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Original Article

Regulatory Requirements for Cosmetics in Relation with Regulatory Authorities in India against US, Europe, Australia and Asean Countries

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ABSTRACT

The cosmetics legislations on account of quality, safety, nomenclature & labeling are much stringent in regulated markets in order to regulate the use of cosmetic products. The safety assessments of cosmetic products is affected by the differences outlined by the regulatory authorities across globe. Nevertheless, there is a need for harmonized regulations throughout India (within the states), even in entire world. As per current study lot of differences are in cosmetic regulations in India when compared to regulated markets like USA, EU and Australia.

The mandatory information need to be made to the public so that public can access the information by writing to the authority and company to get the clarification, through visiting the specific website. The information related to qualitative and quantitative composition and safety assuranceas per claims of the products; existing data on undesirable effects on human health resulting from use of cosmetic products should be accessible to the public. The authoritiesshould follow and reply to all queries and requests in simple language and should maintain the records of all complaints as vigilance trackers. Strict guidelines and regulations can increase attention to cosmetic products and globalization of their market.

Indian regulatory scenario has major issues with the current Indian cosmetic regulations such as Multiple and complex regulations under different bodies, Indian cosmetic definition is not broader encompassing different possible formulations, lack of implementation guidelines of the CDSCO, BIS Standard's development and revision for issues related to cosmetics, non-uniform licensing approvals across various states, discontinued approach across authorities in interpretation of a particular issue. Absence of proper guidelines on product claims interpretation as well as instructive list of cosmetics, which correlate the cosmetic life cycle management process.

Key words: Cosmetics, Regulatory regulations, Harmonization, Authorities& Safety requirements

1. INTRODUCTION

The cosmetics market in India is mounting about 20 percent annually, twice as fast as that of the US and European markets. Although the cosmetic regulations in India are complex and time-consuming, which are needful for pre & post-marketing approvals. It is therefore important for a cosmetic manufacturers, distributers and importers to

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understand the differences in the regulatory system in India when compared to the regulated countries like U.S, Europe, Australia countries. The safety of the cosmetic goods are regulated by diverse regulatory bodies around the globe and all have their own rules and regulations. In this study author has described the comparison between Indian market and other certain regulated market.

Regulators in different countries defined cosmetics in different ways. Examples are given below:

India: As per Drugs and Cosmetics Act 1940 and Rules 1945, Cosmetic means any article intended to be rubbed, poured, sprinkled or sprayed on, or introduced into, or otherwise applied to the human body or any part thereof for cleansing, beautifying, promoting attractiveness, or altering the appearance, and includes any article intended for use as a component of cosmetic. [1]

United States: Defines cosmetics as "articles intended to be rubbed, poured, sprinkled, or sprayed on, introduced into, or otherwise applied to the human body or any part thereof for cleansing, beautifying, promoting attractiveness, or altering the appearance, and articles intended for use as a component of any such articles; except that such term shall not include soap". [2]

European Union: Defines cosmetics as "any substance or preparation intended to be placed in contact with the various external parts of the human body (epidermis, hair system, nails, lips and external genital organs) or with the teeth and the mucous membranes of the oral cavity with a view exclusively or mainly to cleaning them, perfuming them, changing their appearance and/or correcting body odours and/or protecting them or keeping them in good condition". [3]

Definitions is legal line b/w cosmetics &drugs, determine labelling requirements and standards.

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. 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 complications. 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 finest.

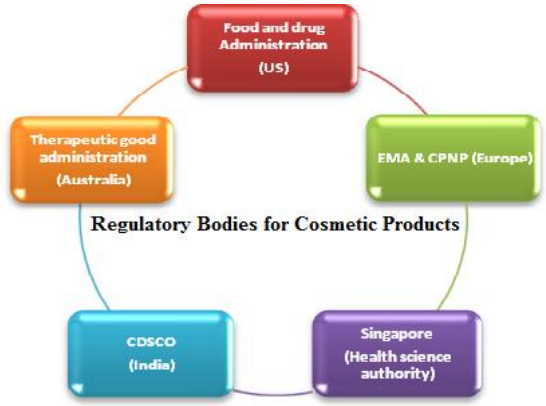
In the US and Europe, cosmetic and personal care products companies work with best scientific and medical experts every day and invest millions of dollars in sophisticated laboratory equipment and facilities to ensure cosmetic product quality and safety. In this study; certain countries (US, EU, India, Australia and ASEAN) requirements are discussed in terms of regulatory aspects which really have impact on the two terminologies: Manufacturing Company responsibilities and Consumers protection-safety standards for the cosmetic products but all responsibilities and standards depend upon the competent authority only.

