CHAPTER 1

Cosmetic Regulation Agencies

INTRODUCTION

The worldwide market in cosmetic continues to be growing rapidly. Every day consumers use cosmetic and personal care products to protect their health, enhance their well-being, and boost their self-confidence. Ranging from antiperspirants, fragrances, make-up and shampoos to soaps, sunscreens and toothpastes, cosmetics play an essential role in all stages of human life. The cosmetic industry is science driven. It is a fast paced and highly innovative sector. It is growing fourfold annually. This makes a significant social and economic contribution to national and regional economies worldwide. Considering the globalization of cosmetics, any regulatory compliance is required to provide quality products that are safe and effective for human use. At the same time, they subsequently create or re-develop products that respond to the ever-changing expectations of consumers in international markets. The cosmetic industry, from manufacturers to traders, must be able to adapt to a constantly changing regulatory framework. Even if there is a tendency to unite cosmetic legislation across countries, enough differences remain and may result in a lack of compliance and product recalls or sanctions. This chapter examines the regulatory status and regulation agencies of particularly of India, US and EU countries. This chapter will focus on the limitations of individual country agencies and establish the need for global harmonization of regulations.

1.1 COSMETIC REGULATIONS IN INDIA

Cosmetic products in India are regulated by the Bureau of Indian Standards (BIS), which prepares standards for cosmetics products under Schedule 'S' of the Drugs and Cosmetics Act Rules 1945. Thirty different types of cosmetics are mentioned in Schedule S, like creams, pastes, skin powders, hair oil, soaps, tooth powders, shaving creams, etc. Any cosmetics in a finished product form that is included under Schedule S of the D & C Rules should conform to the Indian Standards specifications prepared by BIS from time to time.

The Drug Controller General of India (DCGI) controls the activities of the CDSCO, Central Drugs Standard Control Organization, India which discharges regulatory functions relating to drugs and cosmetics in India. CDSCO is a statutory authority established under the Drugs and Cosmetics Act of 1940 and the Drugs and Cosmetics Rules of 1945 to confirm the safety, efficiency and quality of cosmetics, drugs and medical devices. Every state consists of a state-level authority known as the SDCA (State Drug Control Authority) that is responsible for implementing the regulations under the Drugs and Cosmetics Act of 1940.

The Bureau of India Standards Act 1986 is another statutory authority in India that is empowered to prepare standards for cosmetics.

1.1.1 Definitions

Cosmetics

Under the Drug and Cosmetic Act, cosmetics have been defined 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 cosmetics”.

Misbranded Cosmetics

A cosmetic is treated as misbranded if – (A) If it contains a color that is not prescribed; or (B) If it is not labeled in the prescribed manner; or (C) If the label or container bears any statement that is false or misleading in particular.

Spurious Cosmetics

A cosmetic is treated as spurious if- (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.

1.1.2 Some NEW 'Definitions'

Some new definitions introduced under the aforementioned Rules are as follows:

i. "**a Manufacturer is the 'Brand/trade name owner''** and not the 'actual manufacturer; and

ii. **A 'Brand' is a category/class of products** as opposed to being just a trade name /brand. For example, the 'Brand' will include all brands of lipsticks imported by the applicant and not just a particular 'brand name' of Lipstick. Further, for each product class, a separate application needs to be filed. For example, shampoos and conditioners belong to different classes even though they may have a common 'brand name'. The same manufacturer can make a single application for the registration of more than one brand of cosmetics (including its different variants and pack sizes).

1.2 CLASSIFICATION OF COSMETICS AS PER CDSCO

Cosmetics are mainly divided into the four types as described in (**FIGURE 1.1)**.

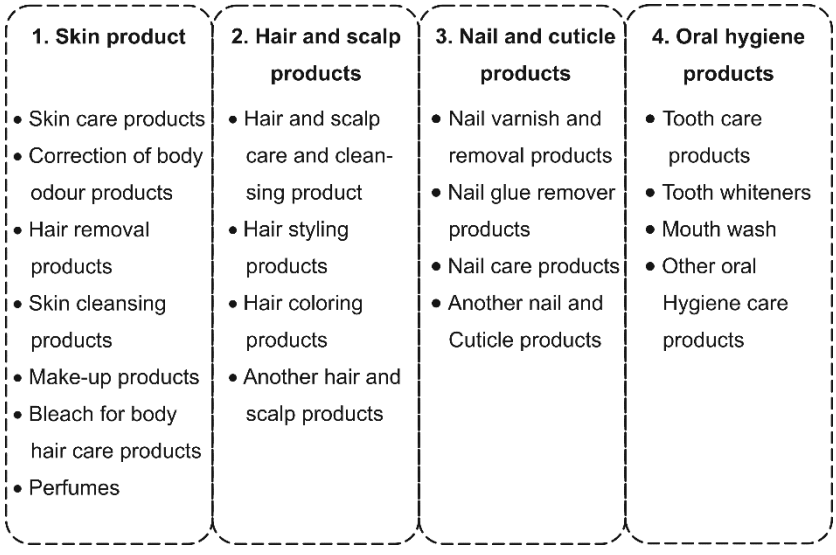

FIGURE 1.1 Four Classes of Cosmetics.

