



Lipstick



Nail Polishes



Perfumes



Eye shadows

# Unit 1 Cosmetics Regulation



Deodorants



Antiperspirants



Soaps



Creams



Shampoos



Toothpastes

# Content

- **Definition of cosmetic products as per Indian regulation.**
- **Indian regulatory requirements for labelling of cosmetics**
- **Regulatory provisions relating to import of cosmetics.,**
- **Misbranded and spurious cosmetics.**
- **Regulatory provisions relating to manufacture of cosmetics –**
  - **Conditions for obtaining license,**
  - **prohibition of manufacture and sale of certain cosmetics,**
  - **loan license, offences and penalties.**

# **Definition : Cosmetic Products (as per Indian regulation)**

**Cosmetic is defined under section 3(aaa) of the Drugs and Cosmetics Act, 1940 as,**

**“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”**

# Why are Cosmetics regulated?

- To ensure that the cosmetics sold in India are **safe, effective and conform** to state quality standards.

# Cosmetics Regulation

- Regulatory bodies frame **rules and regulations** for the manufacturing, sale, labelling, import of cosmetic products
- A great difference is found in cosmetic regulations like, nomenclature, labelling and safety of colorants(s) etc. of different countries. Color additives used in cosmetics must be tested for safety and be listed
- Regulatory agencies in the USA , EU and Japan follow a **stringent regulatory** framework, whereas cosmetics are not so much strictly regulated in countries such as India, Brazil, and China.
- In the USA cosmetics regulation is authorized by FDA and regulated by Food Drug and Cosmetic Act.
- In Europe, the authority for cosmetic regulation is EMEA(Europe, Middle East and Africa) and regulated by council directive 76/768/EEC.
- In India authority for cosmetic regulation is CDSCO (Central Drugs Standard Control Organisation)and is regulated by Drug and Cosmetics Act and Rules.

# Chemicals Prohibited by FDA in Cosmetics

Regulations restrict or prohibit the use of the following ingredients in cosmetics:

- bithionol, mercury compounds, vinyl chloride, halogenated salicylanilides, zirconium complexes in aerosol cosmetics, chloroform, methylene chloride, chlorofluorocarbon propellants and hexachlorophene.
- liquid methyl methacrylate is poisonous and harmful substance that should not be used in fingernail preparations.

# Cosmetics Regulation in India

- Cosmetic Legislation is driven through **Drugs and Cosmetics Act**, and the legislative body is CDSCO (Central Drugs Standards Control Organization) headed by **Drugs controller general of India**.
- the **manufacture** of cosmetics in India is regulated under a system of inspection and licensing by the **State Drug Control Department**
- **import** of cosmetics is regulated under a system of registration by the **Central Drugs Standard Control Organization (CDSCO)**, who is the main authority to regulate activities relating to cosmetics
- Hexachlorophene, Lead or Arsenic compounds and mercury compounds are prohibited to be manufactured and imported.

# DRUG & COSMETICS ACT 1940 & RULE 1945

ACT consist of 5 CHAPTER

CHAPTER 3 - import of drug & cosmetics

CHAPTER 4 - manufacturing ,sale , distribution drugs & cosmetics

RULE of the ACT divided in different parts

part 13 - import of cosmetics

part 14 - manufacturing of cosmetics

part 15 - labeling, packaging , standard of cosmetics

part 15-A - approval of institute for analysis of drug , cosmetics & raw material



# DRUG & COSMETICS ACT 1940 & RULE 1945

**Schedule M2**- GMPs requirements , factory premises , plant, equipment for manufacturing of cosmetics

**Schedule Q** -list of coal tar colours permit in cosmetics &soaps

**Schedule S** -standard for cosmetics finished product

**Schedule U1**-particulars to be shown in manufacturing records of cosmetics.

# Types of Cosmetic License in India

- There are two types of license for setting up a cosmetic business in India.

