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## Cosmetic Regulations in India vs. Globally and Challenges in Harmonization

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### ABSTRACT

Cosmetics market has been increasing tremendously in the world and providing a way in which a person can change his or her appearance and make the product instantly noticeable and attractable. Most consumers use cosmetic and personal care products every day to protect their health, enhance their well-being and boost their self-esteem. Ranging from antiperspirants, fragrances, make-up and shampoos, to soaps, sunscreens and toothpastes, cosmetics play an essential role in all stages of our life and have important functional and emotional benefits. The cosmetics industry is a science-driven, fast paced and a highly innovative sector which grows four folds annually which makes a significant social and economic contribution to national and regional economies across worldwide. Through the purchase of goods and services and the payment of taxes the cosmetics industry generates multiple rounds of economic spending worldwide. Considering globalization of Cosmetics, the regulatory compliance with international regulations is the first step towards ensuring that are safe for humans and the environment, and to subsequently create or re-develop products that respond to the ever-changing expectations of consumers of international markets. The cosmetic industry, from manufacturers to traders, must be able to adapt to a constantly changing framework. Even if there is a tendency to unite cosmetic legislations across countries, enough differences remain and may result in lack of compliance and product recalls or sanctions. In this article, we examine and establish the need for harmonization of regulations globally.

**Keywords:** Cosmetics, legislation, regulation, labelling, nomenclature, safety, Drugs and Cosmetics Act.

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### INTRODUCTION

As the world seemingly strives to become a more globalized and better-connected environment, where new trade agreements are signed between nations and

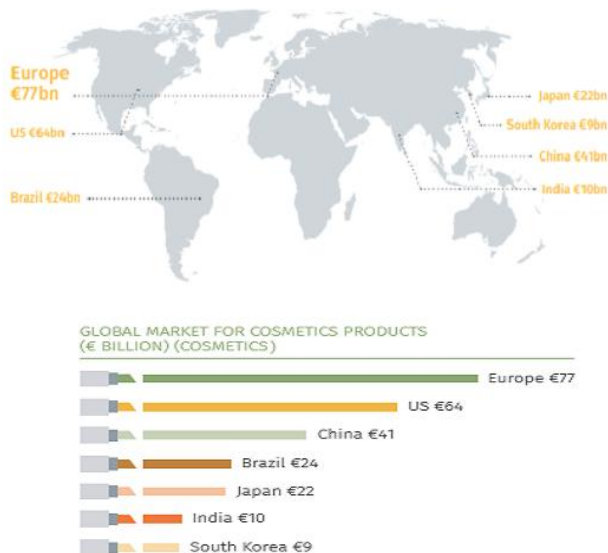
the internet presenting itself as a powerful tool to reach the end consumer, it becomes increasingly important to understand that cosmetic products are part of a regulatory landscape that is far from homogenous. In

fact, significant differences between cosmetic legislations and technical requirements can be a source of major challenges for companies who wish to begin an international venture. While some countries have decided that cosmetics need to be legislated in order to protect both the health and interests of the consumer, and have accordingly set up a regulatory standard against which all the industry must be measured, other countries have not yet reached the same level. Furthermore, this is also reflected in the nature of the authority in charge of the control and market surveillance of cosmetics that are sold or imported into a country; while it is usually the health authorities that assume this function, some countries have assigned this to the commerce or industry administration, to the customs department or the local standardization departments.