1.3 REGULATORY PROVISIONS RELATING TO THE MANUFACTURE OF COSMETICS

1.3.1 Manufacturing License for Cosmetics

The manufacture of cosmetics is regulated under a system of inspection and licensing by each state drug control department as per the provisions of the Drugs and Cosmetics Act, 1940 and Rules. It varies from state to state. The application for a license is submitted through the website of each state in India. Specific procedures vary from state to state.

- The submission of Form 31 along with a license fee of Rs. 2500 and an inspection fee of Rs. 1000.
- The license in Form no 32 that is issued for manufacturing cosmetics for sale or distribution and filing of the application in Form 31.
- The license in Form 32-A is issued for a loan license for manufacturing cosmetics for sale for distribution, and the application is filed in Form 31-A.
- The license on Form 37 is issued for grant or renewal of approval for performing tests on cosmetic or raw material used in the manufacturing thereof on behalf of license for manufacture for sale of cosmetics. 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:
  a. Holds a Diploma in Pharmacy approved by the Pharmacy Council of India under the Pharmacy Act, 1948; or is registered under the Pharmacy Act, 1948.
  b. Has passed the intermediate examination with Chemistry as a subject or any other examination as recognized by the Licensing Authority as equivalent to it.
- The Licensing authority needs to inspect the entire premises where cosmetic production operations are to be carried out before the grant or refusal of the license.

1.3.2 Requirements for Factory Premises for the Manufacturing of Cosmetics

The factory premises for the manufacturing of cosmetics need to follow the conditions given in Schedule M-II. Some general requirements are as follows:

- **The location and vicinity of the premises*:*** The location of the area in which the factory or manufacturing facility of cosmetics and the surroundings are hygienic with proper sanitary conditions. No production should occur within or around a residential area.
- **Building*:*** The building in which production is to be carried should be free from rodents, and insects the height of the rooms of the building should be at least 6 feet from the floor. The construction of the building must be smooth, waterproof, and capable of being kept clean. Concerning floors, they should be smooth, washable, even, and dust-free.
- **Proper disposal and drainage of water used in the premises*:*** Careful and proper disposal or the discharge of wastewater in the production.
- **Staff*:*** The appointed staff should be regularly screened for health issues and not suffering from any infectious or communicable disease. Staff must be provided with safety tools such as masks, hand gloves, and uniforms. Management must ensure the availability of the first aid facility inside the factory premises.

1.3.3 Requirements of Plant and Equipment

The equipment, area, and other requirements recommended for manufacturing various products of cosmetics are **(TABLE 1.1)**.

TABLE 1.1 Equipments, Area, and other Requirements are Recommended for Manufacturing.

Cosmetic product	Requirement
Toothpowders	a. Weighing and measuring devices. b. Dry mixer. c. Stainless steel tanks. d. Powder filling and sealing equipment. An area of 15 square meters with proper exhaust is recommended
Tooth pastes	a. Weighing and measuring devices. b. Jacketed kettle. c. Planetary mixer. d. Stainless steel tanks. e. Tube filling equipment. f. Crimping machine. An area of 15 square meters with proper exhaust is recommended.

TABLE 1.1 *contd…*

Cosmetic product	Requirement
Powder (face powder, cake make-up, compacts, face packs, rouges etc.)	a. A powder mixer of suitable type is provided with a dust collector b. Perfume and colour blender. c. Ball mill or suitable grinder. d. Filling and sealing equipment e. Weighing and measuring devices. f. Storage tanks. An area of 15 square meters is recommended.
Creams, lotions, shampoos, and hair oils	a. Mixing and storage tanks of suitable materials. b. Suitable agitator. c. Heating kettle steam gas or electrically heated. d. Filling and sealing equipment e. Weighing and measuring devices. An area of 25 square meters is recommended
Nail polishes and Nail lacquers	a. A suitable mixer. b. Storage tanks. c. Filling and sealing machine. d. Weighing and measuring devices. Premises: a. It shall be suitable in an industrial area. b. It shall be separated from other cosmetic manufacturing areas. c. Floors, walls, and doors shall be proof. Storage: a. All explosive solvents and ingredients shall be stored in metal cupboards. Manufacture: Workers shall be asked to wear shoes in the section.
Aerosol	a. Air compressor b. Mixing tanks c. Filtering d. Liquid filing unit e. Leak test equipment f. Fire extinguisher An area of 15 square meters is recommended
Eye brows, Eye lashes, Eye liners	a. Mixing tanks b. A suitable mixer. c. Homogenizer. d. Weighing and measuring devices. e. Filling and sealing equipment. An area of 15 square meters is recommended.
Alcoholic fragrance solutions	a. Mixing tanks. b. Filtering, filling, and sealing equipment. c. Weighing and measuring devices. An area of 15 square meters is recommended

1.3.4 The Manner of Labeling

The labeling of cosmetics rules **(TABLE 1.2)** has been elaborated under Section 148 of the Drugs and Cosmetics Rules, 1945.