## Manufacturing license

- The State Government appoints a Licensing Authority **State Drug Control Department**, who inspect and provide license for manufacturing of the products.
  - Any individual or company has to obtain a license from the Licensing Authority to manufacture any products.
- **Importing license**
    - import of cosmetics is regulated under a system of registration by the **Central Drugs Standard Control Organization (CDSCO)**,

# Regulatory requirements to manufacture of Cosmetics

- A **license is required** under the Drug and Cosmetic Rules for the manufacture / sale / distribution of cosmetics.
- This license is issued by state regulatory authorities or a Licensing Authority appointed by The State Government.
- The **application** has to be submitted in **form (Form-31)** along with a **license fee** of Rs. 2500 and an **inspection fee** of Rs. 1000

# Regulatory requirements to manufacture of Cosmetics

- The inspectors are appointed under the Act. They are then required to **submit a detailed report to the Licensing Authority** which can then decide whether to grant the license or not
- Before granting or refusing the license, the Licensing Authority is required to order **inspection of the whole premises** where the operations are to be carried out.

The officer find out whether :

- The applicant has provided **adequate space** for the manufacturing operations , quality control & storage of the raw material , packaging material and finished products .
- The applicant has provided **adequate equipment** and machinery for the manufacture of the cosmetics which he intends to manufacture.
- The applicant has provided **adequate Testing facilities** for the raw material and after finished form of the cosmetics.

# Regulatory requirements to manufacture of Cosmetics

**An application should be accompanied with the following documents (Form No 31 )**

- Layout plan of the factory premises.**
- A list of equipment and Machinery installed .**
- A document about the constitution of the firm.**
- A document showing the possession of the applicant of the proposed premises for the factory.**
- The factory premises are inspected by the officers of the state regulatory agency.**

# Conditions for obtaining Manufacturing license

- The manufacturer has to ensure that the production is done in the presence of a **competent and qualified technical staff** and at least one of the staff persons should possess the following educational requirements:
  - Holds a **Diploma in Pharmacy** approved by the Pharmacy Council of India under the Pharmacy Act, 1948;
  - Is registered under the Pharmacy Act, 1948; or
  - Has passed the intermediate examination with Chemistry as one of the subjects or any other examination as recognized by the Licensing Authority as equivalent to it.

# Manufacture of Cosmetics

In order to manufacture cosmetics in India the procedure has been laid down under the Drugs and Cosmetics Rules, 1945. Schedule M-II classifies cosmetics into 11 broad product categories as:

- 1) Powders,
- 2) Creams, lotions, emulsions, pastes, cleansing milks, shampoos, pomade, brilliantine, shaving creams, hair oils etc.,
- 3) Nail Polishes and Nail Lacquers,
- 4) Lipsticks & Lip Gloss etc.,
- 5) Depilatories,
- 6) Preparations used for eyes,
- 7) Aerosol,
- 8) Alcoholic Fragrance Solutions (Cologne),
- 9) Hair Dyes,
- 10) Tooth Powders and Tooth Pastes
- 11) Toilet Soaps.

# Requirements for Factory Premises

- The essential requirement of the **factory premises** for setting up a cosmetic business have been elaborated under Schedule M-II.
- **Location and Surroundings** should be strongly viewed before starting the construction. The vicinity should be hygienic with proper sanitary conditions. Should not be within or near any residential area.
- **Building:** The building should be free from rodents, insects etc. which can hamper the whole operation. The rooms should be kept smooth, waterproof and also capable of being kept clean. The floors should also be smooth, washable,<sup>11</sup> and dust-free.



# Requirements for Factory Premises

- **Disposal of used water:** The stuffs should make proper arrangements and they should also be careful about proper discharge or disposal of waste water.
- **Staff:** The staffs, appointed for the manufacturing, should free from any communicable or infectious disease. The stuffs are required to use the necessary tools such as hand gloves, masks, uniforms etc. The availability of first aid facility inside the factory premises should also be there.