2. RESEARCH METHODOLOGY

Information and procedure were collected with regard to regulations of cosmetics by deep study of large number of guidelines and regulations. Further information with respect to regulatory requirements specified by regulatory authorities of US, Europe, India, Australia and ASEAN countries were collected. A conceptual framework was framed containing general regulatory requirements for marketing approval of cosmetics in India. Finally, an attempt was made to placed together the parameters and sequence of information and documents required by regulatory authorities for pre or post-development, promotion, registration activities and marketing approval of cosmetic products.

Cosmetic goods are regulated by various regulatory bodies around the globe and all have their own rules and regulations. For better understanding of this chapter the comparison of key features of overall cosmetic regulations are discussed followed by product categorization of cosmetic products in major markets.

Cosmetics has altered definitions based on region or country wise which are available in chapter1 and its similar terms can see in global market like Cosmeceuticals and OTC products, depending on specific type of product being produced, manufacturers may elect to conduct additional testing to ensure the safety and usefulness of their cosmetic products. Cosmetic manufacturers may also perform additional tests to meet specific quality or performance requirements of buyers and consumers.



Borderline Products: Authorities play an extensive role to display in market and different countries having different borderlines and differences in regulatory frameworks can be particularly significant for so-called 'borderline products'. Table 1 illustrates some examples of the different categorization of products under different regulatory regimes. It is important to note that the classification of products depends on the composition of the product (for

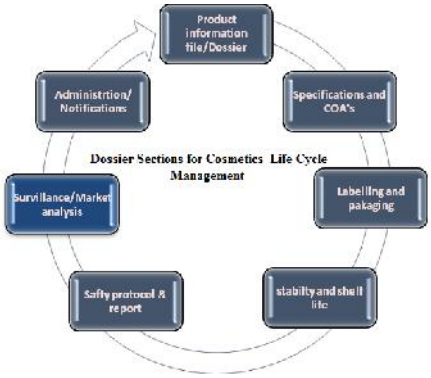
example, the presence of certain active ingredients) and the claims made on the product.

Table 1: Summary of borderline products with some examples

Product category	Country				
	US	**EU countries**	**Australia**	**ASEAN countries**	**India**
Sunscreen	OTC drug	Cosmetics (in positive list)	Therapeutic Good	Cosmetics	Cosmetics
Antidandruff	Drug and cosmetics	Cosmetics	Therapeutic Good	Cosmetics	Cosmetics
Anti-bacterial skin washes	Drug (If Anti-bacterial claim are made)	Cosmetics	Therapeutic Good	Cosmetics	OTC or cosmetics
Anti-acne lotion	OTC drug	Medicinal product	Therapeutic Good	Cosmetics	Cosmetics
Mouth wash	Drug and cosmetics	Cosmetics	Therapeutic Good	Cosmetics	Cosmetics
tooth pastes (Fluoride)	Drug and cosmetics	Cosmetics	Therapeutic Good	Drug and cosmetics	Cosmetics

1. Cosmetic regulatory requirements in certain countries:

Although regulations applicable to cosmetic products are increasingly being harmonized to reduce international barriers to trade, there are still important differences to take into account when marketing or selling cosmetics in major markets around the world. The following sections discuss mandatory and specific regulatory requirements in certain countries such as US, Europe, Australia, India and ASEAN countries:



1.1 US cosmetics requirements:

The cosmetic and personal care products industry supports a strong and vigilant FDA. FDA has abundant regulatory and enforcement authority for cosmetics under the federal Food, Drug and Cosmetics Act. Consumers benefit from having FDA as a strong watchdog for their health and safety, and industry benefits when consumers are confident with the cosmetic safety standards set by the Agency. FDA monitors the safety of cosmetic products that are being marketed by number of ways such as Voluntary Cosmetic Registration Program, Inspections (to manufacturing facilities), Surveys of products (periodically buys cosmetics and analyzes), Cosmetic Ingredient Review (CIR) expert panel and Reports from consumers and health care providers: report cosmetic related problems through MedWatch (FDA's problem-reporting program) [4].

Cosmetic products are regulated by the FDA through different laws like:

"Federal Food Drugs and Cosmetic Act (FD&C 1938)" and "Fair Packaging and Labeling Act".

I. **Product Information:** FDA has categorized the cosmetics as mentioned:Hair Products,Makeup, Nail Care Products, "Organic" Cosmetics, Soaps & Lotions, Tattoos & Permanent Makeup on the other hand the VCRP (Voluntary Cosmetic Registration Program) database as well provides important information on these cosmetics.

