

## **A Comparative Evaluation of Cosmetic Legislations in India and the European Union**

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### **Synopsis**

In current years, cosmetic products have become an important part of human life. The changing lifestyles of customers and an increased awareness for their physical appearance is the main driving force behind the great rise of the cosmetics market worldwide. Though the United States and the European Union are the largest cosmetic markets in the world, India's cosmetic market has shown a compound annual growth rate of 16.39%, with a value of \$13,191.23 million in 2020. There are a number of different ingredients obtained from natural as well as synthetic sources that are used in the manufacturing of cosmetics, some of which might be toxic and may pose a risk to human health. Therefore, it is essential to regulate the manufacturing for the sale and distribution of all cosmetic products worldwide. To ensure the safety and performance of cosmetic products, different countries have formulated their own cosmetic regulations. In India, cosmetics are regulated under the Drugs and Cosmetic Act, 1940 and rules created by the Central Drugs Standard Control Organization under the Ministry of Health and Family Welfare, Government of India. Whereas the European Medicines Agency is the regulatory authority of cosmetic products in the European Union (EU), covering all the 27 EU member states along with Norway, Iceland, and Lichtenstein. Despite all regulating bodies sharing the same objective, the process of cosmetic product registration; manufacturing; licensing systems for import and distribution; labeling; and packaging vary from country to country. The present review provides a comparative insight into the cosmetic regulations in the EU and India, which will not only help in the growth of the cosmetic industry, but also will help in the manufacturing of safe and quality cosmetic products in India.

*Keywords:* cosmetic regulations, EU, drugs, rules, heavy metals

### **HISTORY AND INTRODUCTION**

Cosmetic refers to a range of beauty products intended to alter facial appearance, mask the odor of body parts, and enhance the overall quality of skin and health. The use of cosmetic products is as old as our civilization. It is believed that Egyptians, as early as 10,000 bc,

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used to apply various natural components, scented oils, ointments and their mixtures on their face and body parts to improve color and odor in several religious activities, group events, and even before burial (1). The English word “cosmetic” is derived from the Greek word *kosmetike* (*tekhne*), equivalent to a Latin word *medicamentum*, which means “the art of beautifying, art of anointing or decorating the human body” (2). The term cosmetic was not used until the beginning of 17th century and was first used by Sir Francis Bacon (1561–1626), an author and a scientist (2). It is reported that Egyptians used to live in valleys with natural resources, where they applied the mixtures of olive oil, almond oil, and creams on skin in order to protect it from sunlight and dry winds (3). Kohl, an antimony-based compound and a combination of burned almonds, oxidized copper, and different colored coppers, ores, lead, ash, and ochre, was used by Egyptian women to shape their eye shadow (4). Furthermore, henna, leaf extract from the shrub *Lawsoniainermis*, was commonly used as a hair dye in North Africa and several Asian countries including India (4). In early Common Era (ce), Romanian people used to apply the paste of barley flour and butter for acne treatment. From 1400 to 1600, Italy and France emerged as main centers of beauty products, and used arsenic and lead-based powders in the preparations of facial powders (5). Later on, toxic, carcinogenic, and deadly lead-based preparations in facial powders were replaced by zinc oxide.

Though the new term “makeup” was introduced as a verbal phrase in 1808, it was used as a noun after 1886 (2). In 1920, first liquid nail polish was introduced to the market. Later, Drene® (Procter & Gamble, Cincinnati, Ohio), the first detergent-based shampoo, was introduced into the marketplace in 1934. In 1999, the United States Food and Drug Administration, in association with other country representatives, conducted the first ever Cosmetics Harmonization and International Cooperation (CHIC) meeting in Brussels, Belgium and discussed the safety of cosmetic products, the exchange of data, and an international memorandum of cooperation.