# Regulatory requirements to import of Cosmetics

- In order to ensure quality of cosmetics being imported in India and safety of consumers using these cosmetics, import of cosmetics in India needs to be regulated
- the import of cosmetics is regulated under a system of registration by the Central Licensing Authorities appointed by Central Government.
- The Drugs Controller General (India) functions as the Central Licensing Authority who grants the Import Registration Certificate and regulates the import of cosmetics into India vide Gazette notification G.S.R 763(E) under the provisions of Drugs and Cosmetics Act, 1940.
- Require compulsory registration certificate for importing from DCGI (CDSCO)

# Regulatory requirements to import of Cosmetics

As per D&C Act & Rules 1945 certain cosmetics are prohibited to import in India:

- Any cosmetic which is not of standard quality;
- Any misbranded or spurious cosmetic;
- Any cosmetic for which the import is prohibited;
- Any cosmetic containing ingredient(s) of unsafe or harmful quality;
- Any cosmetic which contain hexachlorophene;
- Any cosmetic in which lead or arsenic compounds are used for coloring purpose;
- Any cosmetic which contain mercury.
- Any cosmetics for personal use

# Regulatory requirements for labelling of Cosmetics

According to Drug and Cosmetics Act in India,

- i) Name and address of the importer;
- ii) Generic or common name of the commodity packed;
- iii) Net quantity in terms of standard unit of weights and measures;
- iv) Month and year of packing in which the commodity is manufactured or packed or imported; and
- v) Maximum retail sales price (MRP) at which the commodity in packaged form may be sold to the end consumer.

# Regulatory requirements for labelling of Cosmetics

- On both the inner & outer labels:-
  - a). Name of the cosmetic.
  - b). Name of the manufacturer and complete address of the premises of the manufacturer where the cosmetic has been manufactured
- On the outer label
  - a). A declaration of the net contents expressed in terms of weight for solids/ semi solids, fluid measure for liquids.
  - b). The names of ingredients in the order of percentage of content.

# Regulatory requirements for labelling of Cosmetics

- Use before (month and year)
- - Declaration of the net contents
- - Adequate direction for safe use
- - Any warning, caution or special direction required to be observed by the consumer
- - A statement of the names and quantities of the ingredients that are hazardous or poisonous
- - Batch number
- - Manufacturing license number
- Import Registration No. (in case of Imports)

# Regulatory requirements for labelling of Cosmetics

- On the inner label
  - a) Where a hazard exists, adequate directions for safe use, warning, caution or special direction required to be observed by the consumer, statement of the names and quantities of the ingredients that are hazardous or poisonous.
  - b) The names of ingredients in the order of percentage of content. -**Batch number** preceded by the letter “B” -  
**Manufacturing license** number preceded by the letter “M.”
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# Misbranded cosmetics

**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 a 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 Cosmetics

shall be deemed to be spurious,—

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

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

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

# Adulterated cosmetics

a cosmetic shall be deemed to be adulterated,-

(a) if it consists in whole or in part, of any filthy, putrid or decomposed substance; or

(b) if it has been prepared, packed or stored under insanitary conditions whereby it may have been contaminated with filth or whereby it may have been rendered injurious to health; or

(c) if its container is composed, in whole or in part, of any poisonous or deleterious substance which may render the contents injurious to health;

(d) if it bears or contains, for purposes of colouring only, a colour other than one which is prescribed; or

(e) if it contains any harmful or toxic substance which may render it injurious to health; or

(f) if any substance has been mixed therewith so as to reduce its quality or strength.

