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A comparative view on cosmetic regulations: USA, EU and INDIA

Srikanth.T[1], Syed sajjad Hussen[1], Anand Abha [1], Vasantharaju SG[1] & Sandeep Gummudavelly[2]

1. Department of Quality Assurance, Manipal College of pharmaceutical sciences, Manipal. Karnataka.
2. Department of Pharmaceutics, Talla Padmavathi College of Pharmacy, orus, kareemabad, Warangal. Andhra Pradesh.

ABSTRACT

Cosmetics market has been dramatically improving around the world. Factors for successful marketing should take into consideration the current market trends & demands, regulatory framework & compliance requirements, efficacy, safety and scientific learning on performance. The current regulations of cosmetics are stringent. There are different regulatory bodies worldwide having their own regulations to ensure safety of the cosmetic products. The major cosmetic market constitutes of European Union (EU), United States of America (USA) .The regulations in these territories are used as a model for the developing world. India, quickly catching up the cosmetic market globally following its own regulations. The regulations which impact directly on the manufacture and sale of cosmetic products include the following: cosmetic definition, licensing, labeling, safety substantiation, stability studies and legal authority. Aspects of these regulations affecting the manufacturing and sale of cosmetic products in the USA, EU and India are discussed in this context.

Key words: Legal authority or legislations, labeling, stability, safety and current amendments.

INTRODUCTION

The manufacture and sale of cosmetic products are regulated by different governmental entities around the world. There may be different specific regulatory systems; they have a common goal of ensuring that cosmetic products are safe and properly labeled. In the industrialized countries these regulations have evolved to the point where they are rather extensive and, largely because the United States and European Union are the two largest markets in the world for cosmetic products. The cosmetics market in India is growing at 15-20% annually, twice as fast as that of

the United States and European market. Indian cosmetic industry is matured enough and responsible to ensure the quality and safety of its products. The cosmetic regulations in India are complex and time consuming for pre marketing approval. It is therefore important for a cosmetic manufacture to understand the difference in regulatory system in India when compare to USA and EU. The aim of the present article is to compare the cosmetic regulations in USA, EU and India which impact directly on the manufacture and sale of cosmetic products include the following aspects.

Legal authority and manufacture of cosmetics for sale

USA:
In the US, cosmetics are regulated by Federal Food, Drug and Cosmetic Act. It is the role of the FDA to oversee the compliance with these regulations. However, as opposed to drugs, cosmetic products do not require verifiable, mandatory compliance (such as FDA approval) before they can be marketed. The Voluntary Cosmetic Registration Program (VCRP) is an FDA post-market reporting system for use by manufacturers, packers, and distributors of cosmetic products that are in commercial distribution in the United States. [1] The VCRP applies only to cosmetic products being sold to consumers in the United States. It does not apply to cosmetic products for professional use only, such as products used in beauty salons, spas, or skin care clinics. It also does not apply to hotel samples or free gifts or cosmetic products you make in your home to sell to your friends.

EU:
EU cosmetic legislations are based on Council Directive 76/768/EEC of 27 July 1976 on the approximation of the laws of the Member States relating to cosmetic products (Cosmetics Directive). [2] As in the U.S., manufacturers are responsible for ensuring that cosmetic products comply with the law before they are marketed. The manufacturer or importer of cosmetics is responsible for demonstrating that the product is safe for its intended use. Regulations are enforced at the national level, and each country in the EU has an authoritative body that is responsible for upholding compliance. [3]

INDIA:
In India the Drugs and Cosmetic Act (1940) operates the regulations of cosmetics. For the manufacture of cosmetics for sale or distribution the manufacturer should build the factory premises according to the Schedule M-II and application for license in the form 31 and along with license fee of Rs. 2500/- and an inspection fee of Rs.1000/- for every inspection to the licensing authority of the state government where in the manufacturing unit is located. And the information is reviewed by (local state) licensing authority and shall be granted in the form 32. [4]

Labeling Aspects
USA:
The regulations for labeling of cosmetics in United States are controlled by FDA under the authority of the Federal Food, Drug, and Cosmetic Act (FD&C Act) and the Fair Packaging and Labeling Act (FP&L Act). The label statements required under the authority of the FD&C Act must appear on the inside as well as any outside container or wrapper. FP&L Act requirements,

for example. Ingredient labeling and statement of the net quantity of contents on the principal display panel, only apply to the label of the outer container.

The labeling requirements of principal display panel (the part of the label most likely displayed or examined under customary conditions of display for sale) must state the name of the product, identify by descriptive name or illustration the nature or use of the product, and bear an accurate statement of the net quantity of contents of the cosmetic in the package in terms of weight, measure, numerical count, or a combination of numerical count and weight or measure. The declaration must be distinct, placed in the bottom area of the panel in line generally parallel to the base on which the package rests, and in a type size commensurate with the size of the container as prescribed by regulation.

