Review Document

The Drugs and Cosmetics Act, 1940

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THE DRUGS AND COSMETICS ACT, 1940

Introduction:

In 1930 India was largely reliant on import of modern medicines until after the first war. In August 1930, the Government of India appointed a drug enquiry committee under the chairmanship of Colonel R.N. Chopra, to go into the subject of adulterated and substandard medications sold in the nation and to suggest the means by which the menace could be controlled. In 1937 a Bill was presented in the Central Legislative Assembly to give effect to the suggestions of the Drugs Enquiry Committee to manage the import of medications into British India.

After the passing of Government of India Act 1935, drugs turned into a common subject and accordingly Center could pass law in regard of just imports.The drug import bill was presented and set for thought before the assembly in 1939. This was not acceptable to people in general and provinces for uniform and thorough enactment. This led to the introduction of Indian Drug Bill in the centre legislature. This prompted the introduction of Indian Drug bill in the central legislation. It was passed and got assent of governor general and the Council and became a Drug Act in 1940.

The Drugs and Cosmetics Act, 1940[1]is mainly concerned with maintaining the quality of drugs and cosmetics and provides for the establishment of a board of technical experts to advise the central and the state governments on technical matters.

Significances of the Act:

1. Outlining the policies and guidelines of Drugs and Cosmetics.
2. Grant of Narcotics licences in medicine formulations.
3. Periodical survey of the performances of Drugs Control.
4. Approval of Drugs Formulations of highly sensitive products such as vaccines, Seras, Large Volume Parenterals and Cyto-toxic products. Grant of Certificate of Pharmaceuticals products (COPP) under W.H.O GMP certification scheme.

[1]https://www.indiacode.nic.in/handle/123456789/2409?view_type=browse&sam_handle=123456789/1362

5. Regulation of sale and distribution of highly sensitive products.
6. Licensing Authority of Drug Manufacturing Establishments (including Ayurveda) with mandatory statutory qualification as laid down in the Drugs & Cosmetics Act, 1940
7. The First Schedule endorses the guidelines to be followed by imported medications and the Second Schedule recommends the norms to be conformed to the medications made, sold or appropriated in India. The norms recommended in the two Schedules are indistinguishable. The Central Government will have capacity to correct the First Schedule, however capacity to change the Second Schedule will rest with the Provincial Government.

Object of the Act:

1. To prevent substandard drugs presumably for treatment and maintaining high standards of medicine.
2. To regulate the import, manufacture,distribution and sale of drugs and cosmetics through licensing.
3. Manufacture,distribution and sale of drugs and cosmetics by qualified persons only.
4. To regulate the assembling and sale of Ayurvedic, Siddharth and unani drugs.
5. To establish Drug Technical Advisory Board (DTAB) and Drug Consultative Committees (DCC) for Allopathic and allied drugs and cosmetics.
6. Maximum penalty life imprisonment and fine of Rs. 10 lakhs or 3 times the value of the confiscated goods, whichever is more.
7. Specially designated courts for trial of offences covered under the Act.
8. Provision for compounding of minor offences.

Administrative structure:

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

Important provisions:

1. The term ‘cosmetic’ is defined in Section 3 of the Drugs and Cosmetics Act. Cosmetic means any article intended to be rubbed, poured, sprinkled or sprayed on, or introduced into, 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. Talcum powder, nail polish, perfumes, lip-stick etc are examples of cosmetics.
2. The term ‘drug’ is defined in the Drugs and Cosmetics Act. A comprehensive definition is given for the term drug in the Act. The Act says that “drug” includes—
    a) 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;
    b) Such substances (other than food) intended to affect the structure or any function of the 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.
    c) All substances intended for use as components of a drug including empty gelatin capsules; and
    d) 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.

3. Section 5 of the Act empowers the central government to constitute the Drugs Technical Advisory Board to advise it and the state governments on technical matters arising out of the administration of the present Act and to carry out the functions assigned to them thereunder.
4. The Drugs Consultative Committee (DCC) is constituted by the Central Government as per Section 7 of the Act. The DCC is an advisory committee and has the responsibility to advise the Central Government, the State Governments and the Drugs Technical Advisory Board on the matters related to uniform administration of the Drugs and Cosmetics Act throughout India. The Drugs Consultative Committee shall consist of two representatives of the Central Government to be nominated by that Government and one representative of each State Government to be nominated by the State Government concerned.
5. Section 12 and 13 of the Act vest the central government with power to make rules prescribing the methods of tests or analysis to be employed for determining standard quality of any drug.
6. Section 10 empowers the central government to restrict import of any drugs or cosmetics which are not of standard quality or which are misbranded, spurious or adulterated.
7. Section 18 of the Act restricts manufacture, sale and distribution of certain drugs and cosmetics which are not of a standard quality or are misbranded, adulterated or spurious.
8. Section 24 of the Act requires every person in charge of any premises, where any drug or cosmetic is being manufactured or kept for sale or distribution, to disclose the place where any drug or cosmetic is being manufactured or kept, whenever asked to do so.
9. Section 26A of the Act empowers the central government to prohibit the manufacture, sale or distribution of any drug or cosmetic, the use of which is likely to involve any risk to human beings or animals or it does not have the therapeutic value as claimed or contains ingredients in a quantity without therapeutic justification.
10. Under section 27 of the Act, the sale, stocking, exhibition or distribution of any adulterated, spurious and substandard drugs or any such drug, which if used by any person is likely to cause his death or harm his body amounting to grievous hurt, is punishable with imprisonment for a term of five years to a term of life and with fine of not less than ten thousand rupees.