FDA encourages cosmetic firms to report product formulations through the VCRP. This programregulates the Product Category Code which consist of a 2-digit number, and indicates the general category, and a letter, which indicates the specific type of product. For example, to find the Product Category Code for a baby shampoo, note that "Baby Products" are category "01." Baby shampoos are listed in this category as item "A.". The summarized below list is following 13 categories:-

01. Baby Products (Shampoos, Lotions, Oils, Powders & Creams), **02. Bath Preparations (**Bath Oils, Tablets), **03. Eye Makeup Preparations (**Eyeliner, Eye Shadow, Mascara), **04. Fragrance Preparations (**Perfumes, Powders), **05. Hair Preparations (non-coloring) (**Hair Spray (aerosol fixatives), **06. Hair Coloring Preparations (**Hair Dyes, Colors), **07. Makeup Preparations (not eye) (**Blushers, Face Powders, Foundations, Lipstick, Makeup Bases), **08. Manicuring Preparations (**Nail Creams and Nail Polish) **09. Oral Hygiene Products (**Dentifrices (aerosol, liquid, pastes, and powders, Breath Fresheners), **10. Personal Cleanliness (**Bath Soaps and Detergents, Deodorants), **11. Shaving Preparations (**Aftershave Lotion, Shaving Cream), **12. Skin Care Preparations** (Creams, Lotions & Powders-Face/Body and Hand),**13. Suntan Preparations (**Suntan Gels, Creams, Liquids, Tanning Preparations).[5]

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II. **Cosmetic Regulation - FD&C Act:**FDA has authority to inspect firms, equipment, unfinished and finished materials, containers with labeling and has listed information about Adulterated/Misbranded ingredients:- **Adulterated:**Injurious to users under conditions of customary use because it contains, or its container is composed of, a potentially harmful substance, chemical contaminant or prohibited ingredient [13,] **Prohibited Cosmetic Ingredients:**Hexachlorophene, Mercury Compounds, Chlorofluorocarbon Propellants, Acetyl ethyl tetramethyl tetralin (AETT), 6-MC, Dioxane&Certain cattle materials, **Restricted Cosmetic Ingredients:**(permissible as unintentional contaminants):Bithionol, Halogenated Salicylanilides,

Chloroform, Vinyl chloride, Zirconium containing complexes in aerosol cosmetic products, Methylene chloride etc.

III. **Labeling:**The cosmetics distributed in the US must comply with the systematic Cosmetic labeling guide published by the FDA under the authority of the FD&C Act. Labeling means all labels and other written, printed or graphic matter on or accompanying a product [6].The main requirements are:

a) Principal Display Panel (PDP):

- **Identity statement**: The common/usual name, descriptive name, fanciful name, Illustration, Prominence, Placement
- **Net quantity**: Quantity of the contents, in terms of weight, measure, numerical count
- **Warning**: If the cosmetic product contains an ingredient for which adequate substantiation of safety has not been obtained, a warning must be placed on the PDP like "Warning - the safety of this product has not been determined"

b) Information panel (IP):

- **Name and place of Business:** Principal place of business, corporate name, Manufactured for xyz, Distributed by xyz and complete Address.
- **Language:** The complete labeling statements required by regulation must be in English. If the label contains any foreign language representation, all statements required local language.
- **Distributor statement**: Add manufactured for xyz or Distributed by xyz.
- **Ingredients name&listing:** Applicant may use INCI name or in absence, but applicant should use the name given by the US Pharmacopeia, NF, Food chemical Codex and USP dictionary of drugs names.

Ingredients must be listed on product labels in descending order by quantity. Exemptions are made for active drug ingredients, ingredients with less than 1% concentration and color additives which can appear in disorder because of small amounts. Fragrance and flavor may be declared in descending order of predominance as "fragrance" and "flavor".

Ingredients declaration: Ingredients must appear clearly and intelligibly, so that an ordinary person under normal conditions of purchase can understand. Applicant must use an appropriate information panel and make sure that the font size is not less than 1/6 inches in height.

Cosmetic Warning Statements: As per FD&C Act, Cosmetics may be hazardous to consumers must be bear appropriate label warnings. e.g.: Flammable cosmetics such as aerosols, cosmetic manufacturers market cosmetic products that do not contain ethyl alcohol as "alcohol free".

Material facts: Applicant should reveal material facts (e.g.: directions for safe use), or applicant's product will be considered as misbranded or adulterated.

Cosmetic Claims: Information on cosmetic labeling, including claims, must be truthful and not misleading. In addition, if a product is marketed with claims for purposes such as treating or preventing disease, or affecting the structure or function of the body, it's a drug according to the law and it must meet the requirements for drugs, even if it affects the appearance because FDA does not have the authority to approve claims before cosmetics go on the market. Cosmetic manufacturers market cosmetic products that do not contain ethyl alcohol as "alcohol free". To prevent the ethyl alcohol in a cosmetic from being diverted illegally for use as an alcoholic beverage, it must contain an added "denaturant" that makes it undrinkable [9].

