6.1. Introduction

Cosmetic products have the legislative control in both developed and developing nations. However, regulatory requirements for the approval of cosmetic products in these nations are unique and distinctive. There are about 193 countries in the world, and none of them have identical regulatory system. Hence, the cosmetic industry is being facing multiple challenges when attempting to market its product around the world. International companies are many and varied, and all faces regulatory obstacles. Some countries require registration of products with the regulator, others do not. All countries disallow some ingredients, but of course not the same ingredients. Till date no single regulatory model is considered to be the best [1].

6.2. Consequences of difference in regulatory framework of cosmetics at International level [2]

Regulatory framework differs significantly between different markets and is far from being harmonized. This has the potential for impact on the competitiveness and economic viability of the industry. The inability to sell similar products across all markets, or the requirement to change test methods, formulations, packaging and advertising, can increase costs for industry in general and companies in particular. Delays and high costs associated with the introduction of new ingredients and products can reduce the potential for market growth.

Barriers to trade

- Reduced ranges of products available for consumers.
- Implementation problems for regulators because products imported from foreign country may not conform with local regulatory framework.
- Increased costs, marketing delays and loss of sales for manufacturers and importers.
- Due to differences in regulatory framework, product innovations have been affected through innovations in ingredients, product composition, and marketing products.

To operate globally for cosmetic manufacturing companies it is very important to know in detail the regulatory requirements in each concerned country. Harmonization is far from reality at this stage and a constant and consistent effort is required by major regulatory authorities to bring in harmonized guidelines with respect to cosmetic products. Till date, regulations regarding to cosmetic products in major market are on records. But when it about regulating cosmeceutical products, it is still at nascent stage. Cosmeceutical products are borderline products having attributes of cosmetic and medicine. Hence, regulating
cosmeceuticals is an area of interest. There are major differences among regulatory authorities regarding cosmeceuticals, starting from the term to the various regulatory requirements.

Cosmetic and drug regulations did not exist in the early 20th century. Probably at that time cosmeceutical term itself was non-existing. A few tragic incidents triggered the government authorities to put forward regulations with regard to safety and efficacy of medicines. Then the regulations with regard to cosmetics and some advanced products were framed. Majority of the countries followed similar path with regard to regulations of medicines, cosmetics, medical devices and some advanced products like cosmeceuticals, nutraceuticals etc.

Regulatory system with respect to cosmeceuticals is said to be at evolution stage, where deliberations are on among various stakeholders of cosmeceutical industry. Regulatory agencies around the globe have not yet formally recognized cosmeceuticals as a separate product category, despite a rapid proliferation of cosmetic products that have a documented and intended pharmaceutical activity and a dermatology knowledge-base that reduces obsolete distinctions between cosmetics and drugs. According to USFDA the definition of cosmetic, and drug is neat and simple. However there is one further legal parameter which thoroughly confounds the issue, that cosmetic must “not affect structure and function of skin.” This statutory differentiation of drugs from cosmetics was probably appropriate for the state of knowledge when the USFDA rules were written, more than a half century ago. Since then the great increase in knowledge of the physiology of skin has brought the law and biology into conflict. The truth is that all topical substances, whether as simple as water or as complex as multi-ingredient moisturizes, inevitably will affect the structure and function of skin. No topical product is completely inert[3]. Now everything that is applied to the skin could be a drug requiring more than a billion USD to put the product on the market.

In 1938, the ideas regarding skin physiology were primitive. Now it is known that skin exposed to water for 48 hours demonstrates cytokine release, producing a condition known as hydration dermatitis. Under electron microscopy, water can produce changes in Langerhans’ cell and mast cell function. Hydration dermatitis is a disease, but water is not a drug. Water is the milieu of life, but it is not an innocuous substance. This leads to the debate that every topical formulation one buys in a supermarket is, by law, a drug! Since everything applied to the skin produces change, so there is need of third category of products known as cosmeceuticals[4].

The concept of cosmeceuticals is comparatively new in India and not much rules and regulations exit to abide by them. Conceptually, they fall under grey area of conventional
drugs and cosmetics. In most countries, a suitable regulatory category for these hybrid products does not exist and therefore most complications in market development arises from a lack of a clear definition and the consequent legal framework for cosmeceuticals.

### 6.3. Current Indian cosmetic regulatory scenario

The current regulatory system in the India does not adequately assure continued access to and safety of cosmeceuticals. By long-standing statute, the world of topical is divided into two opposed groups, drug versus cosmetics.

