

REGULATORY PROTOTYPE FOR COSMETICS IN INDIA

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ABSTRACT

The cosmetics market is changing around the globe dramatically. The cosmetics safety, efficacy, regulatory framework, and marketing of cosmetic products are the important factors of the growth of the cosmetic industry. Cosmetic safety is regulated by diverse regulatory bodies of the globe, that is, the countries that have their own rules and regulations. The cosmetic market in India is Central Drug Standard Control Organization through the Drug and Cosmetic Act, 1940 and Rules 1945. India has stringent rules and regulations for cosmetic products. This manuscript describes the overall cosmetics scenario, requirements for registration of cosmetics import and manufacturing.

Keywords: Cosmetics, Current scenario, Labelling, Regulation, Registration Process.

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INTRODUCTION

Cosmetic is a very diverse product, such as cream, perfumes, lotions, skin cleansing products, and decorative cosmetics sector [1]. The word cosmetic was derived from the Greek word "kosmtikos" that means having the ability, arrange, and talent in decorating [2]. The origin of cosmetics was related to looking, fighting, faith, and superstitious notion and later related to medication [3]. The cosmetic industry generates the use of advanced new technologies to form newer cosmetics with many properties. Many regulatory bodies are regulating the manufacture and sale of cosmetics everywhere in the world [4]. India's cosmetics industry is driven by the increase in personal disposable income of people, increasing the awareness towards body aesthetics, joined with increasing the demand for herbal cosmetics [5]. There is an increase in the adoption of herbal cosmetic products guided to rising of the segment of 15% yearly on the backward of the fact people becoming much aware of possible side effects on the skin by the constant use of chemical formulations-based cosmetics [6]. Indian cosmetics are rising around 20% yearly. In India, it is sufficiently grown and accountable to form sure the quality and safety of the product. The regulations of cosmetics in India are much complex and time-consuming which are needed for both pre-marketing post-marketing approvals. These are important for manufacturers, importers, and distributors of cosmetics to know the regulatory system in India [7]. The definition of cosmetics in India, as per the Drugs and Cosmetics Act 1940 and Rules 1945 Cosmetic is defined as an article meant to be rubbed, sprinkled, poured, or applies to the part of the human body or for cleansing, beautifying, enhancing attractiveness, or altering the looks [8-10]. The cosmetic product does not come under the preview of the drug license [11].

COSMETIC REGULATIONS IN INDIA

In India, cosmetic products are governed under the Drugs and Cosmetics Act 1940, rules 1945, and labeling Declarations by the Bureau of Indian Standards (BIS). The cosmetic standards are set by the BIS, and it is included under schedule "s" of the Drugs and Cosmetics Rules 1945 and also BIS provides the specification for skin creams and lipsticks in the Indian standards (IS) 6608:2004 and 9875:1990 [12,13].

As per the Indian standards 6608:2004, each raw material must need a test of heavy metals, later it has been examined and should meet the following requirements. If these are tested early, the manufacturer may need not to test the finished cosmetic product for arsenic and heavy metals [14].

Rule 134 of Drugs and Cosmetics Rules have certain controls in the use of cosmetics consists of colors, pigments, and dyes in addition to those mentioned by the BIS, and schedule Q. Rule 145 of D&C Rules eliminates the usage of arsenic and lead compounds in cosmetic products of the motive of coloring rule. Rule 135 prohibits the cosmetics import which arsenic or lead compounds that have been used for coloring and Rule 145 D and 135 A prohibits the import and manufacture of cosmetics having mercury compounds [15]. An organogram of cosmetics in the Central Drug Standard Control Organization (CDSCO) division is described in Fig. 1.

Categorization of cosmaceuticals

Cosmaceuticals are cosmetic-pharmaceutical hybrids intended to enhance beauty [17].

Cosmeceuticals are cosmetic products with biologically active components purporting to have medical benefits [18,19].

Cosmaceuticals classification will enable companies of cosmetics to market their product. Cosmaceuticals can be categorized based on the product that has the pharmaceutical reaction and it can be used on ordinary or near-normal skin. The product must have the benefit of fewer skin disorders. Risk profile of the product must be less than that of the skin disorder. Classification of cosmaceuticals is classified as the subclass of cosmetics or drugs [20].

CLASSIFICATION OF COSMETICS AS PER CDSCO

Cosmetics are mainly divided into four types described in Fig. 2 [21,22].