Europe and USA are the largest markets in the world for cosmetic products. In the end user Segments, decorative cosmetics (that modify the appearance of the area to which they are applied, usually by the use of colour, examples are: lipstick, eye shadow, blusher, eye pencil, liquid foundation, powder, mascara, nail polish etc.) have the highest average annual growth rate. [1]

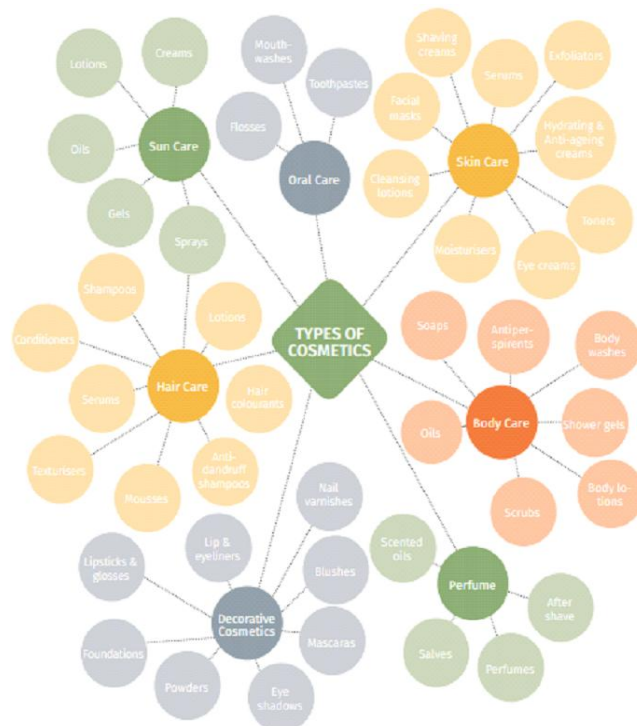
The cosmetics market in India is growing at 15-20% annually, twice as fast as the USA and EU market. Indian cosmetic industries continue to be a beautiful blend of traditional and modern like kajal, sindoor, kum-kum, herbal cosmetics, lipsticks, nail polishes etc. [2] With the current size of the cosmetic industry and its perspectives of growth and advancement in the following years, the regulatory status will be in constant change trying to keep up with the progress being made. However, there is much to learn from the current situation, and it is interesting to be able to provide a snapshot in order to better understand not only what it has to offer at this moment in time but also its limitations.

### SOCIO-ECONOMIC CONTRIBUTION



The cosmetics industry is a science-driven and highly innovative sector which makes large investments in R&D. Most large companies spend between 1.5% and 4.5% of their annual turnover (sales) on R&D and generate large revenue (tabled key markets) which makes a significant social and economic contribution to national and regional economies across worldwide. [3]

### TYPE OF COSMETICS AVAILABLE WORLDWIDE



### OBJECTIVES AND METHODOLOGY

This review aims to provide a general understanding of the current international regulatory framework in place for the design, production and commercial distribution of cosmetics and how legislative differences between countries relate to the cosmetic industry in practical terms. Thus, the aim is to achieve a general vision by examining a cross-section in which all parts may be represented and in which there is enough variety and examples of what the differences are and their implications. The countries that have been selected are India, European union (EU), the United States of America (USA) and evaluate the legislative differences between countries relate to the cosmetic industry in practical terms

### INDIA LEGISLATION

The Indian cosmetics and personal care market is amongst the fastest growing in the world, with compound annual growth rates over the past five years at over 17%. This represents a positive for industry; the nature of the regulatory environment that is emerging provides further grounds for optimism. Cosmetic Legislation is driven through Drugs and Cosmetics Act, and the legislative body is CDSCO (Central Drugs Standards Control Organization) headed by Drugs controller general of India.

As per Drugs and Cosmetics Act, Cosmetic definition under section 3 (aaa) as “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”

Local Manufacturing is enforced by state licensing authorities under the rules of part XIV and schedule M-II of Drugs and Cosmetics Act while Import is regulated via CDSCO under the rules of part XIII of Drugs and Cosmetics Act. [4]

Cosmetic Finish Product Standards are classified under Schedule S of Drugs and Cosmetics Act and should comply with Bureau of Indian Standards requirements. Raw materials, Adjuvants, Preservative, UV filter standards are covered under BIS 4707 (Part 2) as –

Annexure A - Ingredients which must not form part of the composition of cosmetic products

Annexure B - Ingredients which cosmetic products must not contain except subject to restrictions and conditions

Annexure C - Preservatives (with restrictions) which cosmetic products may contain

Annexure D - U.V. filters which cosmetic products (with restrictions) may contain.

