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Cosmetics: Regulatory and market scenario for us and India

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Abstract

The regulatory system and advertising of cosmetic items ensuring safety and efficacy are the most imperative elements for development of cosmetic industry. The safety of the cosmetic goods is regulated by diverse regulatory bodies around the world that all have their own particular rules and regulations. The terminology, labelling and safety of cosmetic product and colorant regulations are different for different nations. USA particularly has stringent enactment keeping in mind the end goal to manage the utilization of cosmetic items. The USA cosmetic and beauty care market generated USD 84 billion and was served as the most valuable market. The regulation of cosmetic products in India are under development while cosmetic market in India serves for USD 6.5 billion and increasing continuously with 25% CAGR rate. In this article there is an attempt to look at the current regulatory situation of cosmetic product, advancement and market situation in USA and India.

Keywords: Cosmetics, market scenario, regulatory guidelines

1. Introduction

According to FDCA a cosmetic is "articles 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"^[1].

Under the enactment the term "cosmeceutical" has no meaning. While the Federal Food, Drug, and Cosmetic Act (FD&C Act) does not consider the term "cosmeceutical," the word uses by the cosmetic industry is to refer to that cosmetic product have medicinal and drug- like advantages^[2].

India's Cosmetic Market Scenario

The cosmetic industry in India is classified into skin care, hair care, oral care, fragrances and colour cosmetic sections and many more. The current market for cosmetic in India is USD 6.5 billion and is expected to reach ~ USD 20 billion with CAGR rate of 25% by 2025. On the other hand, the global cosmetic market is expected to reach ~ USD 450 billion with CAGR rate of 4.3% by 2025. This show by 2025 India will contribute to 5% of the total global cosmetic market and will become one of the top 5 leading global markets in terms of revenue.^[3]

Many international brands such as Mac Cosmetics, Avon, Estée Lauder, L'Oreal, and Willa professionals established in India because of increased demand of products, improving purchase power and increasing image consciousness of Indian clientele. The awareness about cosmetics and developing fashion consciousness are created by social media and favourable demographics and thus plays an important role.^[3]

The awareness in the public of possible dangers in regularly using chemical formulations caused switching to 'safer' herbal and ayurvedic products such as Himalaya, Biotique, Dabur, Lotus, Patanjali, etc. To seize the established player position many Indian & international brands launched multiple products across categories. The increasing demand for cosmetics led to the introduction of products from luxury brands like ShahnazHussain, Forest Essentials and Kama Ayurveda.^[3]

The market of herbal product is not only restricted to India but also expanding in overseas market- the informed export for FY 2015-16 was approximately USD 0.093mn and is expected to increase at a 20% CAGR.^[3]

Online Cosmetic Market

Within last 3-4 years, the increasing internet penetration led to rapid growth followed by addition of this category to Amazon, Flipkart as the key focus area. The online cosmetic market valued at USD 50 million which is 2% of overall Indian cosmetic market. The category is attached to specialists such as Nykaa, Purple etc. moving with increasing e-tailing growth and competing for significant pie in online cosmetics space. Nykaa, the online marketplace started in currently offers more than 600 brands at both offline and online stores. The total sale for 2016 for Nykaa was USD 43

million of which the offline stores contribute to 5%. [3]. The hair care products, with Marico, the market leader are leading with a share of USD 3 bn. This is further followed by oral care products, led by Colgate Palmolive, has the market share of USD 1.74 bn. In skin care products, HUL leads with USD 1.63 billion, followed by fragrance product with Vini cosmetics on lead with USD 0.47 billion. The color cosmetics are headed by HUL again with USD 0.16 billion market share [3].

Classification of Cosmeceuticals

Table 1: The Cosmeceuticals can be classified as given below [7]:

On the basis of Use	On the basis of Function	On the basis of Action site	On the basis of Dosage Form	On the basis of Purpose	On the basis population
Special Use	Hair Growth	Face (excluding body)	Cream	Clean	Child
Non – Special Use	Hair dye	Hair	Emulsion	Perfume	Pregnant and Breast Feeding Woman
	Hair removal	Eye	Aqua	Change Appearance	Old People
	Breast shaping	Lips	Oil	Keep in good condition	
	Deodorizing	Scalp	Gel	Protect	
	Anti-Aging	Shaving Area	Powder	Corrects body odour	
	Anti-Acne	Hand	Spray		
	Anti-Wrinkle	Foot	Film		
	Oil Control	Eyebrow	Wax		
	Make up Remover	Body (Excluding face)	Capsule		
	Moisturizer	Eye lash	Aerosol		
	Exfoliator	Nail			
	Anti-Dandruff	Body Hair			
		Tooth and mouth mucosa			