Penalties: The law provides severe penalties for products that do not meet these standards. Specifically, the law gives FDA the authority [6].

IV. Observation of US cosmetic regulations:

Cosmetic products and ingredients are not subject to pre-market review and approval. Instead, manufacturers are responsible for substantiating the safety of their products and ingredients, and for providing consumers with complete and accurate information regarding a product's ingredients. The sole exception to this approach involves the use of color additives, which are subject to separate FDA requirements.

To enforce its regulations, the FDA collects samples of cosmetic products for examination and analysis through routine inspections of manufacturing facilities, as well as of imported products.

USFDA states that a product can be both drug and cosmetic, the classification of products are arranged & simple and depending upon the product claim. Some of the examples are:-

- A skin product to hide acne is cosmetic but an anti-acne product is drug
- A skin moisturizer is a cosmetic but a wrinkle remover is drug
- An antibacterial deodorant soap is a cosmetic but an antibacterial anti-infective soap is drug
- A lip softener is a cosmetic but a product for chapped lips is drug
- A toothpaste is a cosmetic but an anticaries toothpaste is drug
- A shampoo is a cosmetic but an antidandruff shampoo is drug.

In addition to the Food, Drug, and Cosmetics Act, the Fair Packaging and Labeling Act authorizes FDA to require ingredient labeling of cosmetic and personal care products sold to consumers. Cosmetics are among the safest of all consumer products sold in the U.S. Their continued safety is ensured by FDA's regulatory program and additional safety measures undertaken by the cosmetic and personal care products industry [6].

1.2 Europe Cosmetic Requirements:

National authorities in each EU country are in charge of reviewing the safety assessments and checking products already on the market. Cosmetics Legislation requires that every cosmetic product placed on the market in Europe is safe to use. The EU Cosmetic Regulation 1223/2009 came into force in 2013 and concerns 31 European countries (28 countries of the EU + Norway + Iceland + Lichtenstein) [6]. The regulation is based on three principles:

- Safety of Raw Materials and Ingredients
- Good manufacturing practices
- Invigilating of cosmetic market

These principles translate into requirements for the cosmetic brand (non-exhaustive list):

- Designate a Responsible Person (RP)
- Prepare a Product Information file (PIF) including a Safety Assessment
- Respect the Good manufacturing practices (GMP) for cosmetics
- Comply with Labeling and Packaging requirements
- Ensure notification via the Cosmetic Products Notification Portal (CPNP)

With this regulation, the European Union sets a higher level of transparency for finished cosmetic products, prevents the placing on the market of hazardous substances, and strengthens safety for consumers [6].

The Product Information File: PIF is the mandatory compilation of technical documentation required for each cosmetic product to be placed on the EU market. According to the EU Cosmetics Regulation 1223/2009/EC, the elements of the PIF include but are not limited to:

- Product Description
- Safety Report:
  - Part A: Cosmetic Product Safety Information
  - Part B: Cosmetic Product Safety Assessment Report
- Method of Manufacturing, Evidence of compliance with Good Manufacturing Practices (GMP), Proof of the effect claimed (where justified), Data on Animal Testing, Labeling (taking into account the container and outer packaging), Data on Serious Undesirable Effects [8].

I. **Labelling**:In EU regulations they have as well systematic mandatory information that must be printed in "indelible, easily legible and visible lettering":

- **Name and address of the Responsible Person**: If applicant is outside the EU, it is mandatory to designate Responsible Person (RP), in order to market the product. If cosmetic brand based in the EU, applicant will be acting as the RP by default.
- **List of ingredients**: In decreasing order of weight, except for ingredients below 1%.
- **Country of origin**: Add the mention: "Made in country" unless the product is made in Europe in which case such mention is not mandatory. Note: the "Made in" expression does not need any translation.
- **Nominal content**: The nominal content must appear in grams (g) or milliliter (ml) and in first position.
- **Date of minimum durability (DOMD) & Period after opening (PAO)**: If the durability is inferior or equal to 30 months, manufacturer need to indicate the "hour glass" symbol and print date (MMYY / DDMMYY). If the durability is superior to 30 months then you must indicate the PAO. Manufacturer will need to print the "open jar" symbol with the number of months (M) or year (Y) inside or next to the open jar.
- **Particular precautions of use and warnings**: Depending on the type of cosmetic product, some particular precautions of use and warnings might be useful to consumers or even mandatory in certain cases.
- **Batch number**: is mandatory, although no particular format is required.
- **Product function**: The function of the product must be clearly indicated, e.g.: hand moisturizer as to prevent any misuse.
- **Product claims**: In the labelling, making available on the market and advertising of cosmetic products, text, names, trademarks, pictures and figurative or other signs shall not be used to imply that these products have characteristics or functions which they do not have [6].