In current years, there is an increased interest in cosmetic, beauty, and personal-care products. People are more inclined to use cosmetic products in order to improve their physical appearance, skin softness, body odor, and overall health. As there is a large variety and variability of finished cosmetic products, as well as cosmetic ingredients, their safety to human health is of utmost importance. As previously mentioned, several toxic, carcinogenic components might act as ingredients of cosmetic products that might pose a risk to human health; therefore, it is essential to regulate the importation and manufacturing of all cosmetic products worldwide. Although there are several regulating agencies in different countries to regulate the manufacturing, labeling, packaging, importation, and distribution of cosmetic products, the objective is same: ensure the safety of the product in order to protect the consumers' health. For example, Food and Drug Administration (FDA) is the regulatory body in the US, whereas, the European Medicines Agency (EMA) is the regulatory authority in the EU, covering all 27 EU member states along with Norway, Iceland, and Lichtenstein. In India, cosmetics are regulated by the Central Drugs Standard Control Organization (CDSCO) under the Government of India's Ministry of Health and Family Welfare. Despite all regulating bodies sharing the same objective, the process of cosmetic product registration; manufacturing; licensing systems for import and distribution; labeling; and packaging vary from country to country. Some cosmetic ingredients that are prohibited in one country might be allowed in another country. Similarly, some items that fall under the category of cosmetics in some countries might be categorized as OTC (over the counter) drugs in others. The present contribution provides a comparative insight into the cosmetic regulations in the

EU and India, which will not only help in the growth of the cosmetic industry, but also help in the manufacturing of safe and effective cosmetic products in India.

#### REGULATORY BODY OF COSMETIC LEGISLATIONS IN INDIA AND THE EU

In India, the CDSCO regulates cosmetic products. The Drugs and Cosmetics Act, 1940, originally known as the Drug Act, was passed by the Indian Parliament on April 10, 1940, with the primary objective to ensure the safety and efficacy of the drug and cosmetic products intended for human use, and conformity to the state quality standards. Later, the Drugs and Cosmetics Rules, 1945 came into the existence, giving the provisions for classification of drugs and cosmetics along with the directions of their manufacturing, storage, sale, and display under different schedules and annexures. Under these rules, the first notification for “Import and Registration of Cosmetics” was introduced on May 19, 2010, but was not implemented until April 1, 2013 (6). More recently, on December 15, 2020, the Ministry of Health and Family Welfare passed the Cosmetics Rules, 2020 with the purpose of regulating the importation and manufacturing of cosmetics separately for sales and distribution in India. The Bureau of Indian Standards (BIS), a national standard body, gives the labeling declarations for cosmetic products. Also, BIS gives the standards and requirements for finished cosmetic products as well as cosmetic ingredients listed under Schedule S of the Drugs and Cosmetics Rules, 1945.

The EMA is the regulatory agency of cosmetic products in the EU. The Council Directive 76/768/EEC was the first legislative directive, introduced on July 27, 1976 in the EU, which was formed to govern the composition, labeling, packaging, and distribution of cosmetic products in all 27 EU member countries with the primary objective to protect human health (7). Though Council Directive 76/768/EEC (the old directive) was amended several times, a major amendment was done in January 2003 to ban over 1,100 chemicals in cosmetics on the basis of a safety report provided by the EU Scientific Committee on Consumer Products. On November 30, 2009, the old directive was replaced by a new EU regulation (EC) No. 1223/2009, which was enforced effective July 11, 2013. In comparison to the old directive, new EU regulation included detailed composition and labeling directions, directives on maintenance of product information files (PIF), harmonized notifications, and clearer provisions for the content and format of product safety assessment reports. EU regulation (EC) No. 1223/2009 also included the recent advancements in cosmetic ingredients, such as the use of nanomaterials that were not considered in the old directive (8).

#### DEFINITION OF COSMETIC AS PER INDIAN AND EU LEGISLATION

According to the Drugs and Cosmetics Act 1940, and Rules 2020, cosmetics in India are 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” (9).

As per the Cosmetics Directive (EU regulation 1223/2009, Article 2.1.a), cosmetic is defined 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 correcting body odors and protecting them or keeping them in good condition.” Any product that is placed in the EU market under this category must comply the requirements of the EU cosmetic regulations irrespective of its place of origin or manufacturing.

#### PREMARKET REQUIREMENTS

In India, before placing any locally manufactured cosmetic product in the market, it is mandatory for the manufacturer or responsible person to take preapproval from the State Licensing Authority (SLA). Manufacturers must prepare a dossier file of the product’s information that should contain all the related information such as composition, ingredients, safety data, expiry period, etc. and that must comply the regulations of Cosmetic Rules, 2020 and the Indian Standards as laid down by the BIS. All these details need to be submitted to the SLA along with application form, fees, and other supporting documents. Thereafter, the SLA issues a license for the manufacturing of that cosmetic product for sale or distribution in India. The license shall remain valid in perpetuity, subject to payment of license retention fees before completion of the period of 5 y from the date of issue, unless it is suspended or canceled by the SLA. However, in case of “new cosmetics,” the concept of which has been introduced recently in Cosmetic Rules, 2020, no license shall be granted to a manufacturer by the SLA until the manufacturer takes prior permission from the Central Licensing Authority i.e., the Drugs Controller General of India (9).

