



Comparative Study of Regulatory Requirement of Cosmetics in INDIA to USA and EU

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ABSTRACT

A cosmetic product should be a complete package of all excellent properties comprising of proper safety, efficacy, potency with potential marketing efforts. These characteristics are only possible when we have a good regulatory structure, scheme and organization that can continuously regulate and update the cosmetic products. There are many regulatory bodies doing work efficiently. These bodies provide us with strict regulations which help us in guiding Manufacturing, Importing, Packaging, Labeling and other aspects of trade in cosmetic industry. In USA and EU, it is not easy to produce a product in the market, as one has to fulfill the safety requirements as per the recent regulations. In India, we have Drugs and Cosmetic Act (D &C) and Bureau of Indian Standard (BIS), following which we formulate a product for consumer needs. The cosmetic market is at its peak and can be observed to be at highest in upcoming years. The skin care market is amongst the largest growing as compare to other segments like deodorants, hair care and many more. This review helps in knowing the regulations in cosmetic industry and also the marketing scenario.

Keywords: Cosmetics, regulatory bodies, trading, safety, Drugs and Cosmetic Act

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Received 28 September 2019, Accepted 10 October 2019

INTRODUCTION

Cosmetics are the fastest growing consumer interest market in the world with higher interest rate seen in females than in males. Beauty and personal care products are in use since long ago for enhancing appearance, looks, and perfection. The Indian cosmetic industry is a good combination of synthetic and herbal cosmetics.(2) 15-20% is the rate at which Indian cosmetic market is increasing annually.2,3 Worldwide the sales of cosmetics have certainly enhanced to about \$170 billion dollars per year. (3) For sustaining good market, cosmetic products need to have proper safety and efficacy because of which certain regulations are made worldwide. There are many regulatory bodies to coordinate with the cosmetic products such as CDSCO (Central Drugs Standard Control Organization) working in India and FDA (Food and Drug Administration) working in United States. In EU (EUROPEAN UNION) and USA (United Stated of America) very precise and strict regulations exist so as to coordinate with the usage of cosmetic products.

Cosmetic Global Market

The global cosmetic market is enhancing tremendously day by day and is also expected to grow around USD 716.6 billion upto 2025 measuring the CAGR of 5.9 % (14)

Because of lesser side effects, toxic effects the consumers demand is going towards natural products, anti wrinkle / anti ageing products, and also growth is seen in men's usage products , these all trends can lead to good market future numbers. (14)

The global market has also enhanced due to consumer lifestyle, global economies and more usage of skin care products which includes more of sunscreen due to climatic issues. (13)

Market Segmentation of Cosmetics

Market segmentation is done based on various factors like: Geographics, Demographics, Psychographics, Behavioural

GEOGRAPHICS	DEMOGRAPHICS	PSYCHOGRAPHICS	BEHAVIOURAL
Country, City	Age	Interest, opinions	Benefits, usage
Density	Gender	Lifestyles, values	Intent, occasion
Language	Income, Education	Concerns, personality	User status, engagement