The net quantity of contents statement of a solid, semisolid or viscous cosmetic must be in terms of the avoirdupois pound and ounce, and a statement of liquid measure must be in terms of the U.S. gallon of 231 cubic inches and the quart, pint, and fluid ounce subdivisions thereof. If the net quantity of contents is one pound or one pint or more, it must be expressed in ounces, followed in parenthesis by a declaration of the largest whole units (i.e., pounds and ounces or quarts and pints and ounces). The net quantity of contents may additionally be stated in terms of the metric system of weights or measures. The name and place of business of the firm marketing the product must be stated on an information panel of the label. And the information must be in the English language.

Declaration of Ingredients:
The declaration of ingredients must be in descending order of predominance. Color additives and ingredients present at ≤1% may be declared without regard for predominance. The ingredients must be identified by the names established or adopted by regulation those accepted by the FDA as exempt from public disclosure may be stated as "and other ingredients". Cosmetics which are also drugs must first identify the drug ingredient as active ingredient before listing the cosmetic ingredients.

Label Warnings
Cosmetics which may be hazardous to consumers when misused must bear appropriate label warnings and adequate directions for safe use. The statements must be prominent and conspicuous.

Law Enforcement Authority
According to the enforcement of the law, the FDA may conduct examinations and investigations of products, inspect establishments in which products are manufactured or held, and seize adulterated (harmful) or misbranded (incorrectly or deceptively labeled or filled) cosmetics. [5]

EU:
The requirements of cosmetic labeling under 76/768/EEC directive are:
It should carry the name or trade name and address or registered office of the manufacturer or of the person responsible for marketing the cosmetic product within the Community and weight or volume of product and any precautions and a distinctive identification of the batch number or product reference number. And the expression of expiry date is divided to two types:

1) for products with a minimum durability of less than 30 months: the date of minimum durability indicated by "Best used before the end of ...";
2) for products with a minimum durability of more than 30 months: the period of time after opening for which the product can be used without any harm to the consumer (this information is indicated by a special symbol representing an open cream jar);

The list of ingredients shall be labeled with the use of common ingredient nomenclature is better for all member states should appear in the form of descending order. [6] This information must be in the national or official language or languages of the respective Member State.

INDIA:

According to D&C act in India the labeling requirements for cosmetics are:

Name of cosmetics and name and manufacturing address should carry on the both inner and outer labels. For small size containers on the label instead of mfg address the principle place of mfg and pin code are sufficient. The outer label should contain the amount of net contents of ingredients used in the manufacturing. The inner label addresses the direction of safe use and any warning indication or names and quantities of the ingredients those are hazardous or poisonous in nature.

The label should carry a distinctive batch number and it indicated by the letter "B" and for soaps the month and year of the manufacturing shall be given instead of "B" and this is not apply to cosmetics which are having 10grams or less for solids or semisolids and 25ml or less for liquid state products. On the label the letter "M" is indicate the manufacturing license number. [7]

Safety Aspects

USA:

The FD&C Act does not require that cosmetic manufacturers or marketers test their products for safety, the FDA strongly urges cosmetic manufacturers to conduct whatever toxicological or other tests are appropriate to substantiate the safety of their cosmetics. If the safety of a cosmetic is not adequately substantiated, the product may be considered misbranded and may be subject to regulatory action unless the label bears the following statement: Warning--The safety of this product has not been determined. [8]

EU:

Regarding the safety information of cosmetics the manufacturer or his agent or the person responsible for placing an imported cosmetic product on the Community market should have the data about the assessment of safety of human health of finished cosmetic product.

For safety data manufacturers should take into consideration the general toxicological profile of the ingredient, its chemical structure and its level of exposure.

Should the same product be manufactured at several places within Community territory, the manufacturer may choose a single place of manufacture where that information will be kept available. In this connection, and when so requested for monitoring purposes, he shall be obliged to indicate the place so chosen to the monitoring authority/authorities concerned.[9]

Stability data of cosmetics formulation

EU:

In amendment of "The European Union's Cosmetic Directive" done in 1993, requires expiration dating only for products whose "minimum durability" is less than 30 months. Do not add water or, even worse, saliva to moisten it, because that will introduce bacteria into the product. Risk of contamination increases due sharing multiple people.

The shelf life of cosmetics is predicted on the basis of following information i.e.

• The variety and complexity of cosmetic formulas and packaging.
• The proprietary nature of many products and stability test methods.
• The variety of types of changes that need to be examined, including physical, chemical, microbial, functional or aesthetic changes.

The European Cosmetic Toiletry and perfumery Association published the guidelines about the "Stability testing of cosmetic products" in March 2004. [10]

USA:

Determination of shelf life for products is a part of their responsibility for manufacturer to substantiate product safety. There is no rule or regulation to print expiration dates on the labels of cosmetic products. Voluntary (in house) shelf-life guidelines developed by the cosmetic industry vary, depending on the product and its intended use. [11]

Current Amendments

USA:

On 2010 July 7 Human Resources (HR) 5786 seeks to amend Chapter VI of the Food, Drug and Cosmetic Act, which concerns adulterated and misbranded cosmetics, by adding a subchapter on the regulation of cosmetics.