- **License on form 32 is issued for manufacture/ sale distribute of cosmetics and,Form no. 31 should be submitted.**
- **License on form 32-A is issued for loan license for manufacture/ sale distribute of cosmetics, and Form no. 31-A should be submitted.**
- **License on form 37 is issued for grant or renewal of approval for carrying out tests on drugs/cosmetics or raw material used in the manufacture thereof on behalf of licenses for manufacture for sale of drugs/cosmetics, and Form no. 36 should be submitted.**
- **The applicant must submit the required form to get the license. The applicant is also supposed to submit Rs. 2500 as the fee for license and Rs. 1000 as the fee for inspection.**

# Prohibition of manufacture and sale of certain cosmetics

- **Misbranded or spurious cosmetics and of substandard quality**
- **Cosmetics containing hexachlorophene or mercury compounds**
- **Cosmetics containing color which contain more than-**
  - **2 ppm of arsenic**
  - **20 ppm of lead**
  - **100 ppm of heavy metals**
- **Eye preparations containing coal-tar color**

# Which kind cosmetics import is prohibited?

- **Misbranded cosmetics**
- **Spurious cosmetics**
- **Cosmetic containing harmful ingredients**
- **Cosmetics not of standard quality**
- **Which contains more than 2ppm Arsenic, 20ppm lead, 100 ppm heavy metals.**

# Prohibition of manufacture and sale of certain cosmetics

- From such date as may be fixed by the State Government by notification in the Official Gazette in this behalf, no person shall himself or by any other person on his behalf-
  - (a) manufacture for sale or for distribution, or sell, or stock or exhibit or offer for sale,] or distribute-
    - (i) any drug which is not of a standard quality, or is misbranded, adulterated or spurious;
    - (ii) any cosmetic which is not of a standard quality or is misbranded or spurious;
    - (iii) any patent or proprietary medicine, unless there is displayed in the prescribed manner on the label or container thereof the true formula or list of active ingredients contained in it together with the quantities thereof,
    - (iv) any drug which by means of any statement design or device accompanying it or by any other means, purports or claims [to prevent, cure or mitigate] any such disease or ailment, or to have any such other effect as may be prescribed;
    - (v) any cosmetic containing any ingredient which may render it unsafe or harmful for use under the directions indicated or recommended;
    - (vi) any drug or cosmetic in contravention of any of the provisions of this Chapter or any rule made thereunder;]

# Loan license

- Definition: A person(applicant) who does not have his own arrangements(factory) for manufacture but who wish to avail the manufacturing facilities owned by another licensee. Such licenses are called Loan licenses.
- Loan licenses are issued for: 1) Drugs other than specified in C/C1 & X. 2) Drugs specified in Schedule-C/C1
- PROCEDURE: • A License is obtained from licensing authority on application in prescribed form (No-24-A, 27-A) with prescribed fees (Rs. 6000, 1500) • If the conditions fulfilled ,then license is issued in a prescribed Form (No.25- A, 28-A)

## Loan license

- 1.) A person not having his own manufacturing facilities can get cosmetics manufactured from licensed cosmetic manufacturer under license system. Application for loan license in prescribed form (Form-31-A) along with a fee Rs.3500.00(at present it may be revised) together with other requisite documents should be submitted to the State Regulatory Authorities.
- 2.) The Licensing Authority of the state, after examining that the licensed manufacturer has spare capacity and has agreed to manufacture cosmetics for applicant, will grant loan license.



# Offences and Penalties

OFFENCES	PENALTIES
Manufacture of spurious cosmetics	3 years imprisonment & fine.
Contravention of the provision	1 year imprisonment & Rs. 2000 fine

# Offences and Penalties

## 27A Penalty for manufacture, sale, etc., of cosmetics

- Whoever himself or by any other person on his behalf manufactures for sale or for distribution, or sells, or stocks or exhibits or offers for sale
- any cosmetic deemed to be **spurious** under section 17D or **adulterated** under section 17E shall be punishable with imprisonment for a term which may extend to **three years** and with fine which shall not be less than **fifty thousand rupees or three times to value of the cosmetics** confiscated(seized), whichever is more;
- **(ii)** any cosmetic other than a cosmetic referred to in clause (i) in contravention(violation) of any provisions of this Chapter or any rule made thereunder shall be punishable with imprisonment for a term which may extend to one year or with fine which may extend to twenty thousand rupees, or with both