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A COMPARATIVE STUDY OF COSMETIC REGULATIONS IN DIFFERENT COUNTRIES OF THE WORLD WITH FOCUS ON INDIA

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ABSTRACT

Cosmetics market is changing around the world dramatically. To do successful marketing one should take care of different consideration such as the current market trends & demands, regulatory framework & compliance requirements, efficacy, etc. Regulations of cosmetics and cosmeceutical industry now a day's more 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 (RPA 2004)).The regulations in these territories are used as a model for the developing world. India is quickly catching up the cosmetic market globally and is following its own regulations. The body that governs the cosmetic market in India is CDSCO (Central Drug Standard Control Organization) through the "Drug and Cosmetic Act, 1940 and Rules 1945". The cosmetic definition, labeling, safety and stability studies and the legal authority have their own impact on manufacture and sale of cosmetic products. In this research paper we will discuss about the different rules and regulation that govern the cosmetic industry in different countries throughout the world. A comparison has also been made on the basis of legal authority, labeling, testing, safety and stability studies.

Key words: Cosmetic Regulations, Drug and Cosmetic Act, Current Amendments., Legal Authorities, Labeling, Stability and safety.

INTRODUCTION

Cosmetic industry is one of the complex industries. In this industry manufacturers and distributors are facing new legislations more than ever before. Today the cosmetic industry makes use of new and advance technologies that creates new cosmetics with more properties. The increase demand of cosmetics with more effectiveness has lead to increased research in this particular area. The different government bodies regulate the sales and manufacture of cosmetics all over the globe. Though there are many regulatory bodies separately for each country but the aim of all these regulatory bodies is same and it is to ensure that the cosmetics should be properly labeled and safe enough to use. In the United States and the European countries the cosmetic regulations are extensive since these are the two largest markets in the world for cosmetic products. In India also the cosmetic market is growing with a growth rate of 15 percent to 20 percent annually which is two times as that of the United States and European market (source). Indian cosmetic industry is matured enough and responsible to ensure the quality and safety of its products. The Indian cosmetic regulations are time consuming and much complex. It is very important for importers to take pre market approval before entry in India. It is very important to understand the cosmetic

regulations of India since they are different from USA and EU.

Directive vs. Regulation

A directive, by definition, is a legislative act that serves to direct, indicate or guide. A directive in the EU represents a guide that every member country has to transpose into its national legislation. However, because some countries are stricter than others about adoption of laws, sometimes rules are not equally applied everywhere as intended, resulting in the need to draft multiple versions of the directive specific to each country. A regulation is a legislative act that imposes clear and detailed rules. A regulation is not required to be incorporated into the national laws, but is immediately enforceable in all member states. Keep in mind, a regulation only needs to be translated into the national language of the 27 EU member states. The EU Cosmetic Directive (76/768/EEC) was originally issued on July 27, 1976, as an initial means of ensuring the safe sale and distribution of cosmetic products within the EU Community market. With a primary goal of protecting overall consumer health, the Directive included rules on the composition, labelling and packaging of cosmetic products. But as the cosmetic industry advanced, utilizing new, groundbreaking technologies and innovations, the legislation supporting it needed to change/evolve, too.

On 30th November 2009 the **Cosmetic Regulation 1223/2009** was adopted, so as to replace the EU Cosmetic Directive. The aim of creating regulations is to implement a much better approach to ensure the product safety and faster enforcement, and only translation into the languages of the EU member countries is required. To further break it down, several differences exist regarding notification procedures, the level of standards addressed, as well as labelling protocols for implementation of the 76/768/EEC Cosmetic Directive.

Cosmetic products are subject to legislative regulatory requirements in almost every industrialized country, included Asian countries. A cosmetic can generally be defined as any substance or preparation for human use for the purpose of cleansing, beautifying or altering the appearance commonly to include personal toiletry products (such as shampoos and lotion), beauty products and fragrances), certain cosmetics products (e.g. anti-dandruff shampoo) classified as cosmetics in some countries (e.g. as in the EU, China), in other countries may be regulated as Over-The-Counter drugs (as for instance in the USA) or Quasi-drugs (as in Japan).

Regulations applying to drugs are not specifically adapted to the needs of cosmetics, as they have been developed for products with therapeutic properties. They can be more time-consuming and expensive for manufacturers to meet, and less flexible, but there is no evidence that drug regulations lead to greater safety of non-therapeutic products than cosmetics regulations. In practice, similar key safety tests are carried out on similar products, regardless of their categorisation. Under drug regulations, though, the form of information to be provided and, in some cases, the way tests are carried out, can be less focused on the needs of cosmetics.