TABLE 1.2 Manner of Labeling.

Sec 148 Manner of Labelling	Categories	Inner labels	Outer labels
	Common or generic name of the product.	The name of the cosmetics. If the package has more than 1 product, the name (and the number of quantity) of each product to be mentioned on the package.	
	Name and address of Manufacturer	The name of the manufacturer and complete address of the premises of the manufacturer where the cosmetic has been manufactured. Mention a distinctive batch number preceded by letter "B" and manufacturing batch with "M", Manufacturing Date, Best Before along with manufacturing license number (if any) on the label.	
	Manufacture Date	Date of Manufacture, Prepackaged, or Import of commodity. The rubberstamps can be used, but without overwriting.	
	Expiry date	Use before/Expiry Date (Month and Year) "Use before … (Month and year)"- must be labeled or the expiry date.	
Sec 148 Manner of Labelling Sec 148 Manner of Labelling	**Net Quantity**		The weight of wrappers/containers excluded. "Net Quantity"- if the commodity is not likely to vary because of environmental conditions. If likely to vary- "When Packed" If the package capacity is less than 10 cubic cm or less – quantity declaration to be made on tag, card, tape etc. No Declaration required: - If the net content of the package of perfume, toilet water or the like is less than 60 ml or 30 gm.

TABLE 1.2 ***contd…***

	Warning or Caution if hazard exists	The manufacturer must mention the names and quantities of ingredients that are of hazardous nature. To avoid any risk, the 'Directions for use', any warning or caution must be specified on the inner label. Labelling requirements, if any, specified in the relevant Indian Standards laid down by the Bureau of Indian Standards for the cosmetics covered under Schedule "S".	Labels should contain and clearly mention the list of ingredients that are being used in the manufacturing of the product. The list of ingredients present in concentration of more than one per cent shall be listed in the descending order of weight or volume at the time they are added, followed by those in concentration of less than or equal to one per cent in any order, and preceded by the word "INGREDIENTS".
	Prohibition against altering inscriptions on containers, labels or wrappers of cosmetics	No person shall alter, obliterate, or deface any inscription or the mark made or recorded by the manufacturer on the container, label or wrapper of any cosmetics	
	Prohibition against false or misleading claims	No cosmetic may purport or claim to purport or convey any idea that is false or misleading to the intending user	
	Labelling of hair dyes containing dyes, Colours and Pigments	Hair dyes containing Para-phenylenediamine or other dyes, Colours and pigments] shall be labeled with the following legend in English and local languages and these shall appear on both the inner and the outer labels.	
		Each package shall also contain instructions in English and local languages on the following lines for carrying out the test: "This preparation may cause serious	

TABLE 1.2 *contd*…

		inflammation of the skin in some cases and so a preliminary test should always be carried out to determine whether or not special sensitivity exists. To perform the test, a small area of skin behind the ear or upon the inner surface of the forearm was cleansed using either soap or water of alcohol. Apply a small quantity of the hair dye as prepared for use to the area and allow it to dry. After 24 h, the area was gently washed with soap and water. If no irritation or inflammation is apparent, it may be assumed that no hypersensitivity to the dye exists. The test should, however, be carried out before each and every application. This preparation should on no account be used for dyeing eyebrows or eyelashes as severe inflammation of the eye or even blindness may result."

Note: Quality standards in case of the afore mentioned categories of products must conform to the Indian standards laid down and revised by the Bureau of Indian Standards (BIS) from time to time.

Special provisions relating to Toothpaste containing Fluoride

Under Section 149 A of the Act-

- The fluoride content in toothpaste shall not be more than 1000 ppm and the content of fluoride in terms of ppm shall be mentioned on the tube and carton.
- The date of expiry should be mentioned on the tube and carton.

1.3.5 Cosmetic Products Imported for Sale in India

All cosmetic products that are imported for sale in India now need to be registered with the Central Drugs Standard Control Organization (CDSCO), which has been appointed as the licensing authority for the purpose of these rules.

This new 'registration' requirement primarily regulates the indiscriminate import of beauty and personal care products by traders with no accountability for contents and no mechanism to fix responsibility in case a consumer is not satisfied with the quality. In many cases, because of the lack of regulations on imported cosmetics, they were found to contain hazardous materials. Thus, the new regulation attempts to check the sale of substandard cosmetic products and to harmonize import requirements with those for products manufactured in India.

Approved Products

All cosmetic products those are 'imported' for 'sales and distribution in India are considered and the Indian Food and Drugs Cosmetics Act provide a broad definition of cosmetics-

"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 cosmetics."

