DRUGS AND COSMETICS ACT & RULES

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DRUGS AND COSMETICS ACT & RULES

It is an Act to regulate the import, manufacture, distribution and sale of drugs and cosmetics; WHEREAS it is expedient to regulate the import, manufacture, distribution and sale of drugs and cosmetics.

Objectives of the Drugs and Cosmetics Act:

The Drugs and Cosmetics Act aims to hold medical technology and pharmaceutical companies liable for negligence and sub-standard services provided by them. Regulation of the sale, import, and distribution of drugs and cosmetics by means of licensing.

1. Ensuring that only qualified individuals are involved in the import, distribution, and sale of drugs and cosmetics.
2. Preventing substandard drug quality, presumably in order to maintain high medical treatment standards.
3. Regulation of the production and sale of Ayurvedic, Siddha, and Unani drugs.
4. To form a Drugs Technical Advisory Board (DTAB) and Drugs Consultative Committees (DCC) for allopathic and allied drugs, as well as cosmetics.

Definitions:

Drug:

"Drug includes all medicines intended for internal or external use for or in the diagnosis, treatment, mitigation or prevention of disease or disorder in human beings or animals, and manufactured exclusively in accordance with the formulae described in, the authoritative books of Ayurvedic, Siddha and Unani Tibb systems of medicine."

Cosmetic:

"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."

Adulterated drug:

A drug or device shall be deemed to be adulterated:

1. If it consists in whole or in part of any filth, putrid or decomposed substance;

2. If it has been produced, prepared, packed, or held under insanitary conditions whereby it has been contaminated with filth, or whereby it has been rendered injurious to health;

3. If it is a drug and the methods used in, or the facilities or controls used for, its manufacture, processing, packing, or holding do not conform to or are not operated or administered in conformity with current good manufacturing practice to assure that such drug meets the requirements of this chapter;

4. If it is a drug and its container is composed, in whole or in part, of any poisonous or deleterious substance which may render the contents injurious to health;

5. If it is a drug and it bears or contains, for purposes of colouring only, a colour additive which is unsafe within the meaning of the federal act.

Misbranded drug:

A drug shall be deemed to be misbranded if its label or container or anything accompanying the drug bears any statement, design or device which makes any false claim for the drug or which is false or misleading in any particular.

Misbranded cosmetic:

A cosmetic shall be deemed to be misbranded,

(a) if it contains a colour which is not prescribed; or

(b) if it is not labelled in the prescribed manner; or

(c) if the label or container or anything accompanying the cosmetic bears any statement which is false or misleading in any particular.

Spurious drug:

Spurious or imitation drug products are drug formulations manufactured. concealing the true identity of the product and made to resemble another drug, especially some popular brand, to deceive the buyer and cash on the popularity of original product. The product may or may not contain the active ingredients.

Spurious cosmetic:

A cosmetic shall be deemed to be spurious,

(a) if it is manufactured under a name which belongs to another cosmetic; or

(b) if it is an imitation of, or a substitute for, another cosmetic or resembles another cosmetic in a manner likely to deceive or bears upon it or upon its label or container the name of another cosmetic unless it is plainly and conspicuously marked so as to reveal its true character and its lack of identity with such other cosmetic; or

(c) if the label or container bears the name of an individual or a company purporting to be the manufacturer of the cosmetic which individual or company is fictitious or does not exist; or

(d) if it purports to be the product of a manufacturer of whom it is not truly a product.

Government analyst:

Government Analystl means

(i) in relation to [Ayurvedic, Siddha or Unani] drug, a Government Analyst appointed by the Central Government or a State Government under section 33F; and

(ii) in relation to any other drug or cosmetic, a Government Analyst appointed by the Central Government or a State Government under section 20.

Drug inspector:

Inspector means

(i) in relation to [Ayurvedic, Siddha or Unani] drug, an Inspector appointed by the Central Government or a State Government under section 33G; and

(ii) in relation to any other drug or cosmetic, an Inspector appointed by the Central Government or a State Government under section 21.