MANUFACTURING OF COSMETICS REQUIREMENTS FOR FACTORY PREMISES

The factory premises should comply with few conditions under Schedule M-II. The general requirements are as follows [23]:

Location and surroundings

The factory premises can be located in hygienic conditions and sanitary places shall be maintained on the premises. The area of manufacturing must be ventilated and clean [24].

Buildings

The manufacturing room walls must be up to a height of 6 feet from the floor to carry out the operations. It must be smooth, waterproof, and suitable for being remaining clean [25].

Water supply and disposal of water

The usage of water by the manufacturer for manufacturing purposes should use the drinking water. Suitable arrangements shall be made for the disposal of wastewater [26].

Staff health, clothing, and sanitary conditions

All the workers must be free from communicable or contagious diseases. They need to be supplied with clean uniforms, gloves, and masks wherever required [27]

Cosmetic license for manufacturer

Product details such as quality, safety, and compliance to BIS must be submitted for regulatory review [28].

The manufacturer should get a cosmetic license according to the drugs and cosmetics act 1940.

- Form no: 32 for a license is granted for manufacturing the cosmetics for sale or distribution
- Form no: 31, the application is filed. The application should be submitted along with the fee of Rs.2500 and an inspection fee of Rs. 1000 additional fees will be deposited, if no of the items in any category exceeds ten [29]
- The application is accompanied by the following documents:
 - Layout plan of the factory premises
 - List of equipment and machinery to be installed
 - A document showing the constitution of the firm
 - A document showing the possession of the applicant for the proposed premises for factory, for example, rent receipt.
- Form no: 32A for a license is granted for loan license for cosmetic manufacturing for the sale or distribution and form no: 31A the application is filed
- Form no: 37 for a license is granted or renewal of raw material used in the manufacturing or for conducting tests on drugs for approval on behalf of license for manufacture and sale of drugs and cosmetics [30,31].

Registration procedure for the import of cosmetic

For the importation of cosmetic products in India, a compulsory registration certificate is needed issued by the central licensing authority (CLA) under rule 21 [32].

- The manufacturer or authorized channel can apply for a registration certificate in India
- The application should be submitted to the office of the Drugs Controller General of India under the Ministry of Health and Family Welfare (MoHFW), New Delhi [33]

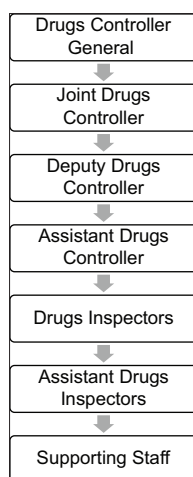


Fig. 1: Organogram of Cosmetics Division in CDSCO [16]

- It should be submitted in both the format as hard copy and also electronically
- The application must be submitted in the prescribed form – 42 along with a cover letter. It is viewed, stamped, and signed by an authorized person. Moreover, original fees payment of registration receipt is required, it is USD250 or equivalent per imported product [34].

Cosmetics are imported from the ports as per the rule 43 of the Drugs and Cosmetics Act [35].

The following can import cosmetics in India

1. The manufacturer must have a registered office in India
2. The authorized agent of the manufacturer
3. It is a subsidiary agent of the manufacturer.
4. Any other importer [36,37].

Time duration for grant of import license

If the application is submitted correctly, the CLA will grant an import license in Form 10, within 3 months from the date of acceptance of an application [38]

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) [41].

REGISTRATION OF COSMETICS IN INDIA**Prohibitions and exemptions**

The following categories of cosmetics are prohibited in India:

- Those cosmetics banned in their country of origin
- Cosmetics comprising of hexachlorophene
- Cosmetics tested for animals later October 13, 2014
- Cosmetics import unless a "use before" or "use by" date on packaging or labels [44,45]

Timeline

The timeline for the registration certificate is granted in form 43, according to rule 129C granted if the application is fulfilled if all aspects and the required information mentioned in schedule D III. The timeline for the registration certificate is granted within 6 months from the date of submission, if it is delayed, the reasons should be recorded in writing; the registration certificate can be granted within 3 months but should not extend more than 3 months from the extended period [46,47].

The validity of registration certificate

The registration certificate is valid for 3 years from the date of issue [48,49].