II. Observation of EU cosmetic regulations:

Cosmetics in EU to avoid the complex have 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 cosmetic products are already classified. EU cosmetic regulations expressly prohibit the use of any substances determined to be carcinogenic, mutagenic, or toxic to reproductive systems. The EU's Cosmetic Regulation also specifies those colorants, preservatives and UV-filters that are approved for use in cosmetic products. Toward this end, manufacturers are responsible for identifying a "responsible person" who can address issues of non-compliance identified by authorities.

1.3 ASEAN COSMETIC PRODUCT REQUIREMENTS:

ASEAN with its 10 member countries (Brunei, Darussalam, Cambodia, Indonesia, Malaysia, Myanmar, Lao PDR, Philippines, Singapore, Thailand and Viet Nam) has always focused on its economic and social growth. Certain cosmetics products (e.g. anti-dandruff shampoos) are classified as cosmetics in some countries (e.g. in EU and China), whereas they may be regulated as over-the-counter drugs in other countries (as in USA) or quasi-drugs (as in Japan).

The ASEAN Ingredient Listings would be the reference document of all ASEAN Member Countries in the review of formulations of cosmetics. It also provide the list of ingredients that are banned or restricted for use, the positive

list of colorants, preservatives and UV filters that are allowed for use in cosmetic products marketed in ASEAN.

- ✓ **The Positive List** indicate ingredients that are allowed for use in cosmetic products.
- ✓ **The Negative List** indicates ingredients that are NOT allowed for use in cosmetic products. It is usually referred to as the Banned List or defined as the List of Ingredients which must NOT form part of the cosmetic products.
- ✓ **The Restricted List** indicate ingredients that are allowed for use in cosmetic products but subject to restrictions and conditions. It define the restrictions on the field of application and/or use, the maximum authorized concentration in the finished product, other limitations and requirements and conditions of use and warning, which must be printed on the labels [14].

In Singapore (Part of ASEAN), Information about the cosmetic product is to be kept in a Product Information File (PIF), which is retained for a minimum period of 3 years after the product is last placed in the market. Upon specific requests from the Authorities, PIF should be made available and accessible to the Authorities for audits within an agreed upon timeframe usually 15 to 60 calendar days or shorter, depending on the urgency of the audit. Audits may be conducted routinely.

I. **Product Information File (Dossier Requirements):**

The main objective of this ASEAN Product Information File (PIF) Guideline is to provide companies placing a cosmetic product in the market recommendations on how to organize and compile the PIF based on a recommended which is similar to EU; PIF format:**Part I**: Administrative Docs. & Product Summary, **Part II**: Quality Data of Raw Materials,**Part III**: Quality Data of Finished Product, **Part IV**: Safety & Efficacy. Basically all mandatory information regarding Quality safety and efficacy are present in Part II, III & IV, which are relevant to Q&Q and safety information for human health of the finished product.

II. **Labelling**:

The labeling guidelines match with EU regulations for all cosmetic ingredients should be listed in descending order by weight. Labeling statements must appear on the outer packaging or, where there is no outer packaging, on the immediate packaging of cosmetic products.

III. **Observation of ASEAN countries cosmetic regulations:**

The ACD aims to limit restrictions on the trade of cosmetic products by streamlining technical controls with harmonization model of 10 countries association, having mutual and collective regulatory framework.This harmonizing regulatory and technical requirements across ASEAN without compromising product safety and quality, which facilitate the flow of cosmetic products across ASEAN Member Countries to increase ASEAN's competitiveness in the region.

They have detailed guidelines on the control of cosmetic products regarding the information of Product Types, Product Presentation, Product Notification, Sample Testing, Adverse Event Reporting, List of Annexes (detailed Information about product presentation type, Labeling requirements, PIF guidelines) and Electronic Submission of Notification.

The levels of ACD implementation could be different among member countries which depend on national regulation background. For e.g.: Indonesia, Malaysia and Thailand, these 3 countries had their existing national cosmetics laws and regulations. In order to implement the ACD in such countries, legal process to transpose the ACD content must be done. For the countries which had no existing cosmetics laws and regulations, such as Singapore, the ACD could be completely implemented. The level of ACD implementation also depends on the country context; culture, language and way of lifestyle.