In the EU, the cosmetics products notification portal (CPNP) is the online notification portal created for the enforcement of Regulation (CE) No. 1223/2009, which requires an online notification before placing a cosmetic product in the market. The online notification includes information on the name and category of the product; the name and address of the responsible person including his contact details; the country of origin in case of import; the first country where the product will be placed on the market; the presence of nanomaterials and CMR substances; the cosmetic product’s formulation; and a compliant label with a photo of the external packaging (if legible). The manufacturer (legal person: individual or company) or responsible person (in case of imported cosmetic product/s) must prepare a PIF. The PIF is a regulatory file that contains the product’s related information such as composition, safety, ingredients, good manufacturing practices (GMP), sampling and analysis, CMR (carcinogenic, mutagenic or toxic for reproduction) substances, nanomaterials, animal testing, and labeling and packaging, and must comply the requirements set by EU cosmetic regulations. Overall, the PIF is divided into two parts: Part A, which contains detailed information of the cosmetic product, and Part B, which is more important and includes the safety assessment information of the cosmetic product. After preparing the PIF, the responsible person shall notify the EU authority online through the CPNP. The product must comply with the Regulation EC No. 1223/2009 and must be safe to human health. Only one notification is required for a product to be marketed in 30 countries controlled by the EU. Any change in composition, unwanted effects after use, recall, etc. must be reported by the responsible person using the CPNP (10). After the notification, the product can be placed into the EU market.

#### REQUIREMENTS FOR IMPORT OF COSMETIC PRODUCTS

The licensing process is totally different in the case of imported cosmetic products in India. Unlike locally manufactured cosmetic products for which the SLA issues a license,

imported cosmetic products must first be registered with the Central Licensing Authority through SUGAM, an online portal, by the importer, original manufacturer, or authorized agent. Only then can the product be placed into the Indian market. After the registration, regulatory persons examine and verify the documents, and, if satisfied, grant an import registration certificate that remains valid in perpetuity, subject to payment of registration certificate retention fees as specified in the Third Schedule before completion of the period of 5 y from the date of its issue, unless suspended or canceled by the Licensing Authority. As per the Cosmetic Rules, 2020, any cosmetic product that is prohibited to be manufactured, sold, or distributed in India shall not be imported in the same or other name, with an exception for analytical purposes. Apart from that, no cosmetics shall be imported unless the “use before” or “use by” date shown on the label, wrapper, or container of the cosmetic is more than 6 mo. from the date of import. Additionally, after November 12, 2014, no cosmetic that has been tested on animals or contains hexachlorophene shall be imported into the country.

In the EU, cosmetic products imported from developing countries may be placed in the market subjected to prior notification through the CPNP. First, the responsible person or the designated person gathers all the information about the product to be imported, such as composition, stability of raw material/ingredients, formula, challenges, manufacturing method, safety documents, and studies to determine whether the finished product complies with the requirements and standards set by EU regulation. The labeling and packaging of the product must also comply with the requirements and regulations of EC No. 1223/2009. After gathering all the information, the responsible person shall prepare a PIF that contains detailed information about the product and safety assessment data and has been examined by a certified toxicologist or pharmacist, and then shall notify the European authority through the CPNP. Overall, the importer or responsible person would be accountable for any query raised by the authorities or public after placing the product in the EU market.

#### LABELING REQUIREMENTS

In India, labeling and packaging requirements are given in Chapter VI of Cosmetic Rules, 2020. As per the rules, no person can sell or distribute cosmetic products that are not manufactured by a licensed manufacturer and do not comply the labeling or packaging requirements. Furthermore, the outer and inner label of the packaged product must carry the following information:

1. The name of the cosmetic product.
2. The name of the manufacturer and complete address of the manufacturing location.
3. Use before or date of expiry (month and year).
4. A distinctive batch number [not applicable if amount is  $\leq 10$  g (in case of solid or semi-solid product) and  $\leq 25$  ml (in case of liquid state), and for soaps] on inner or outer label.
5. Manufacturing license number (on inner or outer label). (In case of imported products, if such provision is not mandatory in the country of origin, such cosmetics may be allowed without mentioning the manufacturing license number, subject to fulfillment of other import regulations).
6. Net content of the product (on outer label).
7. In case of cosmetics, where a hazard exists, every inner label shall clearly indicate adequate directions for safe use; any warning, caution or special direction required to

be observed by the consumer; and a statement indicating the names and quantities of ingredients that are hazardous or poisonous.