According to Drugs and Cosmetics Act, 1940, Drug is “all medicines for internal or external use of human beings or animals and all substances intended to be used for; or in the diagnosis, treatment, mitigation or prevention of any disease or disorder in human beings or animals.”

Cosmetic is defined “any article intended to be rubbed, poured, sprinkled or sprayed on or introduced into or applied to any part of the human body, for cleaning, beautifying, promoting attractiveness or altering the appearance and includes any article intended for use as a component of cosmetic”[5].

According to definition of drug and cosmetic these products do not fit precisely into either the current “drug” or “cosmetic” category. And while cosmeceuticals may be marketed under OTC or cosmetic category which provides a regulatory framework, these may not be sold as medicines. Thus, a present trouble is that there is no sharp dividing line between these categories. The current legal definitions of drugs and cosmetics are archaic and unworkable, as indeed formally noted by dermatology community nearly 20 years ago [6]. The transition towards the acceptability of this new trend of cosmeceuticals is relatively slow as far as regulatory issues are concern.

### 6.4. Rationale to create a cosmeceutical category

Absence of proper regulatory framework and dilemma over the understanding the term “Cosmeceuticals” has become undue advantage for cosmetic manufacturers. Manufacturing, labeling, sale and advertisement of such products need proper regulatory framework to safeguard the interest of consumers and control the cosmeceutical market. This chapter focuses on understanding and analysis of regulatory issues related to cosmeceuticals from different countries. This study attempts to satisfy the need of hour by proposing conceptual regulatory framework to regulate the manufacturing, labeling and advertisement of cosmeceuticals in India. This regulatory framework may help:

- Various stakeholders in the field of cosmeceuticals
Support use of cosmeceuticals by health care professionals
Ensure and provide factual information to public regarding cosmeceuticals
Shall protect the public from unproven claims and unsafe products
Shall drive growth and exports of cosmeceuticals

6.5. Objective

- To analyze the available regulatory guidelines, formulated by regulatory authorities of US, Japan, European Union, Canada, Australia and a few other developed and developing countries with respect to cosmeceuticals or similar products.
- To suggest general data requirements, that may be required for marketing approval of a cosmeceutical product in India.

6.6. Research methodology

Information and views were collected with regard to regulations of cosmeceuticals by contacting regulatory authorities through email. Further information with respect to regulatory requirements specified by regulatory authorities of US, Europe, Japan and Canada were collected. A conceptual framework was formulated containing general regulatory requirement for marketing approval of cosmeceuticals in India. Finally, an attempt was made to put together the parameters and sequence of data required by regulatory authorities for development and marketing approval of cosmeceutical products.

![Schematic presentation of research methodology.](image)
6.7. Discussion

For better understanding of this chapter the comparison of key features of overall cosmetic regulations is discussed followed by product categorization of cosmeceutical products in major markets.

6.7.1.1. Comparison of key features of cosmetic regulations in major markets

Table 6.1. Comparison of key features of cosmetic regulations in major markets [2]