ASEAN has certainly benefited from the EU system, the content in ACD is almost same like the EU Cosmetics Directive as they are behind the EU model and carrying out the additional quality and safety requirement as well in terms of harmonization controlled model [10].

1.4 AustralianCosmetics Regulations:

In Australia, TGA is main regulatory authority and there are also interlinked authorities which are and regulating the cosmetic products. Ingredients in cosmetic products are classified as industrial chemicals, and new cosmetic ingredients are subject to notification to the National Industrial Chemicals Notification Assessment Scheme (NICNAS) for assessment unless they qualify for an exemption, Manufacturers and importers can check the conditions or restrictions of chemicals which are available for use in Australia, using the Australian Inventory of Chemical Substances (AICS) and the NICNAS Cosmetics Guidelines. Several factors influence whether a product is a cosmetic or therapeutic good, including [15]:-

- the primary use or purpose of the product,
- the ingredients in the product and their effects on the body,
- how the product is applied and/or administered, and
- How the product is promoted, represented, presented or labelled.

Therapeutic goods: Therapeutic goods are products that prevent, diagnose or treat diseases, or that affect the structure or functions of the human body.

Cosmetic:A cosmetic is a substance that is designed to be used on any external part of the human body—or inside the mouth—to change its odours, change its appearance, cleanse it, keep it in good condition, perfume it or protect it.One of the main factors isformative whether a product is

a cosmetic or a medicine (or a medical device) is the claims made about the product [15].

The definition of cosmetics in Australia is similar to that of the EU and US, i.e. a substance intended to contact with any external part of the human body, including the mucous membranes of the oral cavity and teeth, in order to clean, to change the appearance of, and to alter odor.The Australian community expects therapeutic goods in the marketplace to be safe, of high quality and of a standard at least equal to that of comparable countries [15].The TGA regulates therapeutic goods through:-

- pre-market assessment;
- post-market monitoring and enforcement of standards; and
- Licensing of Australian manufacturers and verifying overseas manufacturers' compliance with the same standards as their Australian counterparts.

The TGA's approach to risk management involves:identifying, assessing and evaluating the risks posed by therapeutic products, applying any measures necessary for treating the risks posed; andMonitoring and reviewing risks over time [15].

I. **Dossier submission:** Product information technical file need to provide with all documents and evidences as per authorities approved & described product category and subtypes requirements to the authority.

II. **The labelling** requirements of ingredients on cosmeticsare similar to the EU and US regulations.The ACCC (Australian Competition and Consumer commission) promotes competition and fair trade in markets to benefit consumers, businesses, and the community. These activities have included:-

1. Reporting on the outcomes of **a regulatory audit** of cosmetic mandatory injury reports;
2. Completing a number of **cosmetic product surveys**; and
3. The start of a **national surveillance program** aimed at determining the extent of industry compliance with the cosmetics labelling standard.

This approach aims to increase compliance with product safety regulatory requirements and further enhance consumer confidence in the regulatory system for product safety [16].

III. Observation of Australian cosmetic regulations:

TGA has proper system and published detailed information about regulations of products by mentioned number of ways regarding any clarification and query provided online questionnaire for e.g.: “Is my product a cosmetic” to determine whether the ingredients in your product are industrial chemicals. Some products, such as sunscreens, skin whiteners and anti-acne treatments, can be used in a similar way to cosmetics but may be regulated as therapeutic goods.

List of common products that are considered to be cosmetics and learn more about therapeutic goods and therapeutic use. “Naturally-occurring chemicals”: It depends on what processes are used to extract the chemical, such as steam distillation, filtration, precipitation and pressing, controlled by NICNAS requirements. For “Labelling requirements”: All manufacturers, importers, distributors and retailers—must comply with the Australian Competition and Consumer Commission's mandatory standard for cosmetics labelling. They have standards as per therapeutic use, for oral hygiene, dandruff, acne, cosmetics containing sunscreen ingredients, and anti-bacterial skin products. TGA has become more standardized and controlled health authority with strong regulations of therapeutic goods and can easily assess the quality safety and efficacy of product with the help of authority ‘website details.

High disposable income, inclination to look good, availability of new markets and increasing access to bottom of pyramid consumers are some of factors driving the growth of the Australia’s beauty and cosmetics market.

1.5 Indian Cosmetics Regulations:

Cosmetics products in India are regulated under the Drugs and cosmetics Act 1940 and Rules 1945 and Labeling Declarations by Bureau of Indian Standards (BIS). The procedure to be followed in order to manufacture cosmetics in India, BIS sets the standards for cosmetics for the products listed under Schedule ‘S’ of the D&C Rules 1945.And Schedule M-II classifies cosmetics into 11 broad product categories.