8. Import registration certificate number on the label of unit pack (for imported products).

Apart from that, there are some special labeling requirements for hair dyes containing dyes, colors, and pigments, and for toothpaste containing fluoride (not more than 1,000 ppm), which have been described in Chapter VI of Cosmetic Rules, 2020.

In EU, the cosmetic products placed in the EU market must comply the labeling requirements mentioned in Chapter VI, Article 19 of EC No. 1223/2009 and should include the following information:

1. The name or registered name and the address of the responsible person.
2. Country of origin (in case of imported product).
3. Net content of product at the time of packaging (except in the case of packaging containing less than 5 g or 5 mL, free samples, and single-application packs).
4. Date of minimum durability (if durability is <30 mo.). If durability is >30 mo., then duration for which the product is safe to use after opening should be listed.
5. Batch number.
6. Particular precautions to be observed in use.
7. The function of the cosmetic product unless it is clear from its presentation.
8. A list of ingredients.

In the EU, the language of the label is determined by the member state in which product is intended to be used or marketed. Any ingredient that is a nanomaterial must be mentioned on the label by indicating “nano” in bracket.

#### PROHIBITED AND ALLOWED LIST OF INGREDIENTS

In India, the BIS issued a draft “classification of cosmetic raw materials and adjuncts” to specify the requirements for ingredients used in the manufacturing of cosmetics. The BIS has issued a positive list of dyes, colors, and pigments that are allowed (GRAS: generally recognized as safe) for use in cosmetics (IS: 4707 Part I); a negative list of raw materials that shall not form part of the composition of cosmetic products (Annex A); and a list of substances that cosmetic products shall not contain except subject to restrictions and conditions laid down (Annex B) (IS: 4707 Part II). In addition to that, Annex C and D provide a list of preservatives and UV filters that cosmetic products and sunscreen products may contain, respectively.

In the EU, the list of prohibited substances that may cause cancer, mutations, genetic mutations, birth defects, etc., and the substances that cosmetic products must not contain (subject to the restrictions) are mentioned in Annexure II and III of Regulation (EC) No. 1223/2009, respectively. Recently, these lists were amended and mentioned in Commission Regulation (EU) 2020/1683 of November 12, 2020. When compared with (EC) No. 1223/2009, 3 chemicals (1,2,4-Trihydroxybenzene, 4-Amino-3-hydroxytoluene, and 2-[(4-Amino-2-nitrophenyl)-amino]-benzoic acid), when used as a substance in hair and eyelash dye products, were added to the list of prohibited substances as mentioned in revised Annexure II of (EU) 2020/1683. Similarly, six new chemicals that cosmetic products must not contain (except subject to the restrictions laid down) were added in Annexure III.

## REGULATIONS FOR THE USE OF HEAVY METALS IN COSMETICS

In India, Cosmetics Rules, 2020 prohibit the manufacturing and importing of those cosmetics that contain mercury compounds as such lead or arsenic compounds as colorants. The dyes used in the manufacturing of skin creams and lipstick must comply with IS 4707 (Part I) as per the Schedule Q of Cosmetics Rules, 2020; and other ingredients are required to comply with IS 4707 (Part II). Cosmetics Rules, 2020 restricts the use of dyes, colors, and pigments other than those specified by the BIS (IS: 4707 Part I as amended) and Schedule Q. It also indicates the permissible limits for synthetic organic colors and natural organic colors used in the cosmetics as 2 ppm of arsenic (from arsenic trioxide), 20 ppm of lead, and 100 ppm of total heavy metals other than lead. Unfortunately, the IS 6608:2004 states that if all the raw materials have been tested for heavy metals and comply with the requirements, then the manufacturer need not test the finished cosmetic for heavy metals and arsenic.