<table>
<thead>
<tr>
<th>Main Features</th>
<th>EU</th>
<th>USA</th>
<th>Japan</th>
<th>Canada</th>
<th>India</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>General</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Manufacturer has full responsibility for safety of products</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
</tr>
<tr>
<td>In-market control by authorities</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
</tr>
<tr>
<td>Freedom to use any distribution channels</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
</tr>
<tr>
<td><strong>Pre-market requirements</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Notification of products</td>
<td>Not required</td>
<td>Voluntary</td>
<td>Mandatory</td>
<td>Mandatory (with ingredients list)</td>
<td>Mandatory</td>
</tr>
<tr>
<td>Initial notification of producer premises</td>
<td>Compulsory but requirements not harmonized</td>
<td>Voluntary</td>
<td>Compulsory</td>
<td>Compulsory</td>
<td>Compulsory</td>
</tr>
<tr>
<td><strong>Control over ingredients</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Positive lists: Coloring agents, preservatives, UV Filters</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
</tr>
<tr>
<td>Negative lists: Prohibited substances and restricted substances</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
</tr>
<tr>
<td>Scientific advisory committees</td>
<td>SCCNFP (Committee of experts appointed by EU commission) advises on safety of ingredients</td>
<td>Voluntary committee of experts organized by industry advices on safety of ingredients</td>
<td>Government officials and experts (The cosmetic advisory committee)</td>
<td>Government officials</td>
<td>CDSCO, Drug Consultative Committee, Drug Technical Advisory Board and Bureau of Indian standards</td>
</tr>
<tr>
<td>Notification of ingredients to poison centers</td>
<td>✓</td>
<td>×</td>
<td>×</td>
<td>×</td>
<td>×</td>
</tr>
<tr>
<td>Main Features</td>
<td>EU</td>
<td>USA</td>
<td>Japan</td>
<td>Canada</td>
<td>India</td>
</tr>
<tr>
<td>----------------------------</td>
<td>----</td>
<td>-----</td>
<td>-------</td>
<td>--------</td>
<td>-------</td>
</tr>
<tr>
<td><strong>Labeling requirements</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>INCI Labeling of ingredients</td>
<td>✓</td>
<td>✓</td>
<td>Japanese translation required</td>
<td>×</td>
<td>×</td>
</tr>
<tr>
<td>Quantity labeling</td>
<td>Mandatory (Metric labeling)</td>
<td>Mandatory (Metric and non-metric labeling)</td>
<td>Mandatory (Metric only)</td>
<td>Mandatory (Metric) (non-metric-supplementary)</td>
<td>×</td>
</tr>
<tr>
<td>Identity of producer/importer on label</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
</tr>
<tr>
<td>Expiry date</td>
<td>Date of minimum durability if it is &lt; 30 months Period after opening if durability is &gt;30 months</td>
<td>×</td>
<td>Expiration date if shelf-life &lt; 3 years</td>
<td>×</td>
<td>Indicated as “Use before date”</td>
</tr>
<tr>
<td><strong>Testing and safety</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Data on product safety and efficacy</td>
<td>Manufacturers must maintain product information file. (safety and proof of claims) Accessible to competent authorities</td>
<td>No equivalent PIF. If the manufacturer does not have any data to prove safety of his product, the compulsory warning 'The safety of this product has not been determined' must appear on packaging</td>
<td>No equivalent Product information file. Manufacturer must be able to prove safety/efficacy</td>
<td>No equivalent Product information file. Manufacturer must be able to prove safety upon request from authorities</td>
<td>No equivalent Product information file. Manufacturer must be able to prove safety upon request from authorities</td>
</tr>
<tr>
<td>Testing requirements</td>
<td>SCCNFP publishes guidelines</td>
<td>No specific tests required. (Industry guidelines)</td>
<td>No specific tests required. (Industry guidelines)</td>
<td>No specific tests required</td>
<td>No specific tests required</td>
</tr>
<tr>
<td>Animal testing ban</td>
<td>Animal testing and marketing banned</td>
<td>Animal testing allowed</td>
<td>Animal testing allowed</td>
<td>Animal testing allowed</td>
<td>Animal testing allowed</td>
</tr>
<tr>
<td>GMP</td>
<td>Reference in cosmetics directive</td>
<td>Voluntary (Industry guidelines)</td>
<td>Industry guidelines</td>
<td>Voluntary (Industry guidelines)</td>
<td>Reference in Drugs and Cosmetic Act</td>
</tr>
<tr>
<td>Product categories</td>
<td>Drug, cosmetic and OTC drug</td>
<td>Drug, cosmetic and OTC drug</td>
<td>Drug, Cosmetic and Quassi drug</td>
<td>Drug, Cosmetic and non-prescription drug</td>
<td>Drug, Cosmetic and OTC drug</td>
</tr>
</tbody>
</table>

✓ Yes  × Not required

6.7.1.2. Manufacturer responsibility

Cosmetic products in the European union, US, Japan and Canada can be placed in the market without prior approval of regulatory authority. Instead, manufacturers are responsible for ensuring that their products are safe. However, Japan and Canada require...
notification of product names before they are placed on the market (for Canada, notification of the ingredients is required). Some EU Member States also require notification of products. In India product notification is required before placing the product in the market.

6.7.1.3. Negative and positive lists

The EU and Japan both maintain lists of prohibited and restricted substances, together with positive lists for colouring agents, preservatives and UV filters. The negative and restricted lists are updated regularly, on the advice of the scientific advisory committees or equivalent. The US and Canada do not have the positive lists for cosmetic ingredients. This is partly because products containing ingredients subject to positive lists in the EU and Japan, for example UV filters, are regulated as OTC drugs in the US and Canada. This means that they are required to undergo pre-market approval for launching the product. In India lists of prohibited and restricted list is specified by Bureau of Indian Standards (BIS).