Manufacture:

Manufacture in relation to any drug or cosmetic includes any process or part of a process for making, altering, ornamenting, finishing, packing, labelling, breaking up or otherwise treating or adopting any drug or cosmetic with a view to its sale or distribution but does not include the compounding or dispensing of any drug, or the packing of any drug or cosmetic, in the ordinary course of retail business; and —to manufacture shall be construed accordingly.

Patent:

Patent or proprietary medicine means,

(i) in relation to Ayurvedic, Siddha or Unani Tibb systems of medicine all formulations containing only such ingredients mentioned in the formulae described in the authoritative books of Ayurveda, Siddha or Unani Tibb systems of medicine specified in the First Schedule, but does not include a medicine which is administered by parenteral route and also a formulation included in the authoritative books as specified in clause (a)

(ii) in relation to any other systems of medicine, a drug which is a remedy or prescription presented in a form ready for internal or external administration of human beings or animals and which is not included in the edition of the Indian Pharmacopoeia for the time being or any other Pharmacopoeia authorised in this behalf by the Central Government after consultation with the Drugs Technical Advisory Board constituted under section 5

DRUGS TECHNICAL ADVISORY BOARD (DTAB):

- DTAB advise the Central Government and the State Governments on technical matters arising out of the administration of this Act and to carry out the other functions assigned to it by this Act.

Constitutions:

1. Ex. Officio members:

i. Director General of Health Services, shall be 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,

2. Two persons to be nominated by the Central Government from among persons who are in charge of drugs control in the States

3. 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

4. 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

5. One person to be nominated by the Central Government from the pharmaceutical industry

6. One pharmacologist to be elected by the Governing Body of the Indian Council of Medical Research

7. One person to be elected by the Central Council of the Indian Medical Association

8. One person to be elected by the Council of the Indian Pharmaceutical Association

- The nominated and elected members of the Board shall hold office for three years, but shall be eligible for re- nomination and re-election:
- The Board may, subject to the previous approval of the Central Government, make bye-laws fixing a quorum and regulating its own procedure and the conduct of all business to be transacted by it.
- The Board may constitute sub-committees and may appoint to such sub-committees for such periods, not exceeding three years, as it may decide, or temporarily for the consideration of particular matters, persons who are not members of the Board.
- The functions of the Board may be exercised notwithstanding any vacancy therein.
- The Central Government shall appoint a person to be Secretary of the Board and shall provide the Board with such clerical and other staff as the Central Government considers necessary.
- Function of DTAB: The DTAB takes the policy decisions pertaining to technical aspects of the Drugs and Cosmetics Act and Rules and sends the recommendations to the Ministry of Health and Family Welfare, Government of India for its approval. DTAB ordinarily meets twice a year.

GOVERNMENT ANALYST:

- Government analysts are appointed under Section 3(c) by the central government and state governments to test or analyze drugs and cosmetics. They work in Central Drugs Laboratories and the state and Union Territory's drug testing laboratories.

A government analyst has to perform the following duties:

- To analyze samples sent by the Inspector, Custom Officer, or other person in accordance with the provisions of Chapter IV of the Act and to prepare a detailed analysis report in triplicate. The entire protocol of the analysis test should be provided. The report should be sent in a sealed envelope to the Customs Department or the Drug Inspector, depending on the situation.
- Send reports to the government about work done, research done, publications, if any, and keeping drug and pharmaceutical information up to date.
- Before beginning analysis, the government analyst should verify the seal and ensure proper custody of the sample sent for analysis. The analytical report should be submitted in triplicate to the inspector or the appropriate person on Form 13. Form 14-A is used for a purchaser's request for testing or analysis, and Form 14-B is used for the analysis report.

Drug Inspectors:

- Drug inspectors are appointed under Section 3(e) by both the state and federal governments for specific areas or categories of activity. A separate set of inspectors could be assigned to the manufacturing of drug formulations.