4. **Dossier submission:** Product information technical file need to provide with all documents and evidences as per authorities approved & described product category and subtypes requirements to the authority.
5. **Application for Grant or Renewal of a manufacturing license:**

State Drug authorities of Respective States are responsible to issue manufacturing Licenses. The application has to be submitted in Form 31 along with a license fee of 3500 INR with an inspection fee along with required information like [11]:

* List of Equipment, Manufacturing Facility details with minimum area of 15 Sq. Meters,
* Technical Competent personnel details, Relevant SOPs are required for obtaining manufacturing permissions. The specifications should comply the BIS/International Standards.
* The manufacturer has to ensure that the production is done in the presence of a competent and qualified technical staff. Before granting or refusing the license, the Licensing Authority is required to order inspection of the whole premises. The appointed inspectors submit a detailed report to the Licensing Authoritywhich can then decide whether to grant the license or not. Licensing Authority would grant FORM 32, which is License to manufacture cosmetics for sale or for distribution with No. of license and date of issue.

6. Imported cosmetics registration in India:

In Indian market there are so many imported brands are selling/marketing, which have good quality &efficacy as per claim but in terms of safety few cosmetics are very dangerous and harmful for human health as per their own countries testing procedures or regulations and due to lack of strict guidelines or regulations in India they are marketing productsto controlling that there is a Checklist for Pre Screening of Applications for Grant of Registration Certificate in Form 43 under the provisions of Drugs &Cosmetics Rules and authorized by CDSCO, Dossier must submit to authority as perthe requirements for imported cosmetics registration before commercialization in India:- e.g.: Covering letter by the applicant, Form-42, Treasury Challan, POA, Schedule D III, Original copy of Label, FSC/MAletter and Mfg. License, Product spec.& testing protocol, List of countries where Market Authorization or import permission or registration was granted, Pack insert, Soft copies of the information about the brands, products and manufacturer.

Each application will be accompanied by a fee of USD 250 or its equivalent Indian rupees for each Brand.However, the import of the following class of cosmetics is prohibited: Cosmetics that are not of standard quality and Cosmetics containing any harmful or unsafe ingredients. Such as Misbranded cosmetics (meaning cosmetics which contain colours other than those prescribed or are not labeled in the prescribed manner or make any false or misleading claims). Spurious cosmetics (meaning cosmetics which are substitutes for other cosmetics or resemble other cosmetics).

7. **Legal metrology:**This is Packaged Commodity Rules, 2011 having laws and procedures for packaging, labelling, import and tax laws in India. The legal metrology officershaveassess the declaratory compliances of the manufacturer, importer and packer, performed in the interest of the end consumers but as per survey/study, it has stringent and complex compliances& not much in favor of Industries/Importers.
8. **Shelf-life data:** BIS says that, Manufacturer has to conduct suitable shelf life study as per protocols which ensure product integrity throughout the intended shelf-life period through appropriate data. Visible signs of degradation such as fermentation, rancidity, change in colour, and such other tests as applicable to the product shall be used to prove the stability of the product [12].
9. **Labelling requirements of cosmetics:** D&C Rules, 1945 says, labelling requirements must be full fill such as Product name along with site addresson both the inner and the outer labels. If the container is small in size then the principal place of manufacturing and the pin code are enough.The outer label should clearly specify the net contents of the ingredients used in the manufacture of the product.The inner label should contain the 'directions for use' along with any warning or caution that may be necessary. It should also contain names and quantities of ingredients which are hazardous in nature [17].
10. **Safety data:** BIS says that, Proof of safety data/such studies should be available with the Manufacturer/distributer need to be produced, if required. Manufacturer/distributershall suitably inform the consumer, if there are any precautions to be taken while using the products, which are known to show safety concerns in specific individual/population on the labels of such products [12].
11. **Observation of Indian cosmetic regulations:**India has several guidelines and regulations in terms of quality, safety & efficacy and gradually enhancing the standards from EU but the speed is very slow and as all countries are contributing the sale of cosmetics in India, It should adopt the mandatory steps which correlate the safety issues and also need to concentrate on the harmonization activities like regulated countries.

3. RESULTS AND DISCUSSION

Few Key features of cosmetics requirements are mentioned in a summarize way by regulated markets:-

- **Notification to the authority:**

When product is ready to commercialize and if it is having pre or post approval changes in terms of quality and safety, notification is required from the manufacturer side. Cosmetic products in the US and Some EU Member States (not all countries) also require notification (through CPNP) of products where Australia requires notification of product/ingredient names before they are placed on the market. Even the addition or deletion of an active ingredient/excipient to a product or a change to the quantity of such an ingredient creates a new therapeutic good requiring an application to be made for a new entry in the ARTG (Australian Register of Therapeutic Goods). In India notification procedure is not much stringent for raw materials but it is required before placing the product in the market.