Online application for registration of cosmetics

Steps for the online application for registration of cosmetics:

- The portal is accessed using the link <http://cdscoonline.gov.in>.
- After getting inside the link signup and create login credentials
- Submit all information with a valid e-mail id and mobile number and complete the signup process and login into the portal
- Select the type of form and select the department in the form submission section

1. Skin product	2. Hair and scalp products	3. Nail and cuticle products	4. Oral hygiene products
<ul style="list-style-type: none"> • Skin care products • Correction of body odour products • Hair removal products • Skin cleansing products • Make-up products • Bleach for body hair care products • Perfumes 	<ul style="list-style-type: none"> • Hair and scalp care and cleansing product • Hair styling products • Hair colouring products • Another hair and scalp products 	<ul style="list-style-type: none"> • Nail varnish and removal products • Nail glue remover products • Nail care products • Another nail and cuticle products. 	<ul style="list-style-type: none"> • Tooth care products • Tooth whiteners • Mouth wash • Another oral hygiene care products

Fig. 2: Classification of Cosmetics

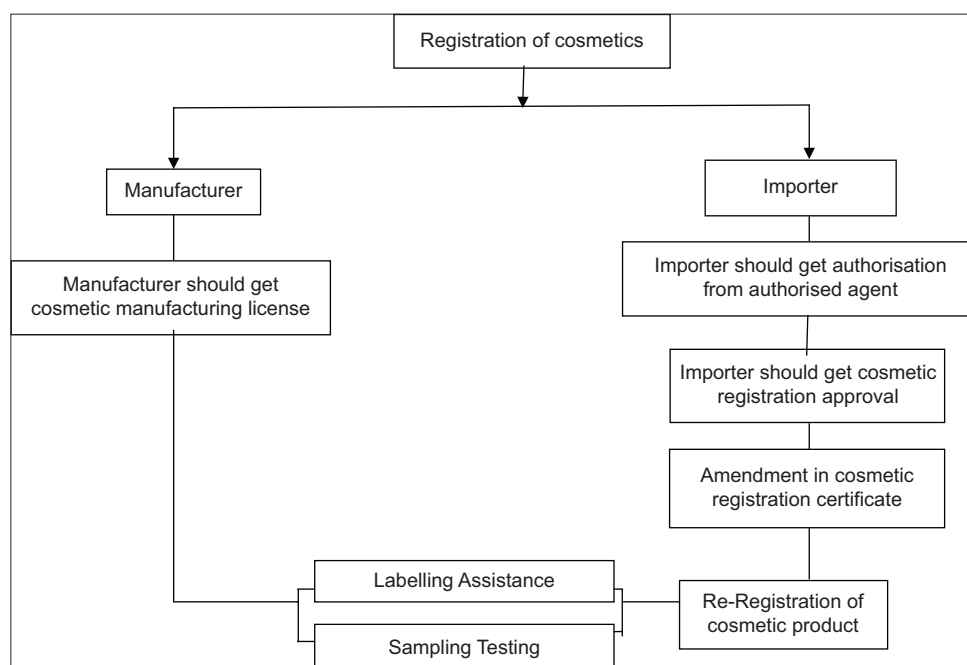


Fig. 3: Registration procedure

- Select the type of application that needs to be submitted, for example, fresh, endorsement, etc.,
- After the final submission, checks the form information and clicks the continue button to the further process. It will be redirected to the preview page. In the preview, users can see the complete details filled by the users. Click on the edit option to change any corrections in the applied form. Later see the form information and click on save and continue the option to carry further process
- If once moved to the checklist page, if any changes in the application form, there is no permission to change. Click on every point to upload documents electronically. The uploaded document will vary from point to point. After uploading all documents, click the submit option to proceed further
- Multiple challans may be uploaded up to a maximum limit of five challans
- Convert the documents into PDF form. A full preview will consist of the information on the payment done by the user. Click on the continue option to proceed further
- To submit the documents electronically, selects the browse button and choose the file from your system click on the submitting button to proceed further. Upload form 42, which is downloaded as a PDF earlier full preview page
- RC application will be uploaded successfully, and the online application will be forwarded to the respective designated office.

The submitted applications will be viewed by the designated officer for compliance with required document registration. The reference number should be noted for future reference

- If the submitted application is well made in all aspects, then it is forwarded to the licensing authority for approval. After approval, the approval letter will be available on the applicant's SUGAM dashboard
- If the application is not satisfactory, then discrepancies in the application are informed to the applicant in the SUGAM portal. After the completion of discrepancies, it is compiled together then processed for approval [50].