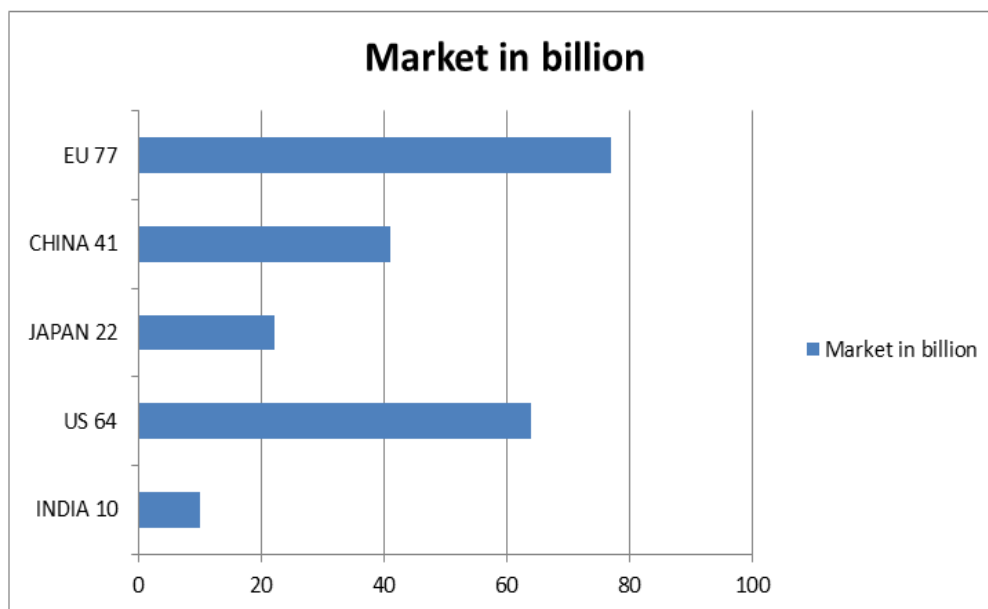
Global Cosmetic Market: Skin Care

As per the usage of products, it has been observed that the market of skin care products is enhancing and this sector is considered to be one of the most varied sector. The formulators are

using newer upcoming technologies like nanotechnology which include usage of liposomes, niosomes in cosmetic industry in order to enhance its usage rate and convenience for potential customers. (13)

This sector is observed to file the maximum CAGR which is 6.2 % in coming years.(14)

Global Market In Billion (2) Figure 1.



Cosmetic Regulations IN USA

The Food and Drug Administration (FDA) is the major governing body.(2) The least requirement for the production, trading and supplying of cosmetics is Voluntary Cosmetics Registration Program (VCRP). FDA can collect the information from VCRP about any aspect of cosmetic product (3).

Apart from VCRP, FDA also has many other ways of providing good health and safety like Cosmetic Ingredient Review (CIR), data from the users, and collects information regarding the cosmetics related problems by MedWatch(1)

For the marketing of a cosmetic product , FDA checks that the firm abides by all the mandates, requirements and procedures. FDA does not go for pre-approval of any cosmetic product for the marketing of it. If the product is in any case deemed to be of risk to human health , is liable of market withdrawal and have to bear with rules and regulation pertaining to it.(2)

The COSMETIC GOOD MANUFACTURING PRACTICES, is the leading body for which certain draft guidelines were published by FDA . These guidelines are not mandatory to follow, but the FDA recommends to follow them, in order to have safe and good products for the end

users. (2)

FDA also performs certain activities to keep a check that if the product is misbranded, adulterated or not. The FDA has prepared a file of banned ingredients which are not to be used in the cosmetic product(.3, 2). The labeling instructions are given by Federal Food, Drug and Cosmetic Act of 1938 and Fair Packaging and Labeling Act. If the labeling instructions don't satisfy with the instructions provided by the act, the cosmetic product is considered to be misbranded. (17), (3)

Table 1: Briefing of Cosmetic Regulations in USA (3)

Rules and Requirements mandate by	and Requirements for Trading	Labeling guidelines	Language on label	Safeguard/safety responsibility
FDA (Food and Drug Administration)	VCRP, CIR	Federal Food, Drug and Cosmetics Act, The Fair Packaging and Labeling Act	English	It is the responsibility of the producer .

Cosmetic Regulations in EU

According to EU guidelines, a cosmetic product can be explained as : any substance or mixture intended to be placed in contact with the 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, protecting them, keeping them in good condition or correcting body odours. (9)

The authority demands for a liable person who will be responsible for any cosmetic product which has to enter in the market or is previously in the market. The cosmetic product under this person should hold all necessary requirements as per the demand of regulations. Any relevant question about the product after its entry into the market will be explained and justified by this liable person only. If there will be any case , like not fulfilling to the particulars of regulations, then that person or the company will be punished. (10)

The cosmetics are manufactured under Cosmetics Good Manufacturing Practices (cGMP). (10)

Product Information File (PIF) :

The liable person who is accountable for the cosmetic product has to present a PIF, for the product to the authority . (9) The liable person has to retain the file of the PIF of a product for at least ten years as long as the endmost bunch of the product is there in the market.