Duties of inspectors of premises licensed for sale

- To inspect all establishments for sale at least once a year.
- To ensure that licensing conditions are being followed.
- To obtain and send the drug for testing or analysis if he has reason to suspect that the drug is being sold or stocked in violation of the Act or Rules.
- To conduct a worded investigation into the complaint.
- To keep a record of inspections.
- To conduct the necessary research.
- To initiate prosecutions for violations of the Act and Rules.
- When authorized by the State Government, detain imported packages containing drugs, the import of which is prohibited.

Duties of inspectors specially authorized to inspect the manufacture of drugs or cosmetics:

The duties to be performed by an inspector are mentioned below. These duties are subject to the instructions issued by the Controlling Authority.

- To inspect, at least once a year, all premises licensed for the manufacture of drugs or cosmetics.
- To ensure that license conditions are met.
- To inspect the plant, manufacturing process and standardisation, storage, technical qualifications, and other details for Schedules C and C (1) drugs.
- To submit a thorough inspection report to the Controlling Authority.
- To collect samples for testing or analysis in accordance with the rules.

Regulatory provisions relating to import of cosmetics:

- Import of certain cosmetics is prohibited under D&C A rules 134A, 135, 135A.
  - Any cosmetic which is not of standard quality.
  - Any misbranded or spurious cosmetic.
  - Any cosmetic containing any ingredient which may render it unsafe or harmful for use under the directions indicated or recommended.
  - Any cosmetic containing hexachlorophene.
  - Any cosmetic in which lead or arsenic compound has been used for coloring.
  - Any cosmetic which contains mercury compound.

- In eighties, the standards framed by Indian Standard Institution were adapted for certain cosmetics.
- 27 cosmetics have been placed under schedule S to the rules & are required to comply with Indian standards & these are:

1. Skin powder
2. Tooth powder
3. Skin creams
4. Shampoo, soap based
5. Hair creams
6. Cologne
7. Aftershave lotion
8. Depilatories, chemical
9. Cosmetic pencils,
10. Toilet soap
11. Baby toilet soap
12. shaving soap
13. Skin powder for infants
14. Tooth paste
15. Hair oils
16. Shampoo, synthetic detergent based
17. Oxidation hair dyes
18. Nail polish
19. Pomades & brilliantines
20. Shaving creams
21. Lipsticks
22. Liquid toilet soap
23. Transparent toilet soap
24. Lipslave
25. Powder hair dye
26. Bindi
27. Kumkum powder

Major/minor actions taken by CDSCO against the applicants manufacturer importers:

- Cancellation of cosmetic registration certificate No. 154/13 of M/s GS. Pharmbutor (Private) Uttarakhand-March 2016
- Cancellation of cosmetic registration certificate No. COS-84/13 of M/s stiefel India Ltd Mumbai Nov-2015
- Cancellation of cosmetic registration certificate No. COS-85/13 of M/s stiefel India Ltd Mumbai Oct-2015

- Rule 134 of D&C A stipulates that no cosmetic shall be imported which contains a coal tar color other than the one prescribed in schedule Q.
- Coal tar color used in cosmetics shall not contain more than:

a) 2ppm of arsenic calculated as arsenic trioxide

b) 20 ppm of lead.

c) 100 ppm of heavy metals other than lead.

Offences & penalties:

Contravention in brief	Penalty
Import of spurious cosmetic or cosmetic containing any ingredient which are harmful for use	Imprisonment for term of 3 years which may extends to 5 years with fine of 5000 rupees.
Import of cosmetic whose import is prohibited under section 10-A	Imprisonment for term of 3 years which may extends to 5 years with fine of 5000 rupees.
Repeated offence of above two	Imprisonment for term of 5 years & fine which may extend to 10000 rupees.
Sale/manufacture of cosmetic which is not of standard or misbranded cosmetic	Imprisonment for term of 3 years which may extends to 5 years with fine of 5000 rupees.