• Full responsibility of the manufacturer for the safety of products;

•In-market surveillance by regulatory authorities;

• No requirements for pre-market registration;

• No restrictions on sales channels;

• Good Manufacturing Practice guidelines (non-legislative, and which may differ between countries) specifically developed for cosmetics; and

• Regulatory focus on product safety (rather than efficacy).

Differences in Regulatory Frameworks

Differences in regulatory frameworks for cosmetics have implications for stakeholders because of the global nature of the cosmetics industry. Global trade in cosmetics is significant, and international companies

account for over 80% of cosmetics production in the EU, (RPA 2004). Companies often seek economies of scale by producing international products that can be sold in all markets. Differences in regulatory frameworks can hinder this process, resulting in:

• Reduced ranges of products available for consumers;

• Enforcement problems for regulators, because products imported into their country may not comply with local regulatory frameworks; and

• Increased costs, marketing delays and loss of sales for manufacturers and importers.

Some of the most significant impacts arise from the requirements applicable to products categorised as over-the-counter (OTC), non-prescription or quasi-drugs. Constraints on making changes to the ingredients used, and the difficulty of obtaining approval for new ingredients, limit the extent to which a single product can be sold across markets. For example, sun products and products with a Sun Protection Factor (SPF) are categorised as cosmetics (subject to positive lists of ingredients) in the EU and Japan, as OTC or non-prescription drugs in the USA, Canada and (if they have an SPF over 4) in Australia, and as functional cosmetics in Korea. In each market, UV filters have to be approved on the basis of safety before they can be used. However, the nature and efficiency of approval processes varies; file preparation and approval takes a few months in Australia, 3-4 years in the EU and 6-8 years in the USA. There are also differences in labelling requirements and permitted claims and different methods for assessing SPF. The result is that only nine UV filters, all older ones, are permitted in all markets. This compares with a list of 26 UV filters approved for use in the EU after stringent safety testing. In the USA, only two new UV filters have been accepted for use since 1978; certain filters have been refused approval in the past, despite US assessments indicating that they are safe, because they have not been used previously in the USA. These differences act as a barrier to trade, as products must be tailor-made for specific markets on the basis of the regulatory process, rather than safety concerns or consumer preference.

COSMETIC REGULATIONS IN DIFFERENT COUNTRIES

Cosmetic Regulations in the European Union

Introduction

The category ‘cosmetic product’, as defined in the EU Cosmetics Directive (76/768/EEC) has borders with a range of product categories, including medicinal products, biocides and medical devices. For example, skin creams designed to moisturise the skin and protect it from UV radiation are defined as cosmetics, whilst anti-acne creams are defined as medicinal products. Unlike the situation in the USA, case law of the European Court of Justice clearly states that a product cannot fall within the definition of two product categories at the same time. Case law1 also specifies that, in classifying a product within one category or another, account must be taken not only of the definitions within the relevant legislation but also of the characteristics of the products themselves. The competent authorities and legal systems within Member States have some discretion in considering the classification of products on a case-by-case basis. This has resulted in some differences in the treatment of products between Member States, but in general the classifications appear similar for most products. The Council of Europe (CoE, 2001) has also prepared an inventory of the situation in various Member States with regard to the classification of individual products. Guidance is provided at national level, for example, the UK Medicine and Healthcare Products Agency’s regularly updated guidelines set out criteria to help competent authorities and legal authorities to determine the appropriate category for a product. 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). 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.

Definition of Cosmetic Products

The EU Cosmetics Directive defines a cosmetic product 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'.*

Pre-market Requirements

There is currently no requirement under the EU Cosmetics Directive for registration of cosmetic manufacturers or importers, or for pre-market approval for cosmetic products imported into or manufactured within the EU. Article 7 of the Directive requires a simple notification to the relevant Member State authority of the place of manufacture or of initial importation into the EU of cosmetic products. Some Member States (for example Belgium and Spain) also request notification of products prior to marketing.

Labelling and Warnings

General labelling requirements are listed in Article 6 of the Directive. Information that must appear on the cosmetic product includes:

• The name and address of the manufacturer or person placing the product on the market;
• The batch number;
• Nominal net content;
• The function of the product;
• The date of minimum durability (if up to 30 months) or period after opening within which the product can be used safely;

A list of ingredients in descending order (including any of a list of 26 fragrance allergens);

• Usage precautions; and
• Warnings for regulated ingredients.