- **Prohibited and restricted lists:**

The US and Europe both maintain lists of prohibited and restricted active or non-active ingredients, together with positive lists for coloring agents, preservatives and UV filters. The negative and restricted lists are updated regularly, on the advice of the scientific advisory committees or equivalent. The USFDA is regulating sunscreensas OTC drugs in the US whereas In India sunscreens come into the cosmetics. BIS has also specified this lists as an annexures (A, B, C, and D) in India but few mandatory elements are much unspecified and flexible, comparativelyUS & EU testing limits/ methods, which must be implemented by Indian authorities.

- **Labelling/Packaging:**

Labelling of cosmetics is required in US, EU, Australia& India using INCI (International Nomenclature of Cosmetic Ingredients) terms. All markets require quantity labelling

using metric units; however, non-metric labelling is also permitted in US. Nevertheless inUS &EU have systematic, detailed and harmonized labelling requirements but In India, labeling requirements are distributed in many authorities which creates complications.

- **Safety testing:**

In regulated countries, authorities have specific standards and tests which required to determine product quality, safety and efficacy. Sponsor/Manufacturers are responsible for ensuring that adequate testing is performed to ensure the safety of their products. In US, EU & AUS. having own testing guidelines in terms of quality control, storage conditions, impurities (by HPLC), shelf life of product and most of the countries are accepted ISO (in vitro) harmonization testing standards and having surveillance activities by the scientific advisory committee and health authorities like these countries CDSCO should also adopt all safety instructions.

- **Data on product safety and efficacy:**

One significant requirement of the EU Cosmetics Directive is that producer/manufacturer must keep a product information file about each product, including the results of quality, 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. 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 in detail are required under the regulations.

4. CONCLUSION

According to deep study, found a lot of differences in cosmetic regulations in India when compare to regulated market like USA, EU and Australia for cosmetic products with respect to applicable acts, regulations, guidelines, listed ingredients, specification of heavy metals , mandatory labeling and notification procedures to competent authority in specified time frame. According to Indian regulations the manufacturer for sale of cosmetics should get the pre-marketing approval before entering to market which is really appreciable whereas not required in USA and Europe. However, the stringent regulations governing cosmetics in each country or jurisdiction have one common goal: To protect the consumer by ensuring safe cosmetic products. For increasing attention to globalization of the cosmetic market, international harmonization of regulations would be useful. According to the International Organization for Standardization and the International Cooperation on Cosmetics Regulation (ICCR) and other major international organizations have been working in this sense.

The harmonization model of two unions by one is EU countries (with all member states) and second is ASEAN countries (with 10 countries association) having mutual and collective regulatory framework so that each country of union/association has to follow his own union's regulations in all aspects, which is best example for other countries around the world.

Company's responsibilities to the consumers also must mention in regulations that cosmetic manufacturer companies should co-operate the community by providing the information about the products which they are using whether it is for men or women. The information has to be made to the consumers on request so that public can access the information by writing to the company to get the clarification, through telephone/Email and by visiting the company website. The information related to Q&Q composition and safety assurance of the products; existing data on undesirable effects on human health resulting from use of cosmetic products should be accessible to the public. The company should follow and reply to all queries and requests in simple language and should maintain the records of all complaints as vigilance trackers.

Consequently, Indian regulatory scenario has major issues with the current Indian cosmetic regulations such as Multiple and complex regulations under different bodies, Indian cosmetic definition is narrow & constricting, when compare to pharmaceutical/drug product regulations, Lack of implementation guidelines of the CDSCO, BIS Standard's development and revision for issues related to cosmetics, Non uniform licensing approvals across various states, Inconsistent approach across authorities in interpretation of a particular issue. Absence of proper guidelines on product claims interpretation as well as instructive list of cosmetics, hence delaying the process of product licensing, trading and product life cycle management.

Presently, the cosmetic regulations in India are unstructured, multipart, divided in unpopular authorities and not only time-consuming but also not well defined on websites for producers &consumers hence cosmetic rules and regulations need to be harmonized for quality, safety and efficacy requirements and Most importantly must be harmonize the guidelines regarding the product development, stability, labeling and safety and efficacy issue as per claim.

In India for better presentation & enhance global marketing included cosmetic life cycle management; all guidelines and regulations must be come together and synchronize at the single Indian national authority which is CDSCO instead of several states guidelines and other small authorities/committees in India.

To protect the consumer by ensuring safe ingredients/finished products; there is need to enhance the regulations of safety information and control standards for cosmetics in India.

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