Currently, there are 28 cosmetics that are placed under Schedule S to the rule and are imported in India only after compliance with the Indian standards. They are:

(1) Skin Powder (2) Skin Powder for infants (3) Tooth powders (4) Toothpastes (5) Skin Creams (6) Hair oils (7) Shampoos soap based (8) Shampoos synthetic detergent based (9) Hair creams (10) Oxidation hair dyes, liquid (11) Cologne (12) Nail Polish (13) Aftershave Lotion (14) Pomades and Brilliantin (15) Depilatories (16) Shaving Creams (17) Cosmetic Pencils (18) Lipstick (19) Toilet soap (20) Liquid Toilet soap (21) Baby Toilet soap (22) Transparent toilet soap (23) Shaving soap (24) Lipsalve (25) Powder Hair dye (26) Bindi (27) Kumkum Powder (28) Henna Powder

Restriction Rule

Prescribes that no cosmetic that contains a coal tar color other than one prescribed in Schedule Q and Indian standards (IS: 4707 Part I) to the above rules and coal tar color used in cosmetics should not contain more than –

1. 2 ppm of arsenic as Arsenic trioxide.
2. 20 ppm of Lead.
3. 100 ppm of heavy metals other than lead calculated as total of respective metals.

Registration Procedure

The trademark owner, who has no manufacturing unit in India but intends to sell his goods by way of import through their appointed importers/distributors/marketers in India, must obtain a registration certificate to continue with their marketing activities in India.

For this purpose an application for registration on Form-42 along with all requisite documents needs to be submitted to Drugs Controller General (I), CDSCO, FDA office in New Delhi.

Guidance document for submission of application for granted of registration certification Form 43 to import cosmetics

- Covering letter
- Power of attorney
- Schedule D III
- List of ingredients
- Labels of proposed products
- Specification
- Package inserts
- Manufacturing licenses
- Free sale certificates
- Non-animal testing declaration
- Declaration for heavy metal and hexachlorophene content [39, 40].

Other documents

- Application form-42
- Fee (Bharatkosh online payment)

Information required from the Manufacturer/authorized Applicant

The rules identify the source of ingredients used in the cosmetic product, its place of manufacture, claimed benefits, and most importantly, its safety standards for human use. Hence, the rules have mandated a compulsory registration that requires submission of an application accompanied by documents that provide such information.

Documents required and Fees

An application for the issue of a Registration Certificate for cosmetics intended to be imported into India needs to be made on a specified form, i.e. **Form 42** either by:

a. the manufacturer himself or
b. by his authorized agent or
c. importer in India or
d. by the subsidiary in India authorized by the manufacturer

Further, the documents to be provided along with the application include:

a. A request letter by the applicant on the letterhead of the importer or the authorized agent applying for the registration was duly stamped and signed by the authorized person.

b. Form 42-This requires details such as the location of the actual manufacturing sites of the products. A single application can cover many brands (read Trademarks/brand names), many variants; many pack sizes, and different manufacturing units corresponding to the products applied.
c. Proof of payment of requisite fee: Original treasury challan indicating the payment of registration fee of **USD 250** or its equivalent in Indian rupees for each 'brand' of cosmetic product.
d. The power of Attorney (in this document the authorized agent of the manufacturer submits the application). This document needs to be notarized and apostilled or legalized by the Indian embassy in that country)
e. Schedule D III (details of the cosmetic products to be imported including the chemical and safety data)
f. Original or a copy of the label and works thereof (this will contain the details of the actual manufacturer and in cases where the manufacturer is not the brand name owner, the label will at least state, 'manufactured in XYZ country')
g. Free Sale Certificate (FSC)/Marketing Authorization
h. Manufacturing License (and attested English translation if not in English), if any: If there are multiple manufacturers for a single product, all manufacturers need to provide these documents.
i. Product specifications and testing protocols: details of ingredients used, quality data etc.
j. List of countries where market authorization or import permission or registration has been granted
k. Package inserts, if any (copies of any leaflets, product specification data that goes inside the packaging must be provided. No specific requirement has been listed, but it must provide information about the potential side effects/-allergic reactions and other safety concerns and remedies available)
l. Copies of the information about the brands, products and manufacturer

Time lines for Processing of Applications

The period for issuance of the registration certificate takes place within six months from the date of submission of the application form along with the required documents (especially details required with schedule D III). The feedback by the department or process and grant of the registration certificates takes place within 2-3 months for application being filed.

The Registration Certificate and Validity

The duration of a registration certificate (which is provided with certain conditions imposed and is given in a specified format-Form 43) is valid for three years from the date of its issuance.

1.3.6 Summary of Procedure for Imports of Cosmetics in India

There is a defined procedure given under the Central Drugs standard Controller of India **(TABLE 1.3 and TABLE 1.4)** where the imported products are registered in India under the Ministry of Health and Family Welfare.

TABLE 1.3 Procedures for Imports of Cosmetics in India.