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);

Testing and Safety

The safety of cosmetic products placed on the EU market is the responsibility of the person who places the product on the market, assured through in-market surveillance. In market surveillance is the responsibility of competent authorities designated by each Member State. Producers or importers of cosmetics must ensure that cosmetic products do not cause damage to human health when applied under normal or reasonably foreseeable conditions of use. The 7th Amendment to the Cosmetics Directive introduced a ban on animal testing of cosmetic products from 11 September 2004 and a ban on animal testing of ingredients not later than 11 March 2009 within the EU. It also

introduced a ban on the marketing of cosmetic products tested on animals and products containing ingredients tested on animals, within the EU or elsewhere, not later than 11 March 2009. The Directive does not require information on the safety of cosmetic products to be submitted to Member State competent authorities before a product is placed on the market. However, manufacturers/importers must retain information, accessible on request to Member State competent authorities at all times, on:

• The qualitative and quantitative composition of the product;

•Physico-chemical or microbial specifications of ingredients and finished product;

• Manufacturing method;

• Safety assessment by qualified person;

• Existing data on any undesirable effects; and

• Proof for certain claims made.

Cosmetic Regulations in the United States of America

Introduction

The Food, Drugs and Cosmetics Act (FD&C Act) defines two main categories of products:

• Cosmetics; and

• Drugs, including the specific sub-category of over-the-counter (OTC) drugs, which can be sold without prescription.

The definition of products as cosmetics or drugs depends on their intended use, which is established on the basis of claims made about the product, consumer perception (which may be established through a product's reputation, or the presence of ingredients with a well-known therapeutic use. According to the FD&C Act, a product may be regarded solely as a drug, solely as a cosmetic or (in contrast to the position in the EU) as both a drug and a cosmetic. The latter are products that meet the definitions of both cosmetics and drugs. This may happen when a product has two intended uses. For example:

• An anti-dandruff shampoo is a cosmetic because its claims indicate that the product's intended use is to clean the hair; but

• It is also considered to be a drug because it contains recognised anti-dandruff ingredients and its claims indicate that it is intended to be used to treat dandruff.

Products classified as both cosmetics and drugs must meet the requirements of regulations for both categories of products.

Definition of Cosmetics

The FD&C Act defines cosmetics as: *'Articles (other than soaps consisting of an alkali salt of a fatty acid and making no claims other than cleansing) 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'.*

Pre-market Requirements

In the USA, cosmetic products are not subject to pre-market approval and companies are not required to submit information on their products or to register cosmetic manufacturing establishments. Manufacturers or distributors of cosmetics may, however, submit information on their products voluntarily through the Food and Drug Administration's (FDA) Voluntary Cosmetic Registration Program (VCRP). If a cosmetic manufacturer files a product formulation with the VCRP, the FDA can advise the company if it is inadvertently using prohibited or restricted ingredients. Manufacturers can thus correct their formulations before attempting to market them in the USA, thereby avoiding the risk of having their products detained and/or denied entry into the USA because of a prohibited ingredient. Manufacturers may also report any adverse reactions.

Labelling and Warnings

Cosmetic labelling is regulated under the FD&C Act as well as the FPLA. According to the regulations, cosmetics produced or distributed for retail sale are required to carry an ingredient declaration on their outer package, while those not distributed for retail sale (e.g. preparations used by professionals on

customers at their place of work) are exempt from these requirements. Country of origin labelling for imported cosmetic products is required by the US Department of Commerce. Cosmetic ingredients must be listed by their established name (INCI names) as laid out in the Cosmetics, Toiletries and Fragrances Association (CTFA) International Cosmetic Ingredient Dictionary. 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.

Testing and Safety

The safety of cosmetic products in the US is the responsibility of the manufacturer, supported by an in-market surveillance system. The FD&C Act prohibits the distribution of adulterated and misbranded cosmetics and requires that cosmetics must be safe for their intended use before being placed on the market. The Act authorises the FDA to conduct inspections of cosmetic firms (on the basis of complaints or suspicion of violation of law) without prior notice in order to assure compliance with the regulations. Although there is no statutory process for reviewing the safety of cosmetics ingredients, a voluntary process, the Cosmetics Ingredients Review (CIR), was established in 1976. The CIR is funded by the CTFA, with support from the FDA and the Consumer Federation of America. It reviews and assesses the safety of ingredients used in cosmetics and publishes the results in the scientific literature. Ingredients are selected for review on the basis of their potential biological activity, frequency of use in cosmetics and extent of skin penetration, amongst other factors. The outputs of the CIR have no legal authority, however, and the FDA is not obliged to act on its findings. There are no mandatory GMP requirements for cosmetics; companies follow GMP guidelines issued by the FDA as well as quality assurance guidelines published by the CTFA. 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.