6.7.1.4. Ingredient labelling

Labelling of ingredients is required in the EU, USA, Japan and Canada using INCI terms (translated for Japan). All markets require quantity labelling using metric units; however, non-metric labelling is also mandatory in the USA and is permitted in Canada and in the EU (until 2009) as a supplement to metric labelling. All markets require the producer/importer identity to be labelled, although in Japan only a Japanese address is acceptable. In India labeling requirement is specified by Bureau of Indian Standards (BIS).

6.7.1.5. Safety testing

No specific tests are required to determine product safety and efficacy. Manufacturers are responsible for ensuring that adequate testing is performed to ensure the safety of their products. In the EU, testing guidelines are issued by the scientific advisory committee, the SCCNFP. In the US and Japan, testing guidelines have been developed by industry.

6.7.1.6. Data on product safety and efficacy

One key requirement of the EU Cosmetics Directive is that producer must maintain a file of information about their products, including the results of safety testing, data on any undesirable effects and proof for certain claims made. These files must be made available to the regulatory authorities on request, and provide evidence that manufacturer have met their responsibility for product safety. No such product information files are required under the regulations in the other major markets, although in Japan and Canada manufacturers must be able to prove the safety of the product (and, in Japan, its efficacy) on request. In the USA, manufacturers may place products on the market without data on safety but such
products must carry a specific warning on the packaging. In India no such product information files are required under the regulations.

After discussing the overall cosmetic legislation of major market along with Indian context, the following part is briefed on categorization of cosmeceuticals in few major markets.

The regulatory environment concerning to cosmeceuticals is changing worldwide. An extensive review of legislation, regulations, guidelines and accepted practices were identified and analyzed regarding the development and marketing of cosmeceuticals.

6.7.2 Categorization of cosmeceuticals in few major markets

An approach took by some jurdications, to create an extra category to accommodate cosmeceuticals category or borderline products, is discussed below.

- **Japan**
  Japan accommodates cosmeceuticals by calling “quasi–drugs”. These are products that exert mild actions on the human body. The ingredients included in quasi-drug must be pre-approved before marketed in Japan. All products claiming to be cosmeceuticals are considered quasi-drugs and require pre-approval before selling in market [7].

- **New Zealand**
  New Zealand law provides a third category called “related products”. Related products are those having therapeutic use as a purpose secondary to the main use. Related products are to be labeled with an appropriate designation and trade name, the active ingredients to be disclosed quantitatively, the product’s true nature, expiry date and batch number, a dose and its frequency, directions for use, and name and address of the manufacture [8].

- **Korea**
  Korea Food and Drug Administration (KFDA) have classified cosmeceuticals or borderline products as “functional cosmetics” such as skin whitening, anti-aging and sun care products. Functional cosmetics prevent melanin pigmentation, spots, promote whitening of the skin, improve skin wrinkles and block or diffuse UV rays to protect the skin. The KFDA is responsible for evaluating and improving safety of functional cosmetics [9].

- **Thailand**
  Under the current cosmetic regulation, cosmetics are classified as “controlled cosmetic” according to the ingredients used. The use of controlled ingredients as part of cosmetic products will require the notification of the products to FDA before being marketed in Thailand [10].
Australia
In Australia the categorization of goods are based on two factors. (a) Claims made about the product and (b) The composition of the product. The products which are at the borderline are classified as therapeutic goods. These goods must use only approved ingredients. The goods must be included in the Australian Register of Therapeutic Goods. Safety and efficacy and Good Manufacturing Practices data must be submitted to regulatory authority. The National Coordinating Committee on Therapeutic Goods (NCCTG) provides guidance on acceptable and unacceptable cosmetic claims [11].

Canada
In Canada cosmeceuticals are also called as “dermo-cosmetics”. Canadian health authorities do not officially recognize cosmeceuticals as an independent cosmetics category. As several product fall into both categories of cosmetic and drug, health Canada has identified category IV to accommodate these products. These products have less regulatory requirements because they have a low risk. The two key factors that are considered in the classification of a cosmetic versus drug are: the composition of the product and the proposed use of a product. Advertising Standards Canada, the Canadian cosmetic, Toiletry and Fragrance Association and the cosmetics division of Health Canada jointly have established the guidelines for cosmetic advertising and labeling claims. These guidelines help cosmetic manufacturer to use wording of a claim on cosmetic products [12].

European Union
Cosmetics in EU are regulated under the Cosmetic Directive 76/768/EEC. To avoid the categorization of cosmeceuticals, EU has clarified by establishing the “Illustrative list by category of Cosmetic Products”. EU has stringent laws where companies are required to submit the proof of the claims made by the product. As borderline products are already classified as cosmetics, EU doesn’t need third category called cosmeceuticals [13].