Points to consider	Procedure
Application form from Central Drug Authority for Import of Cosmetics	An application must be filed with Central Drugs standard Controller of India.
Form-42	The application must be made in form 42 with a cover letter.
Fees-USD 250	The payment shall be USD 250 fees or which is equivalent to the cost of the imported product.
Signed Cover Letter	The office of the Drug Controller shall issue a cover letter that is duly signed and acts as an acknowledgment
Validity of Registration for Import of Cosmetics	The registration is valid for 3 years and after which renewal is necessary to continue the business.

TABLE 1.4 Documents Required for the Imports of Cosmetics to India.

Points to consider	Documents required
Details of Manufacturer	The complete address of the manufacturer and contact information about the manufacturer who does import cosmetics.
Import-Export Code Number	The manufacturer requires an IEC number.
Details of the cosmetics to be registered	This should include the brand name, the date of manufacture, and package sizes that are to be imported in India.
Details of manufacturing license	The details of the manufacturing license under which the cosmetics are being manufactured and the country details where the sales are carried out.
Details of the import from countries	It must mention details of the countries where import permission for that product is granted.

TABLE 1.4 *contd…*

Points to consider	Procedure
Names of the ingredient	It must mention the names of the ingredients in accordance to the international standards, which are accepted as per the percentage contained in the products.
Information about Indian Markets	It must give details about selling in Indian markets. It means that whether the product is already being sold in India and the period.
Undertaking the test not performed on animals	It must be declared at the port when the consignment is released that no test has been performed on animals after 12 November 2014 onwards.

1.4 COMPARISON OF COSMETIC REGULATIONS

Different regulatory bodies worldwide have their own regulations to ensure the safety of cosmetic products. The major cosmetic market comprises the European Union (EU), United States of America (USA). The regulations in these territories are used as a model for the developing world. India quickly catches up the cosmetic market globally following its own regulations. The regulations that directly impact the manufacture and sale of cosmetic products include the following: cosmetic definition, licensing, labeling, safety substantiation, stability studies, and legal authority **(TABLE 1.5)**.

TABLE 1.5 Summary of Cosmetic Regulations.

CONTENTS	USA	EU	INDIA
Authority	FDA	EMEA	CDSCO
Rules and regulations	FOOD, DRUG AND COSMETICs Act	COUNCIL DIRECTIVE 76/768/EEC	DRUGS AND COSMETICS Act
Pre-market approval	Not required	Not required by Cosmetic Directive	Required under state government licensing
Labelling	Should comply with the FD&C and FP&L	Based on Council Directive 76/768/EEC	Should comply with part XV of D&C rules 1945
Expiry date	No date required	Date of minimum durability if durability is 30 months	Indicated as “Use before date”

TABLE 1.5 *contd*…

CONTENTS	USA	EU	INDIA
Post marketing reporting system	Yes. (Voluntary Cosmetic Registration Program)	N/A	N/A
Color additive safety requirement	21 CFR 73, 74, 81, 82	Annex IV of Cosmetics Directive 76/768/EEC	Applicable
The nomenclature of colors	Henna is listed in hair color only	Henna is not listed in Annex IV of Directive 76/768/EEC	Henna is not listed as a color
Labeling declarations	FDA 21 CFR 701 & 740	Article 6 of Cosmetics Directive 76/768/EEC	BIS and PCRO
Label	English	National/Member State	English
Safety	The responsibility of manufacturer.	Manufacturer maintains the Product Information File (PIF).	The manufacturer must maintain records.

1.4.1 Comparison of Definition of Cosmetics

EU

The EU Cosmetics Directive defines a cosmetic product as: 'Any substance or preparation intended to be placed in contact with the various external parts of the human body (epidermis, hair system, nails, lips and external genital organs) or with the teeth and the mucous membranes of the oral cavity with a view exclusively or mainly to cleaning them, perfuming them, changing their appearance and/or correcting body odors and/or protecting them or keeping them in good condition'.

BOX 1.1 DECLARATION ON PRE-PACKAGED COMMODITIES

All pre-packaged commodities imported into India shall conform to the requirements of the Legal Metrology Act, 2009 and the Legal Metrology (Packaged Commodities) Rules, 2011. Under Legal Metrology (Packaged Commodities) Rules, 2011, the importer of pre-packaged commodities should be registered under Rule 27.

The Legal Metrology Act, 2009 (Act 1 of 2010) repeals and replaces the Standard of Weights and Measures Act, 1976 and the Standards of Weights and Measures (Enforcement) Act, 1985. The central government has appointed the date 01.04.2011 from which the provisions of the Act will come into force.

However, a state can enforce the provisions of the Act and Rules made under them after framing its own Legal Metrology (Enforcement) Rules for the state and on notification of the date from which it will come into force.