11. Section 31 of the Act permits confiscation of stock of drugs or cosmetics in respect of which any contravention has taken place under the provisions of the Act.
12. Section 33D of the Act empowers the central government to constitute an advisory committee, to be called the Ayurvedic, Siddha and Unani Drugs Consultative Committee, to advise the central government, the state governments and the Ayurvedic, Siddha and Unani Drugs Technical Advisory Board on any matter related to ayurvedic, siddha or unani drugs.
13. Section 33EEB of the Act allows manufacture of any ayurvedic, siddha or unani drug only if it is in accordance with the prescribed standards. Accordingly, no person can manufacture for sale or distribution any misbranded, adulterated or spurious ayurvedic, siddha or unani drug or any patent; or proprietary medicine; or any other ayurvedic, siddha and unani drug in contravention of any of the provisions of this Act.

Recent Amendment:

1. The Drugs and Cosmetics (Amendment) Act, 2008:

a) Substantial enhancement in punishment
b) Life imprisonment for offenders involved in manufacture, sale and distribution of spurious and adulterated drug likely to cause grievous hurt
c) Minimum punishment of seven years which may extend to life imprisonment
d) Provision for compensation to affected person

2. The Drugs and Cosmetics (Amendment) Act, 2013:

a) The bill contains critical drugs and separate regulatory provisions for medical devices and expensive provisions for regulating clinical trials.
b) Vacancies, Defective, Nominations etc. Not be invalidated proceedings.
c) The appointment, salaries, allowances and pensions payable to the DCGI shall be determined by the central Government.
d) Necessary staffing for central drug authority will be created by the central government in consultation with the former.
e) Power & functions of central drugs authority have been described.

3. The Drugs and Cosmetics (Amendment) Act, 2015:

a) The constitution of Medical Devices Technical Advisory Board

4. The Drugs and Cosmetics (Amended) Bill 2018:

a) The Accreditation Board shall appoint a Registrar to maintain a registry of clinical trials and their outcomes.
b) The Accreditation Board shall constitute a Committee of Experts to examine applications for conduct of clinical trials by accredited investigators.
c) The Accreditation Board shall appoint such officers and staff as are necessary for discharge of its functions under this Act.

Loopholes:

1. Absence of enforcement of existing laws.
2. Weak penal action.
3. Exceptionally profitable exchange.
4. Large-scale sickness in the small scale pharmaceutical industry.
5. Accessibility of improved printing technology that helps counterfeiting.
6. Absence of coordination between different organizations.
7. Numerous retail and wholesale outlets.
8. Absence of control by bringing in/trading nations.
9. Widespread corruption and conflict of interests.

Conclusion:

The Government of India establishes an act which manages the import, produce and dealing out drugs in India. The central idea of the Act is to make certain that the drugs and cosmetics sold in India are safe, secure, fruitful and conform to stipulate quality standards. The drugs covered under the Drugs and Cosmetic Act wide varieties of remedial substances, distinctive and medical implementation. Pursuant the Act cosmetic means any article intended to be rubbed, poured, sprinkled, or sprayed on, introduced into, 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 but does not include soap. It is important to realize that these legal, regulatory and policy measures when implemented will bring unique legal and regulatory challenges. Therefore, it is important to be aware of these developments and be prepared for the challenges in advance.

About the Author

My name is Pooja Mandotar and I am studying Bishop Cotton Women's Christian Law College, Bengaluru. My experience at LEGALEAGLE LAW FORUM, internship was for 4 weeks, which started with a zoom call to explain us regarding the research to be accomplished. After which I was given a set of 6 Bare Acts Title which was supposed to be completed by me. It was a great learning opportunity for me. The research work has made me to accept more in my composing aptitudes and has acquired a lot of certainty in me concerning my capacities to think and efficiently put it down in writing. I would like to thank the Organization for giving out an opportunity like this, especially during a pandemic situation, and a special thanks to the mentors for being so cooperative with me and clearing the doubts in a short span of time.