As per the European Regulations (EC) No. 1223/2009, the use of heavy metals enlisted in Annexure II of amended Regulation (EU) 2020/1683 is prohibited for use in the manufacturing of cosmetics for sale and distribution in EU market. These include heavy metals such as lead, mercury, cadmium, arsenic, antimony and its compounds (except those special cases included as preservatives in Annexure V). According to Article 17 of the regulation, the use of such heavy metals or compounds is allowed only to such an extent that is safe for human use and technically unavoidable under GMPs. The safety of the product must be demonstrated in the safety assessment part of the PIF. It is reported that if the content of lead, cadmium, mercury, and arsenic is more than 2.0, 0.1, 0.1, and 0.5 ppm in various cosmetic products and 0.5, 0.1, 0.1, and 0.5 ppm in toothpaste, then, technically, they are avoidable (11).

## SIMILARITIES AND DIFFERENCES

There are a few similarities in cosmetic regulations of India and the EU:

1. The manufacturer or designated person would be fully responsible for the safety of the manufactured or imported product in both the markets.
2. Follow-up, observation, and verification of safety of the registered cosmetic product by the regulatory authority.
3. No restrictions on sales channels (12,13). However, a few differences also exist among the legislations of both the countries. For better understanding, a comparative view of Indian and European cosmetic regulations is summarized in [Table I](#).

## HIGHLIGHTS OF NEW COSMETIC RULES, 2020 VERSUS DRUGS AND COSMETIC RULES, 1945

By keeping in mind the few shortcomings in Drugs and Cosmetics Rules, 1945 such as multiple licensing systems for imported products; complex process for applying for registration or licenses; lack of safety data information with state regulatory authorities; a time consuming process of license grating etc., the Ministry of Health & Family Welfare, Govt. of India has issued a new set of rules named Cosmetic Rules, 2020 for the manufacturing and the import for the sale and distribution of cosmetics in India separately,

**Table I**  
Comparison of Cosmetic Regulations in India and the EU

	India	EU
<b>Regulating Authority</b>	CDSCO for import and registration State Licensing Authorities for manufacturing for sale and distribution in India.	EMA
<b>Act and Regulations</b>	Drugs and Cosmetics Act, 1940, and Cosmetics Rules, 2020 wef. 15.12.2020	Council Directive 76/768/EEC (27th July 1976), replaced by Regulation (EC) No. 1223/2009 on November 30, 2009
<b>Under/Created By</b>	Ministry of Health and Family Welfare	European Parliament and Council
<b>Primary Objective</b>	To ensure the safety, efficacy, and conformity of cosmetic products to state quality standards	High-level of protection for the safety and health of EU citizens
<b>Premarket Product Approval</b>	Required (from SLA)	Products must be notified before marketing, but preapproval is not required (with the exception of color additives, sunscreen active ingredients, and preservatives)
<b>Premarket Assessment of Product for Safety</b>	Required	Required
<b>Labeling Requirements</b>	Labeling should comply with the provisions of Cosmetics Rules, 2020 and the BIS	Should comply declarations issued by Council Directive 76/768/EEC
<b>Post-Market Reporting</b>	Not applicable	Not applicable
<b>Product's Safety Report (Before Placing the Product in Market)</b>	Manufacturer or responsible person should maintain a report with himself and produce to authority, if required	Should be prepared in two parts: Part A (detailed product's information), & Part B (assessment report), and must be provided to authority upon request
<b>PIF</b>	A dossier file must be prepared by manufacturer or responsible person and should be submitted to State authority at the time of applying for a license	Responsible person should maintain a PIF till at least 10 y after the dispatch of last batch in the market
<b>Is There Safety/ Technical Information Available to Regulatory Authorities?</b>	Complete technical information should be provided to SLA	A full technical dossier on the cosmetic product must be kept available for inspection upon request of the local authorities
<b>Mode of Information of Any Change in Cosmetic Product/S</b>	By online portal and offline mode (SUGAM: an online portal for registration of imported items)	By CPNP
<b>Language of Label</b>	English	English and National Language
<b>Use By Date/Expiry of the Product</b>	Use before or use by date must be mentioned on label	Date of minimum durability should be mentioned on label if durability is <30 mo. If durability is >30 mo., then duration should be mentioned after opening for which the product is safe to use

(Continued)