Current Amendments

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:

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

Cosmetic Regulations in Japan

Introduction

The Act specifies that, as in the EU, products can only fall within the definition of one category and thus have to comply with the requirements specific to this category. Cosmetics regulation in Japan is based on different laws and ministerial ordinances consisting mainly of the *Pharmaceutical Affairs Law* (PAL). Ministry of Health and Welfare *Notification N.331 of 2000*, which states the standard for cosmetics; but also on

Notification N.1339 from the Director- General of the Pharmaceutical Affairs Bureau, Ministry of Health and Welfare, October 9, 1980 for the Standards for Fair Advertising Practices of Drugs, Quasi-drugs, Cosmetics and Medical Devices. In Japan, for legal purposes, cosmetics are divided into *quasi drugs* and *cosmetics*. In the PAL quasi-drugs are defined as items that have a middle action in the body, and include those stipulated by legislation and those designated be them MHLW. Quasi-drugs stipulated by law are for example products intended to prevent bad breath, body odour or heat rush; to promote hair growth, prevent hair loss, remove hair, or for the extermination of mosquitoes or fleas. Quasi-drugs that are designated by MHLW include for instance sanitary cotton, permanent wave solution, bath agents, products for improving chapped skin, dry skin, and itching, medicated cosmetics, therapeutic dentifrices, products for wound disinfection or protection, disinfection for soft contact lenses, etc. Cosmetics are intended to use on the body, for cleansing, beautifying, or increasing the attractiveness of the body, for changing the appearance, and their actions on the body are mild.

Definition of Cosmetics

Under PAL, the term cosmetic applies to: '*Products (other than quasi-drugs) designated to be applied to the body by rubbing, spraying or other similar applications with the aim of cleansing, beautifying or making it more attractive or modifying its appearance and of maintaining the skin and hair in good condition, to the extent that the action of the product on the human body remains moderate*'.

Pre-market Requirements

Prior to the deregulation in 2001, pre-market approval was required for each cosmetic product to be marketed in Japan. This requirement has now been abolished and cosmetic products are no longer subject to pre-market approval. Under the new regulations, companies are required only to provide notification of the product's brand name prior to manufacturing or importing. Manufacturers or importers of cosmetics are also expected to have a licence granted by the authorities upon inspection of the manufacturing site. This licence must be renewed every five years.

Labelling and Warnings

Cosmetics must be labelled with the product name, name and address of manufacturer or importer, content volume, product number or code and a list of ingredients.

Safety and Testing

Responsibility for cosmetic safety rests primarily with the manufacturer. Manufacturers or importers are required to check the safety of their products thoroughly before they are placed on the market and to maintain records of this. The health authorities may require a manufacturer to substantiate product safety. There are no official or mandatory good manufacturing practices (GMP) in Japan, although the Japanese Cosmetic Industry Association (JCIA) has published voluntary technical guidelines for manufacturing and quality control. Furthermore must been taken into consideration the *Standards for Fair Advertising Practices of Drugs, Quasi-drugs, Cosmetics and Medical Devices*. Notification from the Director General of the Pharmaceutical Affairs Bureau, Ministry of Health and Welfare, October 9, 1980 set a bunch of rules that aims at rationalizing the advertisements of drugs, quasi-drugs, cosmetics and medical devices, while preventing them from becoming falsified or exaggerated. A person who puts advertisements of drugs, quasi-drugs, cosmetics and medical devices, shall make efforts to relay accurate information so that users can use the product concerned properly, and there are specific advertisement rules related to names, to the manufacturing method, to the effect or efficacy, performance and safety, with the aim of protecting the customer and the fair competition practice.

Cosmetic Regulations in Canada

Introduction

Legislation in Canada identifies two main categories of products:

• Cosmetics; and

• Drugs (a specific sub-category of which is non-prescription (or OTC) drugs).

Third category is also there which includes health products from natural origin. Unlike in the USA, a product can only be included within a single category. The classification of a product as a drug rather than a cosmetic depends upon the claims made, as well as whether it uses ingredients or combinations of ingredients listed in Category IV monographs (which recognise ingredients as being safe and effective for non-prescription drugs).