**Evolution of Cosmetic Regulation in India
History of Registration Regulations in India**

In India, the import of cosmetic products was not directed till as of late year 2011 thus till then it was not obligatory for the foreign manufactured cosmetics to be enrolled before import into India. Without any administrative structure, fake and sub-standard cosmetics, worth a great many dollars, were being sold in India. The new necessities of 'cosmetics Enrolment in India' were consequently a result of the dumping practices of numerous outside companies wherein a substantial volume of beauty and personal care, the nature of which was a wellbeing in danger, were being sold illegally in India [4].

In accordance with worldwide practices, in 2011 India presented another administrative framework that made obligatory a prior enlistment of foreign manufactured cosmetics items before they are sent out to India. The new framework made obligatory to enroll each thing that goes under the domain of imported cosmetic and indicated the regulatory procedure, the narrative prerequisites and the time span for the issuance of the cosmetic import enlistment endorsement in India. The regulatory exertion was planned to prevent the offering of low quality and false cosmetic products in India and furthermore to convey consistency to the import arrangement for such items [4].

Regulatory Guidelines

They are still under development process. With the new regulatory framework set up from first October 2011, each cosmetic item being imported in India must be appropriately enrolled at the workplace of the licensing

authority i.e. the DCGI - Drug Controller General of India, New Delhi - or any of its nominee. The workplace of the drug Controller works under the Indian drug and cosmetic act of 1940 which directs the assembling, deals, clinical research and import/fare of medications and cosmetic in India [4].

The new controls give an exception for those cosmetic items which are being imported, made for 100% re-exported from India as well as are being transported in mass crude material shape for reprocessing and repackaging in India. In any case, enrolment is obligatory for the cosmetic items which are to be transported in complete form for a direct as-it-is sale in the Indian market [4].

Enlistment is required for all the Indian shippers who are Approved Specialist / Maker / Wholesaler of the cosmetics items being transported in. The foreign manufacture through a properly delegated Approved Agent / through its own Indian Cosmetic Act enrolled and Indian Drug Act licensed subsidiary in India can make an application to the licensing authority for enlistment of the cosmetic items for Imports into India [4].

The Enrollment Expense for each Brand of cosmetic products is US \$250 that incorporates all the pack sizes and variations of that Brand. If the shipper wishes to import at least two brands, then each brand would require an enrollment charge of US \$250 separately. Likewise, the shipper would be obligated to pay the testing charges for securing quality endorsements by the Legislature of India for investigation and examination of the cosmetic brand, if such requests are passed on the application [4].

Under the cosmetic enrollment rules, a Brand is characterized

not as the promoting name of cosmetic products but rather as the product category according to the Annexure list issued by the licensing authority for such purpose. In spite of the fact that the enrollment expenses is at present settled at an initial low measure of US \$250 just for a whole brand class of cosmetics, the candidate needs to satisfy a comprehensive cosmetic dossier/documents necessity for every single kind, pack size and variation of the applied cosmetic brand. On submission of finished product data archives and the application form, the registration endorsement would be issued in a period of a half year from such submission. Once issued, the enrolment authentication will stay legitimate for a long time (3 years) unless it gets scratched off or suspended in the middle of for any reasons, to be informed in writing by the licensing authority [4]

After the enrolment certificate has been granted, the label of cosmetic items must contain the registration number, Name and Address of the firm or individual which holds the Enrollment certificate or is importing cosmetics into India. With the exception of the reason for testing, investigation and examination, no cosmetic item can be imported in case it falls on the list of items restricted for market, distribution and

manufacturing in the nation of its origin. The licensing authority holds the right to review the current items which are as of now display in the Indian market and approve registration on a case to case basis as well as on fast-track course [4].

In India, cosmetics are regulated by Central Drug Standard Control Organization (CDSCO) under Drug and Cosmetic Act 1940& Rules 1945(amended up to Dec. 31st 2016). The Bureau of Indian Standards (BIS) issued standards for ingredient usage in cosmetics.

Before March 2013, there were no requirements to register imported cosmetics, but from April 1st 2013, all cosmetics imported for sale in India require mandatory registration with the Central Drugs General (India) (DCGI).