The PIF contains the following information:

- Proper explanation and description of the cosmetic product.
- It should include the cosmetic product safety report (CPSR) of the relevant product.
- Also, explanation regarding the manufacturing procedure and document for its conformity with the CGMP.
- Proper evidence regarding the results holed by the cosmetic product.
- Proper documents on if any animal testing has been done.(11)

Table 2: Briefing of cosmetic regulations EU.

Rules and Mandate	Manufacturing guidelines	Safety Assessment	Nomenclature of ingredients	Efficacy testing
EMEA	CGMP	PIF (Product Information File)	Inventory of Cosmetic Ingredients	Sensorial testing, Instrumental testing

Cosmetic Regulations In India

The Cosmetics in India are controlled and regulated under Drug and Cosmetics Act 1940 and rules 1945.(1) The cosmetics law building body in India is CDSCO (CENTRAL DRUGS STANDARDS CONTROL ORGANISATION) which is controlled under Drugs Controller General of India.(2) Bureau of Indian Standards (BIS) is the national Standards Body of India, which provides with the Labeling regulations as well as sets standards for cosmetic products under Schedule ‘S’ of the Drugs and cosmetics Act.(1)

Manufacturing Requirements for Cosmetics In India

The first step to start manufacturing of cosmetics classified under Schedule - M-II is by obtaining the license by the licensing authority of the particular state drug authority. An application will be needed which gets submitted in Form 31, which will further include a license fee and an inspection fee.

Moreover, other information will also be needed:

- Whole design of the factory premises.
- Total list of equipment which has to be installed
- It has to be ensured by the manufacturer that the production is done under a competent and qualified technical staff and minimum of one staff should hold Diploma in Pharmacy approved by the Pharmacy Council of India under the Pharmacy Act, 1948; or is registered under the Pharmacy Act, 1948; or has passed the intermediate examination with Chemistry as one of the subjects or any other examination as recognized by the Licensing Authority as equivalent to it.

- Prior to allowing or declining the license, the authority of license is required to arrange an inspection of the whole area where the process has to be carried out. The inspector then has to provide a proper and detailed report to the Licensing Authority, who will further make a decision if the license has to be granted or not.
- A Form 32, is mandatory which Licensing Authority will provide as a License in order to manufacture cosmetic products.(1,5)

Importing Requirements In India

The cosmetic industry in India is a rapidly growing industry and products should be of high safety and efficacy. Ministry of Health and Family Welfare of India has made compulsory registration of cosmetics products in order to import them.

WHO CAN IMPORT COSMETICS?

1. Manufacturer holding a registered office in India.
2. Authorized agent of the manufacturer.
3. Subsidiary agent of the manufacturer (6)

PROCEDURE FOR REGISTRATION FOR IMPORT

- Firstly, the imported cosmetic product should be registered with central drug standard control organization (CDSCO) by giving application in FORM 42 along with a cover letter.
- The registration certificate will be obtained within 6 months of the submission of application form.
- Then, the registration would be accepted till 3 years after which renewal would be required for the further continuation.

FOLLOWING DOCUMENTS ARE REQUIRED FOR REGISTRATION

- Proper Import Export code (IEC).
- Evidence or documentation of payment of registration fees.
- Information about the manufacturer and its manufacturing unit.
- Proper information of the cosmetic product which includes its brand name, its quantity, date of manufacturing.
- Total record of countries where the product has to be imported.
- Total list of constituents and ingredients in terms of the international nomenclature as well as the amount of the particular ingredient used.
- Document of specimen of label along with its specifications. 6

Labelling Guidelines

As per the D&C act of India, there are certain labeling guidelines written as below.