United States of America
According to USFDA there is no legal definition of cosmeceutical products. In the US there are three categories such as drugs, cosmetics and OTC drugs. USFDA states that a product can be both drug and cosmetic. USFDA classify products depending upon the product claim. In US the classification of products are neat and simple. Some of the examples are:

- A suntan product is a cosmetic but a sunscreen product is a drug
- A deodorant is a cosmetic but an antiperspirant is a drug
- A skin exfoliant is a cosmetic but a skin peel is a drug
- A skin product to hide acne is cosmetic but an antiacne product is a drug
A skin moisturizer is a cosmetic but a wrinkle remover is a drug.

An antibacterial deodorant soap is a cosmetic but an antibacterial anti-infective soap is a drug.

A lip softener is a cosmetic but a product for chapped lips is a drug.

A shampoo is a cosmetic but an antidandruff shampoo is a drug.

A toothpaste is a cosmetic but an anticaries toothpaste is drug.

A mouthwash is cosmetic but an antigingivitis mouthwash is a drug.\[^{14}\]

The categorizations of borderline or similar products are discussed with some examples in major markets.

**Table 6.2. Categorization of borderline products with some examples**\[^{2}\]

<table>
<thead>
<tr>
<th>Product category</th>
<th>EU</th>
<th>United States</th>
<th>Japan</th>
<th>Australia</th>
<th>New Zealand</th>
<th>Canada</th>
<th>India</th>
</tr>
</thead>
<tbody>
<tr>
<td>Antiperspirants</td>
<td>Cosmetic</td>
<td>OTC drug</td>
<td>Quasi-drug</td>
<td>Therapeutic</td>
<td>Good</td>
<td>Cosmetic</td>
<td>Non-prescription drug</td>
</tr>
<tr>
<td>Antidandruff Shampoos (mass market)</td>
<td>Cosmetic</td>
<td>Drug and Cosmetic</td>
<td>Quasi-drug</td>
<td>Therapeutic</td>
<td>Good</td>
<td>Related Product</td>
<td>Drug</td>
</tr>
<tr>
<td>Moisturisers with Sunscreen</td>
<td>Cosmetic</td>
<td>Drug and Cosmetic</td>
<td>Cosmetic</td>
<td>Therapeutic</td>
<td>Good</td>
<td>Cosmetic</td>
<td>Cosmetic</td>
</tr>
<tr>
<td>Antibacterial Skin Washes</td>
<td>Cosmetic</td>
<td></td>
<td>Cosmetic</td>
<td>Quasi-drug</td>
<td>Therapeutic</td>
<td>Good or Therapeutic Good</td>
<td>Cosmetic (antibacterial cleanser). Drug (kills germs; antiseptic).</td>
</tr>
<tr>
<td>Anti-acne lotion</td>
<td>Medicinal product</td>
<td>OTC drug</td>
<td>Quasi-drug</td>
<td>Therapeutic</td>
<td>Good</td>
<td>Cosmetic</td>
<td>Non-prescription drug</td>
</tr>
<tr>
<td>Medicated Skin Cleansers (for acne)</td>
<td>Cosmetic</td>
<td></td>
<td>Cosmetic</td>
<td>Quasi-drug</td>
<td>Therapeutic</td>
<td>Good or Therapeutic Good</td>
<td>Cosmetic (as a cleanser for acne-prone skin). Drug (treatment or control of acne).</td>
</tr>
<tr>
<td>Mouthwashes</td>
<td>Cosmetic</td>
<td>Drug and Cosmetic</td>
<td>Quasi-drug</td>
<td>Therapeutic</td>
<td>Good or Cosmetic</td>
<td>Related Product or Cosmetic</td>
<td>Drug or Cosmetic</td>
</tr>
<tr>
<td>Toothpastes (fluoride)</td>
<td>Cosmetic</td>
<td>Drug and Cosmetic</td>
<td>Quasi-drug</td>
<td>Therapeutic</td>
<td>Good or Cosmetic</td>
<td>Related Product</td>
<td>Drug</td>
</tr>
</tbody>
</table>

\[^{14}\]
The borderline products are cosmetic in one market. Same product is OTC drug, non-prescription drug or medicinal product in another market.

After analyzing the above legislation, regulations, guidelines and accepted practices for borderline products or cosmeceuticals in major countries, an attempt was made to prepare the much needed regulatory framework for cosmeceuticals in India.