Definition of Cosmetics

Cosmetics are defined as: *'Any substance or mixture of substances, manufactured, sold or represented for use in cleansing, improving or altering the complexion, skin, hair or teeth and includes deodorants and perfumes'.*

This definition includes toothpaste (non-fluoride), skin lotions, cleansers, shampoos, conditioners, hair dyes, personal care products and soaps.

Pre-market Requirements

There is no requirement for pre-market approval or registration for cosmetics. The Cosmetic Regulations, however, require every manufacturer to submit a completed Cosmetic Notification form to the competent authorities within 10 days from the day on which the product is placed on the market. The notification must include:

• The name and address of the person or entity identified on the product label;

• The name of the Canadian distributor;

• The product name;

• The purpose of the product; and

• A list of ingredients with the exact concentration or range.

The list of ingredients is compared to the Cosmetic Ingredients Hotlist, to ensure that the product does not contain prohibited or restricted ingredients (except in line with the prescribed restrictions) or ingredients that would classify the product as a drug. If there are problems with ingredients, the company can be required to reformulate the product, re-label it or register it as a drug. Cosmetic notification does not, however, constitute a product evaluation or approval procedure, and does not indicate that the cosmetic meets the requirements of the Food and Drugs Act and Cosmetics Regulations.

Labelling and Warnings

The inner and outer label of a cosmetic product is required to show:

• The product identity in English and French;

• The name and address of the manufacturer or distributor; and

• A statement of net quantity and any necessary warnings or directions in English and French.

Safety and Testing

Responsibility for cosmetic safety rests primarily with the manufacturer. There are no requirements for specific testing to be carried out for cosmetics. Manufacturers may be required to submit safety data on any ingredient in response to concern arising from its structural relationship to other substances posing potential health risks, complaints or other sources. The Consumer Products Safety Bureau has the power to inspect any sites where cosmetics are manufactured, packaged or stored. There are no specific GMP requirements for cosmetics manufacture; however, the Canadian Cosmetics, Toiletries, and Fragrances Association (CCTFA) have published voluntary industry GMP guidelines.

Cosmetic Regulations in China

Introduction

Cosmetics legislation in China is currently under review, and may be subject to considerable change in the near future. Because plans for future changes have not yet been finalised or published, this Section describes the current regulatory framework.

Legislation in China identifies two main categories of products:

• Cosmetics (including the specific sub-category special use cosmetics); and

• Drugs.

China has a quite complicated system for registration of cosmetic products. Any importer shall in the first place apply for registration of its cosmetic products to get a certificate for marketing which can be of two types depending on importing non special purpose cosmetics or special purpose cosmetics. Since September 1, 2008 the certificate must be granted by the State Food and Drugs Administration (SFDA) which, before the products can be lawfully distributed in Chinese market, will be responsible for the acceptance of the application for hygiene license of imported cosmetics, China-made special cosmetics and new ingredients of cosmetics. After the registration process, certification of labelling for manufactured and also for imported cosmetic products shall be applied from PRC's Administration for Quality Supervision and Inspection and Quarantine (AQSIQ) before they are imported into China. Therefore, the approved certificate and number registered by SFDA and certification of labelling plus stickers attached to imported cosmetic products are necessary documents that cosmetic exporter shall obtain when exporting any of its cosmetic products into China. Besides this two main governmental agencies in charge of registration of imported cosmetics (SFDA and AQSIQ), other non-governmental organizations are also required to be involved in the registration process, including cosmetic sanitation inspection institution in national level appointed by the Ministry of Health (MOH) and the agent representative of an importer.

Cosmetic Products

Current regulations define cosmetics as: '*Those daily used chemical products applied on the surface of any part of the human body (such as skin, hair, nails and lips) by way of smearing, spraying or other similar methods to keep the body clean, to get rid of undesirable smell, to protect the skin, to make up the face and to increase the beauty of the appearance*'.

Pre-market Requirements

Cosmetic manufacturers in China must be registered and all manufacturing sites must have a Hygiene Licence as well as a Production Licence. The Hygiene Licence is issued by the Bureau of Public Health (BOPH) and takes between six and twelve months to obtain. It is valid for four years and must be submitted for review one year before its expiry.