Domestic cosmetics in India don't require registration, but 11 categories of cosmetics (cosmetics require auditing of factory premises, space, plant, machinery and other requisites) must obtain a loan license before manufacturing.

Cosmetics that have been tested on animals are prohibited from import into India. Besides, cosmetics with Hexachlorophene, Lead or Arsenic compounds and mercury compounds are prohibited to be manufactured and imported.

Table 2: Existing Main Cosmetic Regulations in India [9]

Regulation	Function	Effective date	Status
Drug and Cosmetic act 1940 & Rule 1945 (amended up to Dec 31,2016)	Overreaching Regulation on Manufacturing and Importing distribution and sale of cosmetics	21-12-2016	In Force
Guideline on registration of import cosmetics	Guidance to instruct registration for cosmetics imported for sale	31-3-2013	In Force
Classification of cosmetics raw material and adjuncts Part 1 & Part 2	List of ingredient Which are prohibited and restricted in cosmetics	15-5-2016	In Force

Competent Authority

The Central Drug Standard Control Organization (CDSCO) is the principle authority to manage activities relating to cosmetic products and proclaim similar regulations. Under CDSCO, the central Drug General (India) (DCGI) is built up as the executive sector to manage activities, for example, application for enrollment or permit.

Other functions of CDSCO include:

- Pre-screening of application got by the candidate regarding enrollment of the import of the cosmetic.
- Investigation of uses identifying with enrollment of cosmetic items for Import into the nation according to the prerequisites of drug and cosmetic Act 1940 and Rules, 1945 there under.
- Critical examination of different applications for NOC/Elucidation identifying with cosmetic items import.
- Planning of draft answers to RTI, VIP references and Parliament Question identified with cosmetic.
- Answering to Government correspondences/BIS as and when required.
- Handling of public enquiries/hearings identifying with cosmetic import enrollment process and giving direction thereto.
- Handling of public/NGOs/Buyer gatherings complaints/grievances with respect to gauges of cosmetic items.
- Revision of pre-screening agenda and planning of SOP according to the present working techniques on evaluation of application for import and enrollment of cosmetic items.

- Alteration of Drug and cosmetic Rule, 1945 concerning registration of import of cosmetic items.

Additionally, the Department of Indian Gauges (BIS) gives specifications of certain cosmetic products, and issued records for precluded/permitted ingredient utilized as a part of cosmetic.

Us Regulatory Scenario

The FD&C Act does not recognize any such category as “cosmeceuticals.” A product can be a drug, a cosmetic, or a combination of both, but the term “cosmeceutical” has no meaning under the law. FDA explain cosmetics in their act as cleansing, beautifying, or altering the appearance of human body by rubbing, sprinkling, pouring or spraying the formulation for intended use[FD&C Act, sec. 201(i)].Among the products included in this definition are skin moisturizers, perfumes, lipsticks, fingernail polishes, eye and facial makeup preparations, shampoos, permanent waves, hair colours, toothpastes, and deodorants, as well as any material intended for use as a component of a cosmetic product[2].

Approval Requirements

FDA does not have a premarket approval system for cosmetic products or ingredients, with the important exception of colour additives. Drugs, however, are subject to FDA approval. Generally, drugs must either receive premarket approval by FDA or conform to final regulations specifying conditions whereby they are generally recognized as safe and effective, and not misbranded. Currently, certain but not all over-the-counter (OTC) drugs (that is, non-prescription drugs) that were marketed before the beginning of the OTC Drug

Review (May 11, 1972), may be marketed without specific approval pending publication of final regulations under the ongoing OTC Drug Review. Once a regulation covering a specific class of OTC drugs is final, those drugs must either – Be the subject of an approved New Drug Application (NDA) [FD&C Act, sec. 505(a) and (b)] or Comply with the appropriate monograph, or rule for an OTC drug [5].

The regulations published by the Food and Drug Administration (FDA) are all codified in Title 21, Code of Federal Regulations (21 CFR). The regulations applicable to cosmetics are stated in 21 CFR parts 700 to 740. The color additive regulations applicable to cosmetics are found at 21 CFR 73, 74 and 82.

The FDA pursued to set up a plan on the dissimilarity between a cosmetic and a drug in three different ways [5].

1. FDA provided suitable business correspondence that sets forward suggested advice on the categorization of product.
2. The paperback and different instructional stuffs with examples of product categorization were released by the FDA.