6.7.3. **Key components of a regulatory model for cosmeceuticals in Indian context**

6.7.3.1 **Definition of cosmeceuticals**

There is a need to revise the definition of cosmetic in line with our present knowledge of the skin. The definition of cosmetic according to Drug and cosmetic Act, 1940 is narrow and restricted compared to EU, ASEAN and Japan. The definitions should recognize that virtually all topical agents have some effect on the structure or function of skin and that the distinction between drugs and cosmetics is better based on risk-benefit analysis, indication for product use, and character of the skin changes resulting from product use. The cosmeceuticals can be defined as topically applied product with both cosmetic and pharmaceutical functionality.

6.7.3.2 **Categorization of cosmeceuticals**

Categorization of cosmeceuticals will enable cosmetic companies to market their product. Cosmeceuticals could be characterized on the basis of: the product that has the pharmaceutical activity and can be used on normal or near normal skin. The product should have a defined benefit for minor skin disorders (Cosmetic indication). As the skin disorder is mild the product should have a very low-risk profile. Cosmeceuticals should be categorized as subclass of cosmetic or drug [15].

6.7.3.3 **Dossier requirements** [16]

The regulatory requirements for approval and marketing of cosmeceutical products should contain information based on the qualitative and quantitative composition of the products. The dossier should be under four major headings

i. An administrative dossier

ii. An ingredient dossier

iii. A finished product dossier

iv. A post market dossier
The requirements for above four dossiers are discussed below

i. **An administrative dossier**

In this dossier an applicant should submit trade name of the cosmeceutical product and responsible person in the company, manufacturer name or distributor name.
The dossier should mention the product categories like skin care, hair care etc.
The integral composition of the product should be disclosed in administrative dossier. To ensure safety assessments, responsible person should be appointed by the company to maintain product files related to registration of the product.
The responsible person shall ensure compliance with guideline like safety assessment, product information file, good manufacturing practices, sampling and analysis, product notification, restrictions for substances, animal testing, product labeling, product claims, information to the public and information provided on substances.
For each cosmeceutical product placed on the market the responsible person shall ensure compliance with the relevant obligations set out in the regulations. For an imported cosmeceutical product, each importer shall responsible for the specific cosmeceutical product which he places on the Indian market.
In case of distribution of products (distributor) shall be the responsible person, when he places a product on the market under his name or trademark or modifies a product already placed on the market in such a way that compliance with applicable requirements may be affected. Furthermore responsible person shall take necessary corrective measures if cosmeceutical product fails to deliver and does not conform to the regulations. Further as a corrective action the failed product should be withdrawn from the market or recalled, as the case may be.

ii. **An ingredient dossier**

Cosmeceuticals by definition contains ingredients that have an intended pharmaceutical effect, so it should be possible for the manufacturer and ingredient suppliers to prove this.
An ingredient dossier should contain detailed information about identity of ingredient suppliers and composition of the ingredients supplied. However, procedure for registration of new ingredients should be relatively simple. Registrations of combination of ingredients as well as individual ingredients are recommended.
The dossier should have physio-chemistry and microbiology of the ingredients including the physio-chemical and microbiological inspections. Further, toxicity data including oral, dermal and inhalation toxicity, local toxicity, like skin irritation, sensitization, photo allergy and photo–irritation should be included in dossier when relevant. The dossier should contain
repeated dose toxicity data, additional relevant toxicological data. Additionally, the dossier should mention list of animal tests performed with the ingredients.

iii. A finished product dossier

The finished product dossier should contain details of manufacturing, safety, efficacy, claims and labeling of cosmeceutical products.

Manufacture of cosmeceuticals: Applicant should get manufacturing license from regulatory authority. The manufacturing premises should be inspected by FDA. Even the approval of manufactures premises should be necessary when located outside the country concerned. To facilitate safe product, GMP of pharmaceutical products must be followed for the manufacture of cosmeceutical products. The respective state FDA shall be made responsible for inspection of compliance with GMP in plants. The complete details about the names, addresses of the directors of the company and addresses of the manufacturing premises and registered office of the manufacturer should be maintained.

A copy of the site master file shall be maintained containing a brief description of the manufacturing process of the cosmeceutical products to be manufacture, details of the standards followed by the company for Good Manufacturing Practices, product evaluation, Name, qualification and experience of technical staff under whose supervision the cosmeceutical products will be manufactured, copies of ISO or any other certifications, if any, obtained by the firm for its manufacturing facility.