It introduced the Safe Cosmetics Act of 2010 for amends the Federal Food, Drug, and Cosmetic Act to expand the regulation of cosmetics, including requiring:

(1) Annual registration of any establishment engaged in manufacturing, packaging, or distributing cosmetics for use in the United States;
(2) New fees to provide for oversight and enforcement of cosmetics regulations;
(3) Ingredient labeling and disclosure of information on ingredients; and
(4) Adverse event reporting.

And requires the Secretary to establish a list of prohibited or restricted ingredients and a list of ingredients that are safe without limits for use in cosmetics and establish minimum data requirements and test protocols to be used by manufacturers to assess the safety of cosmetic ingredients. Sets forth provisions related to:

- Nanotechnology in the formulation of cosmetics;
- The voluntary and mandatory recall of cosmetics; and
- Alternatives to animal testing.

Establishes the Interagency Council on Cosmetic Safety to share data and promote collaboration on cosmetic safety among federal agencies. Deems a cosmetic that fails to meet the requirements set forth by this act to be adulterated. Deems a cosmetic that fails to meet the labeling requirements under this act to be misbranded. [12]

EU:

The Cosmetic Products Regulations has amended by the publications of Commission Directive 2010/3/EU and 2010/4/EU in the Official Journal of the European Union

1. Commission Directive 2010/3/EU of 1 February 2010 amended, for the purpose of adaptation to technical progress, Annexes III and VI to Council Directive 76/768/EEC concerning cosmetic products.

The Scientific Committee on Consumer Safety (SCCS) concluded in its opinion of 15 April 2008 that Ethyl Lauroyl Arginate HCl is safe for the consumers, when used up to a maximum authorized concentration of 0,8 % in soap, anti-dandruff shampoos, and non-spray deodorants. It should therefore be included in Annex III to Directive 76/768/EEC. It was also concluded that it is safe for the consumers, when used up to a maximum authorized concentration of 0,4 % as a preservative in cosmetic products. However, the Committee considered that it should not be used in lip products, oral products and spray due to mucosal and respiratory tract irritation potential. It should therefore be included along with these restrictions in Annex VI to Directive 76/768/EEC.

2. Commission Directive 2010/4/EU of 8 February 2010 amending, for the purpose of adaptation to technical progress, Annex III to Council Directive 76/768/EEC concerning cosmetic products.

This publication is about the non-oxidative hair dye substances which are provisionally allowed for use in cosmetic products until 31 December 2010 under the restrictions and conditions laid down in Part 2 of Annex III to Directive 76/768/EEC. For these two non-oxidative hair dye substances, HC Orange No 2 and 2-hydroxyethylamino-5-nitroanisole, listed under reference numbers 26 and 29 in Part 2 of Annex III, the SCCS gave its final opinions on their safety. The SCCS recommended maximum authorized concentrations in the finished cosmetic product of 1,0 % for HC Orange No 2 and of 0,2 % for 2-hydroxyethylamino-5-nitroanisole. Therefore, HC Orange No 2 and 2-hydroxyethylamino-5-nitroanisole can be definitively regulated in Part 1 of Annex III. [13]

INDIA:

Some amendments have been notified in the labeling clause of D&C act, which are

I. The ingredients should be declared in the descending order of their concentrations down to 1% and in any order below 1%.

II. Use before date instead of best use before date which was earlier declared as xx months/year from the date of packaging.[14]

Recently cdsco published the Gazette Notification regarding Import & Registration of Cosmetics .it is further to amend the D&C act about the rules for import of cosmetics. Previously there was no legislation for the registration of cosmetics in India. Now this rule says “no cosmetic shall be imported into India unless the product is registered under these rules by the

licensing authority appointed by Central government". The amendment comes into force with the effect from 1st day of April 2011. [15]

Table 1: Summary of cosmetic regulations

CONTENTS	 **USA**	 **EU**	 **INDIA**
AUTHORITY	FDA	EMEA	CDSCO
RULES AND REGULATIONS	FOOD,DRUG AND COSMETIC Act	COUNCIL DIRECTIVE 76/768/EEC	DRUGS AND COSMETICS Act
PRE-MARKET APPROVAL	Not required	Not required by Cosmetic Directive	Required under state government licensing
LABELLING	Should comply with the FD&C and FP&L	Based on Council Directive 76/768/EEC	Should comply with part XV of D&C rules 1945
EXPIRY DATE	No date required	Date of minimum durability if durability is <30 months. Period after opening if durability is >30 months	Indicated as "Use before date"
POST MARKETING REPORTING SYSTEM	Yes. (Voluntary Cosmetic Registration Program)	N/A	N/A

CONCLUSION

Lot of differences in cosmetic regulations in India when compare to USA and EU. According to Indian regulations the manufacturer for sale of cosmetics should get the pre-marketing approval before entering to market but not required in USA and EU. In the statement of labeling the expression of expiry date is different in the three regions. In the EU its depend on durability of product in 30 months, but in the USA there is no legislations for expiration date. However, the stringent regulations governing cosmetics in each country or jurisdiction have one common goal: To protect the consumer by ensuring safe ingredients and finished products. And there is need to enhance the regulations of safety information and control standards of cosmetics in India. The main aim of this article is to show the variations of cosmetic regulations between countries, so there is need to harmonize the regulations regarding the safety, stability, and labeling issues.

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