supreme Court on DRUGS, MEDICAL LAWS AND MEDICAL NEGLIGENCE (1st ed.).

Licensing Authority

The members of the licensing authority should have 5 years experience in the manufacture of testing of goods.

Prohibition in Drug and Cosmetics

Cosmetics

1. Cosmetics containing harmful ingredients and not of standard qualities.
2. Cosmetics that contain more than 2ppm Arsenic, 20ppm lead, 100ppm heavy metals.
3. Misbranded and Spurious Cosmetics.
4. Cosmetics containing mercury, hexachlorophene compounds.

Drugs

1. Misbranded, adulterated, spurious drugs[4]
2. Patent drugs with undisclosed formula
3. Expired drugs.
4. Physician's sample.

Prohibition of Manufacture

1. Drugs of no standard quality
2. Drugs of risk to human beings
3. Preparation containing claymates
4. Drugs with no therapeutic value
5. Drugs of Schedule J.

Licenses for Drug Manufacture[5]

1. Schedule C and C1 drugs
2. Schedule X drugs
3. Loan license
4. Repacking license
5. Drugs for examination, analysis, test.[6]

Import of Drugs Under License

1. Schedule C/C1
2. Schedule X
3. Import for test

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[4] Dr. B. S. Kuchekar (8 January 2008). Pharmaceutical Jurisprudence.
[5] "Drugs and Cosmetics Act", 1940.
[6] Pillay (30 November 2012). Modern Medical Toxicology.

4. Import for personal use
5. New drugs.
6. Substances not used for medical use
7. Substances as drugs and foods as condensed/ powdered milk, malt, ginger, pepper, cumin, oats, cereal, cinnamon.

Import of Schedule X Drugs

1. The licensee should have adequate storage facilities
2. The license should be properly granted
3. The Applicant should be reputable in trade, business, or occupation.
4. The licensee should not have convicted any offences of this act.

Repacking License

The process of breaking up the drug from a bulk container into small packages and labeling it for sale and distribution. It is granted for drugs other than Schedule C/C1 and X.

Functions of the Drug Technical Advisory Board

The elected members of the Board hold office for 3 years and eligible for re-election.

1. Advices the Central and State governments in technical matters of administration.
2. Modifications and Amendments will be made in the Act with the consultation of the Board.

Drugs Consultative Committee

It is an Advisory Board constituted by the Central Government. 2 representatives of the Central Government and 1 representative of State Government.

It has the power to regulate its own procedure and advice the Government to secure uniformity throughout India.

Conditions for Importing Drugs for Personal Use

1. Drugs must be of bona fide personal use
2. More than 100 doses imported with license
3. Applies on the form no- 12A, 12B.
4. Up till 100 doses imported without any permit, as in passenger's luggage.
5. Declared to the custom collectors

Conditions for Importing Drugs for Examination, Test, Analysis

1. License applicable under Form 11
2. Inspector should be allowed to over check the records.[7]

[7] Reckitt Benckiser (India) Ltd. vs Union Of India And Anr on 10 July, 2015

3. The place should be specified in the license.

The drugs which are not used for medical purposes and are used as food substances are the ones that can be imported without a license.

Law Relating to Sea and Customs

The customs collector who is authorized on behalf of the Central Government may detain imported packages, which contains the specified drugs or cosmetics, where the import is prohibited by the Act.

The drug controller takes the specific action required and sends it to the Drug Control Laboratory for analysis.

Recent Amendment of 2017

The Ministry of Health and Family Welfare, published the 10th Amendment rules in October 2017, to exercise the powers bestowed by Section 12 with Section 33 of the Act of 1940.

The duration of the license is provided under Forms 20, 20A, 20B, 20BB, 20F, 20G, 21, 21A, 21B, 21BB.

Form 25A provides advance license, which will remain valid, if the retention fee is paid, before the expiry of 5 years from the date of issue.

In case of failure to pay the fee before the specified due dates, the licensee will be liable to pay license retention fee, in addition to the late fee of 2%, up to 6 months. Failure to pay, will be regarded as cancellation of license.

In order for the grant of license through manufacture, there is Inspection held by the Drug Inspectors.

Inspection for the confirmation of compliance held once in 3 years term.

In addition, Form 25, Form 25B, 25F, 32, 32A, Form 33, Form 37.

The license with regard to manufacturing will be done in coordination with Zonal/ Sub Zonal offices of CDSCO. In their absence, the Drug Inspector from CDSCO (HQ) will do the joint inspection. Moreover, further improvements to be made in enforcing new rules in CDSCO will valuably be accepted.

11th Amendment Rules, 2019

Implementation in the permanency of licenses. The amendment would ensure the smooth processing of applications for grant of manufacturing licenses and promote the Drugs and Cosmetics (Amendment) Rules, 2019. It has been notified by the Central Government on 10-01-2019, after consultation with the Drugs Technical Advisory Board (DTAB), in the exercise of the powers conferred under Sections 12 and 33 of the Drugs and Cosmetics Act, 1940 (23 of 1940),

to further the "Principal Act". These amendment rules shall come into force from 10-01-2019.In the ease of doing business for drug manufacture and drug distributors.

Inspection of Sale Premises

1. To send sale samples for analysis
2. To detain packages of imported Drugs.[8]
3. To investigate the complaint and institute prosecution, with search principles with regard to offences.
4. To check the conditions of licenses being fulfilled or not, and to inspect the authorized shops.

Offences and Penalties

1. The manufacture of spurious and adulterated drugs that cause death Imprisonment not less than 5 years, extends to life imprisonment and a fine of Rs. 10,000. In addition, 2-6 years imprisonment, with a fine of Rs. 10,000
2. The manufacture of adulterated drugs which does not cause death1-3 years imprisonment and a fine of Rs. 5000. In addition, 2-6 years imprisonment, with a fine of Rs. 10,000
3. Manufacture of drugs with contravention to the provision
   Imprisonment for 1-2 years. The drugs which are not used for medical purposes and are used as food substances are the ones that can be imported without a license.

THE DRUGS AND MAGIC REMEDIES ACT, 1955.

An Act initiated for the control and prohibition of advertisements of the drugs, for the purpose of remedies alleged to possess magic qualities.[9] As per the Act, the magic remedy includes the talisman mantra Kavacha, or any other form of charm, which possess miraculous powers for diagnosis, cure, treatment, or prevention of disease in human beings.

There should not be any publication in the form of advertisements, referring drugs for the use of miscarriage in women, improvement of the capacity of human beings for sexual pleasures, correction of mensural disorder in women.

No person will take part in the advertisement which gives a false impression or for misleading people.

[8] Shree Baidyanath Ayurved Bhawan vs Collector Of Central Excise on June, 1985.
[9] Procter And Gamble India Ltd. vs Municipal Corporation Of Greater, 30 September, 2003

The schedule for diseases specified under the Act, appendicitis, atherosclerosis, blindness, blood poisoning, cancer, deafness, diabetics, uterus diseases, female diseases, fever, insanity, venereal diseases, AIDS.

Drugs and Cosmetics Amendment Act, 2008

It focused mainly in the enhancement of punishments.

Life imprisonment involves manufacture, sale, distribution which causes grievous hurt.

Provides a minimum of seven years imprisonment up to life imprisonment. Provisions were also added for the compensation for affected parties.