Penal Provision

- Manufacturing, packing, selling, or importing any prepackaged commodity is prohibited unless it in a standard quantity and carries all prescribed declarations. Section 18(1) Penal provision is Section 36(1)
- Any advertisement mentioning the retail price of packaged commodity shall also contain the net quantity there of Section 18(2)
- If the net quantity in a pre-packaged commodity is short or excess beyond the prescribed MPE, the offense will be punishable under Section 36(2)

Under Legal Metrology (Packaged Commodities) Rules, 2011, the importer of pre-packaged commodities should be registered under Rule 27. The registration will be done by the Director or controller of Legal Metrology of the State and the registration fee are Rs. 500. Wherever the requirements of labeling are given in FSSA (Food Safety & Standards Act, 2006) or CDSCO regarding food items, the labeling requirements under FSSA shall prevail over the labeling requirements of Legal Metrology.

Important sections of the Legal Metrology Act 2009:-

Every unit of weight or measure shall be in accordance with the metric system based on the international system of units. The base unit of –

(i) Length shall be the Meter;

(ii) Mass shall be the Kilogram;

(iii) Time shall be the Second;

(iv) Electric current shall be the Ampere;

(v) Thermodynamic temperature shall be the Kelvin;

(vi) Luminous intensity shall be the Candela &

(vii) The amount of substance shall be the molecule Mole.

US

The FD&C Act defines cosmetics as: 'Articles (other than soaps consisting of an alkali salt of a fatty acid and making no claims other than cleansing) 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'.

1.4.2 Comparison of Cosmetic Label Elements

Labeling is the most sought-after section of cosmetic products for two reasons- 1. as it furnishes the first-hand information about the product to the outside world; 2. as most of the cosmetic products are readily available over the counter and are subject to consumption without any prescription. Hence, there are some set guidelines for labeling cosmetic products.

1. United States (U.S.)

In the U.S., the Food and Drug Administration controls labeling under the Food, Drug and Cosmetic Act (FD&C Act) and the Fair Packaging and Labeling Act (FPLA). The label of a cosmetic product in the United States consists of two main sections: principal Display Panel and Information Panel.

Principal Display Panel

A principle display panel consists of information that indicates the nature and the use of the product. The information is conveyed through a common name or illustration. The label also informs about the net contents of the cosmetic product.

Information Panel

The following information must be mentioned in the information panel:

- If the distributor and the manufacturer of the product are different, it must be clearly mentioned on the label.
- Material facts must be mentioned on the label to ensure there are no misleading labeling practices.
- If the cosmetic harm consumers, the product label must bear the respective warnings and precautions.
- The product must provide an extensive list of the ingredients used in the cosmetic product.

2. European Union (EU)

In the EU, the cosmetic labeling requirements are regulated under the EU Cosmetics Regulation 1223/2009. According to this, the label must provide the following information about a cosmetic product:

- Purpose of the cosmetic product
- Name and address of the responsible person
- In the case of imported product, the origin country must be mentioned on the label
- The net content of the ingredients of the product
- The usability duration of the product
- Precautions
- Product identification or batch number
- A list of ingredients

BOX 1.2 Benefits of Implementing GMP by Industry

The objective of the Cosmetic Good Manufacturing Practice (GMP) guidelines is to ensure that products are consistently manufactured and controlled to the specified quality. It is concerned with all aspects of production and quality control. Rigorous adherence to Good Manufacturing Practice (GMP) minimizes the risk of adulteration or misbranding of cosmetic products. Some benefits are listed below-

- Avoid mix-ups in labels or cosmetic ingredients and other production errors.
- Prevent equipment and tools from getting contaminated.
- The prevent staff unintentionally introducing germs into the facility (e.g. by working with an open wound, not using a hairnet, and so on).
- Raw materials (including water) were adequately tested for quality before use.
- Easy replicating manufacturing procedures with proper documentation in place and hence avoiding deviations in quality.
- Avoid printing labels containing errors, misinformation, and/or not having the fully required information.
- Prevent selling products that are unintentionally harmful or hazardous, causing health issues or adverse skin reactions.
- Easy in tracing and identifying potential issues that cause customer complaints.

1.5 GOOD MANUFACTURING PRACTICE IN COSMETICS

Cosmetic Good Manufacturing Practices (GMP) relate to a set of comprehensive guidelines that help the cosmetic industry consistently manufacture safe products and of high quality. As its name implies, GMPs are concerned with the manufacturing or production processes that impact the **safety**, **consistency**, and **quality** of the end product.

Every cosmetic industry has a responsibility to ensure that products created and ultimately sold are safe, effective, and of consistently high quality **[BOX 1.2]**.

Safety refers to the prevention of unintentional contamination, spoilage, or misuse of final products that may cause undesirable reactions and other health effects. It can involve practices such as sourcing raw materials from a reputable supplier, ensuring facilities are cleaned appropriately, educating staff about regular hand washing, and proofreading labels before printing.

Consistency relates to the ability to control manufacturing variables and processes so that a consistent outcome is achieved each time. For example, the formulation used, the types of raw materials selected, the sanitation protocols followed, and the technical ability of the cosmetic chemist are just some of the variables that can influence product quality. Each, if not controlled, can lead to quality variations from batch to batch. Creating accurate and thorough documentation is vital in reproducing product quality and achieving consistency.