- The cosmetic product name as well as the manufacturer address should be properly mentioned on both the inner and outer labels.
- In case the container is of smaller size, there is no need of mentioning the manufacturing address rather mentioning only principal manufacturing place and its pin code would be adequate.
- On the outer label, there should be proper information about the total quantity of ingredients used in the product.
- On the inner label, which should say 'DIRECTIONS FOR PROPER USE' with specifically indicating any piece of advice or warning which is important for the safe use of the product. Other than these, the label should also specify if there is any ingredient which is harmful in the product.
- Apart from these the label should have some basic elements such as proper batch number, license number, and these should be denoted with specific letters like 'B' for batch number and 'M' for manufacturing license number. (7, 1)

Packaging Guidelines

For the packaging of products three major laws are considered i.e LEGAL METROLOGY LAW, DRUGS AND COSMETICS LAW AND BUREAU OF INDIAN STANDARDS (BIS) .(7)

The Packaging of cosmetic product comprises of :

- PRIMARY PACKAGING: it is a particular medium which initially packages a commodity and is in immediate reach to it.
- SECONDARY PACKAGING: It is the second most layer surrounding the primary packaging. This layer is in immediate reach to the buyer.
- TERTIARY PACKAGING: it is being added for reasons like delivery, transportation, protection . (12), (15)

Packaging Materials

Glass:

Glass is being extensively used in cosmetic industry because of its lower cost, easy gripping, and stagnant properties, transparency which makes easy usage of glass in the industry. When a product is light sensitive , amber coloured glass is used for protection against light . (12)

Plastic:

It is one of the most commonly used material because of its nature like unbreakable , economical , easy availability and easy handling . Although plastic material is misused in the market, still it is highly used. The cosmetic industry uses polypropylene, poly(ethylene terephthalate) form of plastic generally. (16)

Metals:

the lipstick container mostly comprises of can and tubes which is made up of metal. Metals in the product work by preventing environmental degradation, soaring temperature and moisture degradation. (16) the disadvantage of metals is they always need an additional layer of coating so that there should not be any kind of decomposition. (12).

GUIDELINES ON MISBRANDED AND SPURIOUS COSMETICS**FOR MISBRANDED COSMETICS**

According to D&C, act cosmetics is said to misbranded when:

- It holds any dye, color, pigment which is not advised.
- It is not directed or labeled in a proper advised way.
- If the label, or whole of the container provides with any deceptive or false information.

FOR SPURIOUS COSMETICS

According to D&C act, a cosmetics is said to spurious when:

- It is imported with any name that refers to some other cosmetics
- It creates emulation, replacement, of any cosmetics or is having similar name as that of any cosmetic product.
- If the label or whole of the container specifies any name of the individual or any firm as the manufacturer of the cosmetic, which that individual or firm is not.
- If it creates deception of being a product of a company or manufacturer of which it is not.

(8,5)

PRICING OF COSMETICS

The pricing in INDIA is set up according to MRP (Maximum Retail Price). With this MRP, any of the packaged product can be sold out to the user or the costumer. This MRP is a combination of all the relevant taxes, transport charges, commissions of the dealers, charges of publication, containers with packaging , and the end delivery.(4)

SAFETY ASPECTS AND DATA

According to BIS, the manufacturer should be well equipped with proof of safety sheet/ data/ or anything pertaining to tell that the product is harmless. If in case there are any indications or special instructions on how the product has to be used, should be informed to the consumers by the manufacturer or the distributor. These special instructions should be well mentioned on to the label of the cosmetic product. (1)

Table 3. Briefing of cosmetic Regulations in India, (3)

Governing body	Rules and mandate by	Expiry date	Language on container	Colouring agent	Packaging law
CDSCO	Drugs and cosmetics act	Mentioned as “BEST BEFORE THE DATE”	English	Dyes and pigments	Legal metrology law, Drugs and Cosmetics Law

CONCLUSIONS

According to the regulations, in USA, EU and INDIA, it was found out that the regulations of INDIA was way behind the regulations in USA AND EU. They have much more strict actions in terms of quality, safety, efficacy of a cosmetic product. These strict actions are necessary for consumer health and for avoiding any toxic effects due to cosmetic products. Now a days, the trend is moving towards the herbal cosmetics and people are also preferring them because of its natural origin and no side effects. India is moving ahead in the herbal cosmetic market day by day. However, when safety aspects are concerned, the regulators have made strict rules and mandates to maintain the safety of product , like in EU there is a Product Information File which provides authority with complete information regarding the product, still some more investigation is needed when safety is a chapter for a product. We need to have more transparency, rigid, tough , inelastic and uniform regulations in order to make them perfect for consumers consumption and usage.

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