**Table I (Continued)**  
Comparison of Cosmetic Regulations in India and the EU

	India	EU
<b>Manufacturing License Given By</b>	Manufacturing license is compulsory and given by SLA (CDSCO does not grant license to manufacture cosmetics in India)	“Certificate of manufacture” equivalent to “Certificate of free sale” is given by state member country
<b>Registration License for Imported Cosmetic Products</b>	Required Registration Certificate is required for import of all cosmetic items and issued by CDSC	Required 'Certificate of free sale' (equivalent to Certificate of Manufacture) is required to freely distribute throughout EU
<b>Validity of Registration Certificate</b>	5 y unless canceled or suspended and remains valid in perpetuity	—
<b>Animal Studies For Testing of Cosmetic Products And Ingredients</b>	Completely ban. Furthermore, any cosmetic product that is tested on animals is not allowed to import in India	Completely ban ( <i>in vitro</i> studies are allowed)
<b>Safety Warning/Cautions on Label</b>	On inner label only	On inner and outer label
<b>Use of Lead and Arsenic Compounds in Cosmetics</b>	-Prohibited (for the purpose of coloring) -Allowed in traces with maximum limit when used as permitted synthetic organic colors and natural organic colors	Prohibited, but traces are allowed if unavoidable by GMPs and does not pose any risk to human health
<b>Mercury Compounds in Cosmetics</b>	The manufacturing and import of cosmetics containing mercury compounds is prohibited in India	Prohibited, but traces ( $\leq 1$ ppm) are allowed does not pose any risk to human health
<b>How Are the Regulations Enforced?</b>	By state authority and the CDSCO	By a competent authority appointed by each state member in its country with the cooperation of EU Commission
<b>Prohibited/Allowed Raw Materials Chemicals for Use in Cosmetic Products</b>	BIS has divided chemicals in two parts: Part I Colorants (generally recognized as safe and allowed) Part II enlist generally recognized as safe chemicals, allowed preservatives and UV filters	2,442 substances are banned and listed in Annexure II of cosmetic regulations Restricted and allowed ingredients (Colorants, conservative agents and UV filters) are listed in Annexure III and IV-VI, respectively

enforced from December 15, 2020. The key amendments done in new Cosmetic Rules, 2020 are as follows.

*The concept of “new cosmetics.”* The concept of new cosmetics is introduced in new Cosmetic Rules, 2020 and was not present in previous regulations. The term “new cosmetic” is defined as “a cosmetic which contains a novel ingredient that has not been used anywhere in the world or is not recognized for use in cosmetics in any national or international literature.” According to the rules, manufacturers or importers must seek the approval from the Central Licensing Authority before applying for a license or the registration of new cosmetics in India. The safety data information should made be available with Central Authority and the product must comply the safety standards specified by BIS.

*Import and registration of cosmetics.* Though no major change was made to the registration process of imported items, a significant reduction in registration fees was made. Additionally, the new rules streamline the process for applying for a registration certificate. The importer can make a single license application and seek a single registration certificate for the import of one or more cosmetics manufactured by the same manufacturer in a single manufacturing unit. The new rules also prohibit the import of cosmetics if:

1. The manufacturing, sale, or distribution of the cosmetic in question is prohibited in the country of origin.
2. The “use before” or “use by” date is less than 6 mo. from the date of import.
3. The cosmetic contains hexachlorophene.
4. The cosmetic has been tested on animals after November 12, 2014.

*The manufacturing of cosmetics for sale or distribution.* Under new rules, a self-declaration needs to be furnished by the applicant confirming compliance with GMPs and other prescribed requirements. The licensing process remain the same in the case of manufacturing of cosmetics for sale and distribution in India.

*Quality of cosmetics and recall.* The new rule prohibits the manufacturing or import of cosmetics that do not comply with the safety and quality standards set by Cosmetics Rules, 2020 and BIS. If the manufacturer or responsible person believes that the product placed in the market is likely to pose a health risk to humans, the product must be recalled immediately, and the same information should be reported to the state or the Central Licensing Authority with valid reasons.

## CONCLUSION

Despite the difference in Cosmetic Regulation of India, EU, or any other country, the main objective of all remains the same, human safety. Unlike in the EU, premarket approval is required for all the cosmetic products in the Indian market. The new cosmetics rules have consolidated, streamlined, and upgraded the safety and regulatory requirements to import or manufacture cosmetic products for sale and distribution. The new rules improved the accountability and responsibility of importers and manufacturers to ensure the safety and quality of their cosmetic products. The registration and licensing system became more user-friendly with reduced fees and more validity. SUGAM, an online portal for the registration to import and sell cosmetics in India, has made the overall process easy, more efficient, and more transparent with a tracking system. There have been continuous efforts to harmonize and align regulations globally through the International Cooperation on Cosmetic Regulation (ICCR), which is the continuation of CHIC.

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