Quality relates to a product's ability to satisfy certain criteria based on its attributes and characteristics. The concept of 'quality' is often operationalized and defined according to objective requirements, such as color, odor, viscosity, and pH. It also encompasses issues such as safety and purity. GMP helps companies manufacture products consistently high in quality from batch to batch.

In certain countries, GMPs for cosmetics are endorsed and highly encouraged by national authorities but are not mandatory.

1.6 OVERVIEW OF COSMETIC GOOD MANUFACTURING PRACTICES GUIDELINES

Not necessarily cosmetic GMP forms part of legal regulations of a country. It can differ from region to region; in the US and Canada, implementing GMP standards is not mandatory but highly encouraged by the FDA and Health Canada, respectively.

The **ISO 22716** guidelines form the internationally accepted standard related to cosmetic GMP; countries such as the US, Canada, and those within the EU incorporate ISO 22716 guidelines within their own cosmetic GMP recommendations or regulations. ISO 22716:2007 provide guidelines for the production, control, storage and shipment of cosmetic products.

In ASEAN countries, the GMP Guidelines have been produced to offer assistance to the cosmetic industry in compliance with the

provisions of the ASEAN Cosmetic Directive. As this document is particularly intended for cosmetic products, clear delineation from drug or pharmaceutical product GMP should be kept in mind.

The following is a general overview of some areas that may be relevant for cosmetic business trying to implement GMP.

1.6.1 Documentation & Records

The process of documentation refers to the act of writing down the many facets of how something is carried out or conducted. The resulting document can be called a 'record' or collectively referred as 'documentation'. Cosmetic GMP emphasizes the importance of capturing all production processes and workflows in writing, whether in paper or electronically.

Not only should documentation exist to guide what must be done, records should also be created to capture what was done each time a specific batch is created. When issues arise, the maintenance of accurate records helps businesses quickly identify what went wrong and why. It also provides evidence that GMPs are being followed.

1.6.2 Buildings & Facilities

The operational premises of cosmetic business should offer a clean, safe, and hygienic environment that minimizes the risk of contamination. The facilities should be organized in a methodical way (e.g. there should be an adequate division of production, storage, and packing activities) and there should be appropriate cleaning, sanitization, and pest control protocols in place.

1.6.3 Equipment Used

All equipment used, such as bowls, utensils, and measuring tools, should be clean and prevent the adulteration of finished cosmetics with foreign material, dirt, or cleaning products. They should be stored properly and calibrated periodically if needed. If broken or no longer suitable for use, they should be fixed or replaced.

1.6.4 Personnel

Cosmetic GMP highlights the importance of ensuring that employee are adequately trained, experienced and qualified so that their behavior contributes to safety and quality rather than compromising it. They should also have the necessary backing from the company (in the form of training, supervision, education, resources, safety equipment, and so on) to perform their job appropriately and with cleanliness.

1.6.5 Raw Materials

All raw materials should be organized and labeled with relevant identifiable information (name, lot number, and control status) so that they can be traced at any point in the manufacturing process. Additional guidelines are stated for water, color additives and restricted cosmetic ingredients.

1.6.6 Production Processes

Appropriate documentation and records should be created to capture all aspects of the production process. The guideline recommends establishing standard operating procedures (SOPs) for all processes. An SOP is simply a clearly written instructional document that clarifies in detail how a specific production activity is conducted.

1.6.7 Laboratory Controls

Cosmetic GMP emphasizes that testing should be conducted for raw materials, in-process samples, and finished product samples to see if they comply with relevant quality criteria and specifications. While complete laboratory testing may not be feasible for smaller cosmetic businesses, it is important to have protocols in place that allow raw materials and finished products to be regularly examined for issues such as contaminants or purity.

1.6.8 Internal Audit

The purpose of conducting an internal audit is to evaluate the overall performance of a quality management system. It should be able to identify the system's strengths and weaknesses and advise a plan of action to overcome failings in GMP. A good internal audit should be unbiased and strive toward continuous improvement through rigorous self-reflection.

1.6.9 Complaints, Adverse Events and Recalls

Any complaints or adverse events reported on a particular product should be recorded and evaluated thoroughly. This review process should be documented using standard operating procedures (SOPs) and applied to both written and verbal complaints.

A systematic complaint logging and review process helps businesses hone in on the source of those events, in turn recognizing potential issues with safety or quality. For instance, a complaint regarding the odor or color of a product can flag a possible issue with spoilage or contamination. Similarly, a complaint about an incorrect label could signal a possible mix-up that could affect other products

within a batch. Adverse events, which include complaints of undesired bodily reactions in response to the product, should be evaluated with extra care.

If a severe or high-risk safety or quality issue is suspected, a company may conduct a total product recall. Again, relevant documentation should be created to ensure there is a systematic plan of action that could lead to swift and efficient product recall.