It fetched court action to meet the legality of cosmetic product categorization with a label that contained what the organization adduces to be drug claims. From this body of literature and precedent developed over six decades, a number of well- developed examples are [5]:

- A deodorant comes in cosmetic, but an antiperspirant is in the drug.
- A shampoo comes in a cosmetic, but antidandruff is in the drug.
- An antiquaries tooth-paste is a drug, but toothpaste comes in cosmetic.
- An Ant gingivitis mouthwash comes in the drug, but mouthwash is in cosmetic [5].

Cosmetics export requirements in U.S.

Cosmetics requirements are different in other countries form U.S. but there may be situations where the products for export don’t comply with FD&C Act or Fair Packaging and labeling Act for cosmetics marketed domestically. The product meant for export will not be considered adulterated or misbranded if it,

- Meets specifications of foreign purchaser
- Is not in conflict with laws of country in which is intended to export
- Is labelled on the outside of shipping package intended to export
- Is not offered for sale in domestic commerce (FD&C Act, Section 801(e))

The product for export must comply with the regulations of country in which the product is exported.

Table 3: Summary of cosmetic regulations [8]

Content	India	Usa
Authority	CDSCO	FDA
Rules & Regulation	D&C Act1940 AND Rules1945	FD&C Act
Labelling	It should comply with part XV OF D&C ACT 1940 and rules 1945	It should comply with the FP&L AND FD&C
Pre-Marketing Approval	Requirement under the state government	Not required
Post Marketing Reporting System	N/A	Yes
Expiry Date	Not required	Indicated as’ use before date’

Labelling Requirements

Label is the first thing which a customer sees while buying a product from the market. So it must be ensured that enough information is presented on the label to satisfy the customer.

FDA regulates cosmetic labeling under the authority of the Federal Food, Drug, and Cosmetic Act (FD&C Act) and the Fair Packaging and Labeling Act (FPLA). The regulations for labelling a cosmetic are given under FDA’s Cosmetic Labelling Guide and Cosmetic labelling regulations (21 CFR 701 and 704 respectively). These regulations are made to prevent the public consuming these products from health hazards and deceptive practices. They help in the decision making process of the consumer that whether to buy a product or not [6].

There are no such regulations for Pre-Market approval of label under FDA’s labelling guide. It is responsibility of manufacturer/ distributor to ensure that the products are labelled properly. A product which is misbranded is illegal to bring in the market for commercialization. If the product is not found according to the regulations then it is subjected to regulatory actions. Some of the parameters that describe the product as misbranded are: [6]

1. Its labelling is false or misleading,
2. Its label fails to provide required information,
3. Its required label information is not properly displayed

4. Its labelling violates requirements of the Poison Prevention Packaging Act of 1970 [FD&C Act, sec. 602; 21 U.S.C. 362].

Terminologies

1. Labeling

This term refers to all labels and other written, printed, or graphic matter on or accompanying a product [FD&C Act, sec. 201(m); 21 U.S.C. 321(m)].

2. Principal Display Panel

This term refers to all labels and other written, printed, or graphic matter on or accompanying a product [FD&C Act, sec. 201(m); 21 U.S.C. 321(m)].

3. Information Panel

This term refers to a panel other than the PDP that can accommodate label information where the consumer is likely to see it. The bottom of the product is not used to place the label as the information on the label must be prominent and conspicuous [21 CFR 701.2(a) (2)] [6].

Permission to Label Cosmetic as “FDA Approved”

FDA does not give the permission to label, advertise and commercialize the cosmetic as FDA approved. This applies

even if the establishment is registered or the product is on file with FDA's Voluntary Cosmetic Registration Program (VCRP) (21 CFR 710.8 and 720.9) [6]

Therapeutic Claims

If the product label has the therapeutic benefits of the products mentioned on the label, then it will be considered as Drug. Promoting a product with claims that it treats or prevents disease or affects any part of body part or structure will make the cosmetic, a Drug. So, a proper set of guidelines has to be followed while mentioning the therapeutic benefits of the products on the label [6].