Regulatory provisions related to manufacture of cosmetics:

- A license is required under the D&C rules for the manufacture of cosmetics for sale & distribution.
- The license is issued by state regulatory authorities.

How to obtain license:

- Application (form no 31) along with license fees of rupees 2500 & inspection fees of 1000 rupees accompanied with following documents-

i. Layout plan of factory premises

ii. A list of equipment & machinery installed.

iii. A document about the constitution of the term.

iv. Document showing the possession other applicant of the proposed premises for the factory.

- Factory premises are inspected by the officers of the state regulatory agency.

- The officer shall find out whether:

i. The applicant has provided adequate space for manufacturing operations, quality control & storage of raw materials, packaging & finished products.

ii. The applicant has provided adequate equipment & machinery.

iii. The applicant has provided adequate testing facilities.

- The manufacturer has to ensure that the production is carried out by competent & qualified technical staff.

Requirements of factory premises for manufacture of cosmetics:

(A) General requirements:

- Shall be located in a sanitary place & hygienic conditions shall be maintained.
- Walls of room should be at a height of 6 ft from the floor, it should be waterproof.
- Water used should be of potable quality.
- Suitable arrangements shall be made for disposal of waste water.
- All workers should be free from contagious or infectious diseases. They shall be provided with clean uniforms & gloves wherever required.

(B) Requirements of the plant & equipment:

Powders:

- Powder mixer of suitable type
- Perfume & colour blender
- Ball mill or suitable grinder
- Filling & sealing equipment
- Weighing & measuring
- Storage tanks
- An area of 15 m2

Creams, lotions, shampoos & hair oils:

- Mixing & storage of the suitable materials
- Suitable agitator
- Heating mantle
- Filling & sealing equipment
- Weighing & measuring device.

Lipsticks:

- Vertical mixer
- Mixing vessels
- Tripple roller mill or ball mill
- Weighing & measuring devices
- An area of 15 m2

Hair dyes:

- Stainless steel tanks
- Mixer
- Filling unit
- Weighing & measuring device
- Gloves & masks

Toothpaste:

- Weighing & measuring devices
- Kettle steam, gas or electrically heated
- Planetary mixer
- Tube filling equipment
- Crimping machine

Prohibition of the manufacture and sale:

- Cosmetics which are not of the std quality or misbranded, adulterated or spurious.
- Patent or proprietary cosmetics.
- Risky to human beings or animals.
- Preparation containing cyclamates.
- Any cosmetic in which lead and arsenic used for coloring purpose.
- Any cosmetic which contain mercury compound.

Loan license:

- A person not having his own manufacturing facilities can get cosmetics manufactured from licensed cosmetic manufacturer under license system.
- Application for loan license is prescribed form (form 31-A) along with a fee Rs 6000 together with requisite documents should be submitted to the state regulatory authorities.
- Licensing authority of state, after examining that the licensed manufacturer has spare capacity & has agrees to manufacture cosmetics for applicant, will grant loan license.

Requirements pertaining to labeling of cosmetics:

- Name of product along with the manufacturing address must be mentioned on both the inner & the outer labels.
- If the container is small in size then the principal place of manufacturing & the pin code are enough.
- The outer label should clearly specify the net contents of the ingredients used in the manufacture of the product.
- The inner label should contain the directions for use along with any warning or caution that may be necessary.
- A distinctive batch number mention by letter 'B' along with manufacturing license number mention by 'M' must be present on the label.
- Quality standards in case of the aforementioned categories of products must conform to the Indian stds laid down & revised by the Beauro of Indian stds (BIS).

References:

- http://www.cdsco.nic.in
- https://www.fda.gov/Cosmetics/default.htm
- http://www.bis.gov.in/
- https://cliniexperts.com
- Pharmaceutical jurisprudence., Dr. G.K. Jani