1.7 THE ROLE OF ISO 22716 IN COSMETIC GMP

ISO 22716 is an international standard of good manufacturing practices (GMP) for the cosmetics manufacturing industry and describes the basic principles of applying GMP in a facility that produces finished cosmetic products. This guideline offers organized and practical advice on the management of human, technical, and administrative factors affecting product quality.

ISO 22716 provides a widespread approach for an organization's management of quality systems through practical methods.

It covers manufacturing, storing, packaging, testing, and transportation processes. It does not apply to research and development activities or the distribution of finished cosmetic products. Even though the standard focuses on product quality, it excludes the safety of the employee engaged in production or the protection of the environment. The guidelines have been approved and accepted by many global regulatory bodies, such as the Food & Drug Administration (FDA), the International Cooperation on Cosmetics Regulation (ICCR) and the European Committee for Standardization (CEN).

These guidelines cover the quality aspects of the product but as a whole do not cover safety aspects for the personnel engaged in the plant, nor do they cover aspects of protection of the environment.

The guidelines in ISO 22716:2007 are not applicable to research and development activities and the distribution of finished products.

1.8 NEW RULES FOR THE INDIAN COSMETIC INDUSTRY

Effective 15th December 2020, CDSCO laid out a fresh set of protocol for importation, manufacture labeling packing, sale, and distribution of cosmetics (as defined by the Drugs & Cosmetics Act 1940) in India under **Cosmetics Rules 2020**. To ensure a smooth transition, all licenses granted under the former Drugs and Cosmetics

Rules 1945 will be deemed valid till their expiry or for 18 months from the date of start of the new regulations, whichever comes later.

Any cosmetic product manufactured outside India can be made available in the Indian market if the product formulation, label text, and claims on the label and website are compliant with the Cosmetic Rules 2020. Also, all cosmetics products entering India must be registered through the e-Governance portal (SUGAM) by applying in Form COS-1. The form is submitted either by the manufacturer or the authorized agent in India. Upon thorough review of the application form, CDSCO provides the registration certificate via Form COS-2. Few other highlights of the new regulations are mentioned below:

Import and Registration of Cosmetics in India

- The import **r**egistration certificate shall now remain valid for five (5) years from the date of issue.
- The statutory fees for imported cosmetics have been significantly reduced.
- Import of cosmetics is prohibited if (a) the “Use Before date” is less than six (6) months from the date of import, (b) the cosmetic contains hexachlorophene, a chemical preservative known for harmful effect on humans, (c) the cosmetic has been tested on animals after November 12, 2014.
- No cosmetic product whose manufacture, sale, or distribution is prohibited in the country of origin can be imported.

Cosmetics Manufacture for Sale or Distribution in India

- The manufacturing license / loan license shall now remain valid for five (5) years from the date of issue.
- Mandatory self-declaration by applicant to confirm product compliance with good manufacturing practices and other guidelines.
- In the case of manufacturing units at more than one premise, separate licenses must be obtained for each unit.

Quality and Ingredients

- To enable consumers to make more informed choices, it is now mandatory for manufacturers to declare all ingredients of their products, including those with concentrations of less than 1%.
- Raw materials specified in Annex A of the Indian Standard ISO: 4707 Part 2 as amended from time to time shall not be added in the cosmetic product.

- No cosmetic shall be imported or manufactured that contains dyes colors and pigments other than the one specified by the Bureau of Indian Standards

Voluntary Recall of Cosmetic Products

- If a manufacturer or authorized agent has reason to believe that a certain cosmetic product that has been imported, manufactured, sold or distributed is likely a health risk, it is obligatory for him to initiate procedures to recall the product from the market with immediate effect and inform the Central Licensing Authority citing reasons for withdrawal.

New Cosmetics

The Cosmetic Rules, 2020 has defined the term 'New Cosmetics' for the first time as a "cosmetic which contains novel ingredient and has not been used anywhere in the world or is not recognized for use in cosmetics in any National and International literature". To import or manufacture New Cosmetics in India, one must seek permission from Central Licensing Authority (CLA). Application in Form COS-12 must be accompanied with requisite data on safety and efficacy and must comply with IS 4011: 2018 standards for testing. Once the compliance is completed the authority may grant due permission to import the cosmetic subsequently in Form COS-3.

LEARNING QUESTIONS

1. Name the authority that regulates cosmetics in India.
2. Name the authority that regulates cosmetics in the EU.
3. Name the authority that regulates cosmetics in the USA.
4. Explain what option cosmetic manufacturers and distributors have for registering their facilities and products.
5. Define the term "premarket approval" and discuss whether it is necessary for cosmetic products in the US and EU, respectively.
6. Explain how a manufacturer can assure and maintain high quality of its products.
7. Discuss how the use of cosmetic ingredients is restricted in the US and EU, respectively.
8. Explain that is responsible for the safety of cosmetic products in the US and EU, respectively.