Renewal

Applicants have to file a Form 43 issued by the CDSCO earlier than its expiry to continue importing cosmetics has a validity of 3 years [51].

Documents required for the renewal registration certificate

- Original copy of the power of attorney
- Necessary fees
- Form 42 duly filled and signed with the list of products to be renewed
- Original certificate of free sale/Marketing Authorization letter/Manufacturing licenses, if any
- Copy of endorsement certificate and original RC were granted earlier
- Undertaking/self-declaration mentioned there are no changes in earlier shared information on product details such as test method,

specifications, label, and composition; these all should comply with rule 148 of drugs and cosmetics rules 1945 [52,53].

Labelling aspects

India has a cosmetic labeling requirement as per the Drugs and Cosmetics act, The Legal Metrology Act 2009, ECO Labelling Standards by BIS [54]. The label should contain the name of the cosmetic, address of the manufacturing industry; these should be mentioned on both the sides of the label is the inner and outer sides of the labels [55]. The inner label of the cosmetic product should contain if any warning indication, the directions of use, and names and composition of the ingredients that are hazardous or poisonous. The outer label must include the quantities of net contents of ingredients used in manufacturing. For the small containers, the principle of manufacturing and pin code is sufficient [56,57].

The labels should mention the batch number it is mentioned by a letter "B" and for soaps, the months and years of the manufacturing may be mentioned instead of letter B and these are not applicable for the cosmetics having 10 g or less for the solid or semisolids and liquid 25 ml or <25 ml for the state products. Moreover, in the label letter, "M" denotes the license number for manufacturing compulsorily [58,59].

CURRENT COSMETIC MARKET SCENARIO IN INDIA

In India, the cosmetic product is categorized as skincare, haircare, oral care, color cosmetic sections, fragrances, and more. The cosmetic market in India is currently USD 6.5 billion it is anticipated to reaching up to USD 20 billion with a compound annual growth rate of 25% by 2025. Moreover, on the other side expected to reach USD 450 billion with a compound annual growth rate of 4.3% by the global cosmetic market by 2025. India will hand out 5% of the global cosmetic market and it comes under one of the top 5 global markets [60].

CURRENT AMENDMENTS

In the Drugs and Cosmetics act, the labeling section notified few amendments they are, the ingredient must be announced in the declining order of different concentrations decreasing to 1% and in any order below 1%. Use before the date in preference to best use earlier than the date which was declared earlier as XX months/year from the packaging date [61].

Recently, CDSCO published the Gazette notification regarding the registration of cosmetics and import. To amend the rules for cosmetics import, early for the registration of cosmetics, there was no legislation in India. A present, this rule tells that any cosmetics cannot be imported into India unless the product is registered under these rules by a licensing authority it is appointed by the central government. The amendment came into force in 2011 from the 1st of April [62].

The MoHFW notified the Cosmetic Rules 2020 on December 15, 2020, with an aim to separately codify and update the rules relating to import, manufacture, labeling, sale, and distribution of cosmetics in India [63].

NEED FOR COSMETOVIGILANCE IN INDIA

Cosmetovigilance is defined as the process of collection, analysis, and assessment of adverse reactions and events appearing in consumers in order to identify any potential health risk, thus guaranteeing a further strengthened safety for consumers [64]. India consists of a huge population, and the marketing of cosmetics is also high. Dermatitis and other related conditions are more frequent in India and cosmetics are implied in the same. Adverse events to the use of conventional agents are also informed frequently, for instance, Kajal and Kumkum dermatitis. The import of cosmetics examined in animals is restricted in India as specified in section 135 B of the D&C Act. Because of that appropriate regulation for cosmetics ingredients, a proper vigilance system is also needed to safeguard the health of the Indian population. Cosmetovigilance is used to control hazardous ingredients in cosmetics

preparations and thus enhance the assurance of the use of these ingredients [65].

CONCLUSION

Each country has different rules and regulations and different requirements for market Cosmetics. India has stringent rules and regulations and also stringent provisions regarding manufacturing, import, sale, and distribution of cosmetics. It is essential to improve the regulations of safety information and control standards of cosmetics in India. The main aim of all these particulars in India is mainly to ensure the safety, quality, and efficacy of cosmetic products to market the product to the consumers with safe ingredients and safe labeling.

AUTHORS' CONTRIBUTIONS

All the authors have contributed equally.

CONFLICTS OF INTEREST

There are no conflicts of interest.

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