Safety of cosmeceuticals: An important consideration in cosmeceutical development is safety. It is important to recognize that no regulations for cosmeceutical safety are in place at present. Cosmeceuticals are considered as cosmetics by Indian regulatory authorities and, as such, are regulated like cosmetics. As with existing drug and cosmetic groups, cosmeceuticals should have premarket testing requirements. The safety evaluation of cosmeceuticals may therefore, resemble the safety evaluation of other OTC products. The need of the hour is to define reasonable standards for safety testing to enable regulatory agencies to evaluate cosmeceuticals thoroughly but in timely manner. Before placing the cosmeceutical product on the market the responsible person shall submit, through electronic means, the following information to the regulatory authorities.

The cosmeceutical product safety report should contain following information:

- The trade name of the product, address of manufacturer or distributor.
- The product information file should state product category
- The name and address of the responsible person where the product information file is made readily accessible
The country of origin in case of import
The member state where the product is placed on the market
The contact details of a person for communication if needed
Quantitative and qualitative composition of the product
Identity and details of supplier and manufacturer of ingredients
Physical /Chemical characteristics and stability data
Microbiological tests data
Toxicity data including acute oral, dermal and inhalation toxicity, local toxicity, including skin irritation, eye irritation, sensitization, photo-allergy and photo-irritation when relevant.
List of animals tests performed with the finished product
Impurities, trace ingredients and information about packaging material

Product notification can be made to authority through an online application. Applications shall be processed faster and timeline should be set. Additional time shall be given to answer queries/objections, if any, raised by relevant regulatory authority. Submission of Product details (Safety, Quality, and Compliance to Bureau of Indian Standards) at the time of notification should continue as current practice and additional data can be stored as 'Product information file' with details maintained at the concerned manufacturing location for the regulators review. Product information file should contain the product safety report of cosmeceutical which must be kept up-to-date and shall clearly mention the responsibilities of manufacturer and the safety assessor.

Cosmeceutical efficacy

At present there are no regulations for cosmeceutical safety, even there are no regulations for cosmeceutical efficacy. Typically, human clinical testing should be carried out under the guidance of a research laboratory or dermatologist with defined parameters to substantiate efficacy. To evaluate a new cosmeceutical product which claims a beneficial physiological effect, it very important to address three issues?

- Can the active ingredient penetrate the stratum corneum and be delivered in sufficient concentrations to its intended target in the skin over a time course consistent with its mechanism of action.
- Does active ingredient have specific biochemical mechanism of action in the target cell or tissue in human skin?
- Are there published peer-reviewed, double–blinded, placebo-controlled, statistically significant clinical trials to substantiate the efficacy claims?
The laboratory and clinical data should be available for the review by the regulatory agencies.

**Claim guidelines for cosmeceuticals**[^20]

In Indian context cosmeceutical claim guidelines are not on records compared to European Union and ASEAN countries. This can be facilitated by introduction of permissible and non-permissible claim guidelines for cosmeceuticals. Cosmeceuticals are currently defined by the claims that are made about their intended use. Cosmeceutical claim is any public information primarily provided for marketing purposes on the content, the nature, the effect, the properties, or the efficacy of the product.

Before claiming an intended use or indication, manufacture must hold adequate evidence to support all claims made about a product.

The claims on a cosmeceutical product should be supported by information on the finished product itself. Claims should be supported by scientific, relevant and clear evidence such as experimental studies. Claims must be true, valid and not misleading. Claims should not lead to unsafe or inappropriate use of a product. The advertising has to be done considering average consumer. Exaggerated therapeutic claim should to be avoided. The example of anti-aging product is given below.

The acceptable claims for anti-aging cosmeceutical products shall be:

- Effectively repair the visible signs of the skin’s aging process
- Reduce fine lines
- Minimize fine lines
- Reduce the signs of aging
- Slows appearance /look of aging/premature aging
- Slows signs/the look of aging/premature aging
- Protect against the visible signs of aging
- Fades dark spots
- Cover up age spots
- Hide age spots

**Labeling / product information of cosmeceuticals offered for sale**[^21]

Adequate labeling of cosmeceutical products shall ensure following details on the label.