Product labelling if the they are both a drug and cosmetics

If a product is an over-the-counter (OTC) drug as well as a cosmetic, its labelling must comply with the regulations for both OTC drug and cosmetic ingredient labelling [21 CFR 701.3(d)]. The drug ingredients must appear according to the OTC drug labelling requirements [21 CFR 201.66(c) (2) and (d)] and the cosmetic ingredients must appear separately, in order of decreasing predominance [21 CFR 201.66(c)(8) and (d)]. [6]

Language on the Label

The labelling information that is required by the law or the regulation must be mentioned on the label in English with one exception i.e. for the products that are distributed solely in a U.S. territory where Puerto Rico language is used. [21 CFR 701.2(b)]. [6]

Information on Label [6]

The following information must be displayed on the Principal Display Panel:

1. **Identity Statemen:** It must indicate the nature and use of the product either by common or usual name, descriptive name, and easily understood name by the public or an illustration [21 CFR 701.11].
2. **Net quantity of Contents:** The quantities have to be mentioned on the label for each ingredient in terms of weight, measure, numerical count or a combination of numerical count. [21 CFR 701.13].
3. **Name and Place of Business:** Information about the manufacturer, packer or the distributor including their street address, city, state, ZIP code and phone number have to be mentioned clearly on the label. [21 CFR 701.12(a)]
4. **Distributor's statement:** If the name and address are not those of the manufacturer, the label must say "Manufactured for..." or "Distributed by..." or similar wording expressing the facts [21 CFR 701.12(c)].
5. **Material Facts:** Directions for safe use of a product must be clearly mentioned on the label, if the product contains such ingredients which can harm the user [21 CFR 1.21].
6. **Warning and Caution Statements:** They should be specific and clear without being written in ambiguous language. Cosmetics that may be hazardous to consumers must bear appropriate label warnings e.g. Flammable cosmetics [21 CFR 740.1].
7. **Ingredients:** The information of ingredients must be arranged in a descending way of predominance for the products which are to be sold on a retail basis to consumers. It must bear the label "For Professional use only" [21 CFR 701.3]. If the product is drug also, then it must comply with the OTC drug and cosmetic labelling guidelines.

Adulterated or Misbranded Cosmetics

If the cosmetic contains a substance which causes harm to the consumers under customary conditions of use i.e. if it contains a filthy, putrid, or decomposed substance; if it is manufactured or held under insanitary conditions; or may have become harmful to consumers; or if it is not a hair dye and it contains a non-permitted color additive, then the product is considered as Misbranded [6].

A cosmetic is considered as misbranded if its labelling is false or misleading or does not bear the required labelling information or the container is made or filled in a deceptive manner [6].

Cosmetic Labelling

Labelling includes all the printed or graphic matter present on label as well as all the written form accompanying the product. Cosmetics that are marketed in US must comply with the regulations published by FDA under the authority of the FD&C and the FP&L Act. The label should be present on both the sides of container inside as well as outside. The labelling requirements are codified at 21 CFR 701 and 740 [6].

Laws and Regulation

The manufacturers and importers of cosmetics which are marketed in US have to follow the provisions of the Federal Food, Drug and Cosmetic Act (FD&C Act), Fair Packaging and Labelling Act (FP&L Act).

The regulations published by the Food and Drug Administration (FDA) are all codified in Title 21, Code of Federal Regulations (21 CFR). The regulations related to cosmetics are stated at 21 CFR, parts 700 to 740 (21 CFR 700 to 740) [6].

Cosmetic as Drugs

The products which fulfil the requirement of a cosmetic and are used to treat or prevent disease, or affect the structure or functions of the human body are considered as drugs. These products must comply with both drug and cosmetic provision of the law. E.g. sun tanning preparations intended to protect against sunburn, antiperspirants that are also deodorants, and antidandruff shampoos [6].

The regulatory requirements for drugs are more extensive than the requirements applicable to cosmetics. For example, the FD&C Act requires that drug manufacturers register every year with the FDA and update their lists of all manufactured drugs twice annually. Additionally, drugs must be manufactured in accordance with current good manufacturing practice regulations as codified at 21 CFR 210 and 211 [6].

Most of the cosmetics are dispensed as Over the Counter Drugs but every new Drug has to undergo safety and effectiveness test before they become ready for commercialization [6].

Conclusion

The focus of this article is to show the variations of cosmetic regulations between countries, so there is need to harmonize the regulations regarding the safety, stability, and labeling issues. The finding of this review is to conclude the comparative regulatory framework for cosmetic products and to give an account of the market scenario of USA and India. Despite of many differences among these regulations, the availability of quality products in market is the prime objective of each country's laws and regulations.

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