Product registration requirements differ between ordinary and special use cosmetics and between domestic and imported cosmetics:

• *Domestic ordinary cosmetics* do not require pre-market registration. Instead, local authorities must be notified within two months after the product is first marketed;

• *Domestic special cosmetics* are subject to a pre-market registration process. A safety assessment is required that should include acute toxicity, animal skin and mucous tests, mutagenic and short-term biological screening tests for carcinogenesis and chronic toxicity, etc. There are specific requirements for each product type. The safety assessment is undertaken by an Expert Group and other relevant bodies with the actual approval granted by the MoH;

• *Imported ordinary cosmetics* require a Hygiene Permit of Imported Cosmetics. When a cosmetic is imported for the first time, foreign manufacturers and their agents are required to submit a Cosmetic Import Health License to the Ministry of Health (MoH). The cosmetic must undergo an extensive conformity assessment and registration process. Upon approval of the cosmetic, the manufacturer is awarded a production licence (for each product category manufactured at the site and valid for a period of five years) and an approval number. This process could take up

to a year. In addition, all imported cosmetics must be registered with the GAQSIQ. This is also a complex process, and can take four to five months; and

• *Imported special cosmetics* must follow the same procedures as imported ordinary cosmetics, as well as the pre-market registration process applied to domestic special cosmetics.

Labelling and Warnings

Labels must provide the name and address of the manufacturer or person placing the product on the market; the batch number; nominal net content; country of origin; date of manufacture; usage instructions and warnings and the expiry date. All required information must be in Chinese. The Chinese HSC regulations (1990) also state that 'No indications, curative effect and medical terms are allowed to be written on the label, on the inner packing or on the specification sheet of cosmetic products'.

Testing and Safety

Article 9 of the Chinese HSC regulations (1990) requires an application to be made to the health administrative department under the State Council for approval before a new kind of material is used to make cosmetics. The term 'new kind of material' refers to natural or synthetic ingredients that are used in cosmetics for the first time in China. All new ingredients, as well as new approved uses of ingredients, are thus required to undergo a safety evaluation based on specified procedures and methods. The MoH does not accept foreign data and all cosmetic products must undergo testing within China. Article 31 of the same regulations makes producers responsible for the safety of their products. It states that:

Cosmetic Regulations in the Mercosur Countries

Regulation of Cosmetics

Mercosur was created by Argentina, Brazil, Paraguay and Uruguay in 1991, with association agreements signed with Chile and Bolivia in 1996. Each of these countries has its own regulations governing cosmetic products, although there exists an agreed framework among the four full members of Mercosur for regulating cosmetics.

Cosmetics regulations in the Mercosur share a number of key features:

• Harmonised definition of cosmetics;

• Harmonised negative and positive lists;

• Harmonised labelling requirements (with certain exceptions);

• Manufacturers' responsibility for safety of cosmetic products, but with registration of products prior to marketing;

. Pre-market registration and/or licensing of cosmetic manufacturing establishments is generally required, except in Argentina where compliance with the relevant regulations results in automatic approval and registration; and

• Adoption of good manufacturing practice (GMP).

• **Definition of cosmetic products**: Mercosur adopted a harmonised definition of cosmetics in Resolution No. 31, 1995. It is essentially the same as the EU definition of cosmetics with minor differences between the various countries: '*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'*;

• **Controls over ingredients**: lists of prohibited and restricted ingredients, approved preservatives, UV filters and colouring agents are modelled on the EU lists. When updating or amending the lists, Mercosur countries take account of lists from a range of other countries, including the EU and the USA;

• **Labelling:** labelling requirements are similar to those in the EU Directive (excluding those introduced by the 7th Amendment), including the use of INCI names11; and

• **Safety and testing**: responsibility for cosmetics safety lies with manufacturers, who are expected to adopt GMP, similar to the EU position.

Cosmetic Regulation in 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.

Labeling Aspects

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.

Current Amendments

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.

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.

Main Similarities in Cosmetics Regulation

The main features of regulations for products categorised as cosmetics in the four main markets. Features common to cosmetics regulation in all four markets include:

• Full responsibility of the manufacturer for the safety of products;

• In-market surveillance by regulatory authorities; and

• No restrictions on sales channels.

Main Differences in Cosmetics Regulation

The main differences between regulatory regimes for cosmetics in the four main markets concern:

• Controls over ingredients through positive and negative lists; and

• Requirements for maintaining data on product safety and efficacy.

CONTENTS	USA	EU	INDIA
AUTHORITY RULES AND REGULATIONS	*FDA* *FOOD, DRUG AND COSMETIC Act*	*EMEA* *COUNCIL DIRECTIVE 76/768/EEC*	*CDSCO* *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*

Figure 1: A comparison of cosmetic regulations between USA, EU and India. (Srikanth.T, et al, 2011)

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