- Accurate labeling includes clear placement on the product label of its identity, the name and the address of the manufacture or distributor
- Batch number
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- The nominal content or quantity of the product contained therein (by weight or volume)
- The ingredients listed in rank order using specific nomenclature and other ingredients
- Clearly differentiate active ingredients and other ingredients
- Date of minimal durability if less than 30 months, period after opening if durability exceeds 30 months.
- Precautions and directions for use: All safety warnings related to the use of the product must be placed prominently on the label
- Product function
- Ingredient labeling in international nomenclature of cosmetic ingredients (INCI)

iv. A post market dossier

Post Market surveillance: With simplification of product licensing procedure, the Indian FDA authority can focus on in market control of safety of cosmeceuticals and any unscrupulous practice with shared responsibility by Industry. In market controls can be supported through periodical (yearly) submission of market audit data of cosmeceutical products. The key features of the in-market control system include:

1. Avoidance of time-consuming and expensive pre-market licensing/registration of products.
2. The company responsible for placing the cosmeceuticals on the market is also responsible for the regulatory compliance, for the safety and efficacy of the product, and must be able to justify this on authority investigation.
3. Effective in-market control by competent national authorities monitoring the market to check compliance with regulations. Market surveillance is performed through random control on the market (in retail shops), by routine checks compliance with regulations or by systematic control of given product categories, if a problem arises, like a consumer complaint.
4. In case of non-compliance there can be penalties of varying strength and if the manufacturer fails to prove that cosmeceutical product is safe for use, the product shall be withdrawn or recalled from the market.
5. It encourages companies to ensure product safety and therefore it offers better health protection benefits.
7. It increases the competitiveness of the market.
8. It ensures that new products will be available to consumers more quickly.
9. It guarantees equal treatment of all companies \(^{[22]}\).
6.7.3.4. Introduction of post-marketing vigilance for cosmeceutical products

Post -marketing vigilance system usually focus on adverse reactions of drugs, recently much consideration is given to medical devices, blood products, biologics, special nutritional and natural products, whereas less attention has been addressed to adverse reactions related to cosmetic or cosmeceutical products. Germany and Sweden are the two countries that have a formal cosmetovigilance system.

The well-structured cosmetovigilance system is not only to investigate but also to prevent the risk of adverse reactions through cooperation and coordination among different scientific experts, health authorities, industry/manufacturers and consumers organizations. This could contribute to increased safety of cosmeceuticals use which is important for the safeguard of public health.

6.7.3.5. Information accessible to the public

The cosmetic companies should co-operate the public by providing the information about the products which they are using. The information has to be made to the public on request but it should not to be published. Even the public can access the information by writing to the company, through telephone and by visiting the company website. The information related to qualitative and quantitative composition of the products; existing data on undesirable effects on human health resulting from use of cosmeceutical products should be accessible to the public. The company should answer all the queries and requests in simple language and should maintain the records of all complaints, requests and answers given by the company.

6.7.3.6. Advisory body: (Cosmeceutical Consultative Committee)

Cosmeceutical Consultative Committee should be constituted by Central Government to advise the central and state governments on technical matters arising out of the administration. The Cosmeceutical Consultative Committee should be constituted comprising members from industry, consumer activists, medical profession, academia and regulatory authorities. The members that may be included in Cosmeceutical Consultative Committee are listed below:

1. Member from cosmetic industry
2. Member from Pharmaceutical industry
3. Regulatory expert from Indian Pharmaceutical Industry
4. Expert from academic institution involved in basic research of cosmeceuticals.
5. Dermatologist
6. A beautician
7. Social worker
8. Government official (from FDA)
9. Representative of Consumer organization

The Cosmeceutical Consultative Committee shall advise the Drug Controller General of India on policies to promote the safe and appropriate use of cosmeceuticals and enhance public health and wellness through use of cosmeceuticals. The advisory board can help Indian regulatory authority for building workshops for basic understanding of advancements in cosmetic technologies and helping big and small scale industries to implement new suggested practices for taking the onus of safety and quality of products

6.8. Conclusion

Cosmeceuticals already exist in Indian market. They are next generation of skin care products. The development and tremendous growth in cosmeceutical sales have attracted the attention of regulatory authorities. As far as regulatory framework is concerned for this category, there are no specific guidelines with respect to cosmeceuticals in India. Few countries have initiated and have classified cosmeceuticals. Looking at the booming Indian cosmeceutical market, it is high time that Indian regulatory authority should initiate and work for the development of cosmeceutical category. It is also important that access to beneficial cosmeceutical products should not be delayed by unnecessary constraints, it is equally important to reject cosmeceutical products which are irrational and cause harm to consumers. By studying the present scenario, an attempt was made to provide a general requirement which gives a basic idea of the data requirement to be submitted for marketing approval of cosmeceuticals.

Further alignment of regulatory frameworks related to cosmeceuticals in future could contribute to the removal of barriers to trade and encourage innovation, while ensuring a high level of protection for consumers.
6.9. References