Further, on raw materials control; hexachlorophene is not allowed in imported cosmetics, while allowed in local soap manufacturing in concentration not exceeding 1% w/w with a labelling instruction “Contains Hexachlorophene – not to be used on babies” Lead, Arsenic and mercury compounds are not allowed in finished formulation and testing on animals is completely banned.

Dyes, Colors & Pigments are classified in BIS 4707 (Part 1) and Schedule Q, as –

- Coloring agent allowed in all cosmetics products
- Coloring agents allowed in all cosmetics products except those intended to be applied in the vicinity of the eyes, in particular eye make-up and eye make-up remover
- Coloring agents allowed exclusively in cosmetics products intended not to come into contact into contact with mucous membranes
- Coloring agents allowed exclusively in cosmetics products intended to come into contact only briefly with the skin

Additionally, restriction on heavy metals of Synthetic Organic Colors and Natural Organic Colors are shall not contain more than:-

- (i) 2 parts per million of arsenic calculated as arsenic trioxide.
- (ii) 20 parts per million of lead calculated as lead.
- (iii) 100 parts per million of heavy metals other than lead calculated as the total of the respective metals.

Labeling requirement is governed by Rule 148 of Drugs and Cosmetic act, covers –

- Name of the cosmetic

- Name of the manufacturer and complete address of the premises of the manufacturer where the cosmetic has been manufactured
- Use before (month and year)
- Declaration of the net contents
- Adequate direction for safe use
- Any warning, caution or special direction required to be observed by the consumer
- A statement of the names and quantities of the ingredients that are hazardous or poisonous
- Batch number
- Manufacturing license number
- INCI in descending order of weight or volume at the time they are added, followed by those in concentration of less than or equal to one percent, in any order, and preceded by the words “INGREDIENTS”.
- Import Registration No. (in case of Imports)

Addition to D&C Act requirement, the following information should be a part of labeling as per Legal Metrology Act [5]

- Manufacturing date
- Consumer care & registered office details
- Importer name and address details (if import)
- Month and year of import (if import)
- MRP (Inclusive of all taxes)
- Package containing soap, Shampoos, toothpaste and other Cosmetics and Toiletries shall bear the Red or brown dot for products of non-vegetarian origin and green dot for products of Vegetarian origin
- Font compliance (Area, Size and Letter) – As per Rule 7 to 9 of LM Act

\*other statutory declarations which are common in D&C and LM are captured under D&C labelling requirements

India regulations are mostly influence with EU legislation, BIS (statutory body of Raw materials control in India) is following EU REACH compliance, any update in EU legislation is followed by India

## EUROPE LEGISLATION

In Europe, the Directive 76/768/EEC [6] came into force in the year 1976, with a two year margin for member states to transpose this directive. Although several amendments were introduced, this regulation stayed in place until 2013, when the new European Directive 1223/2009 replaced the old one introducing several important changes.

### The old Directive 76/768/EEC

Despite having been published in 1976, this legislation continues to be very much present nowadays. It stays on in the direct or indirect influence it has had over the regulatory status of cosmetics all over the world; whether it is as reference material or as a direct transposition or acceptance of the standards that are set in this directive, many countries have assimilated it into their legal structure.

The definition of what constitutes a cosmetic; “*cosmetic product shall mean any substance or mixture 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.*” [6]

This directive gives a positive definition by including three different characteristics:

**Cosmetic product:** A cosmetic can not only be a mixture, which is what we may traditionally regard it as, but it can also be a single ingredient.

**Area of application:** A list of areas where a cosmetic product can be applied or used is given, in which all areas can be considered as external in so much as mucous membranes can be considered as outwardly.

**Function:** Arguably the most interesting part of the definition as it separates the cosmetic product from any other kind of products based on its intended use.

Together, these characteristics clearly define what constitutes a cosmetic product and allows for the classification into different categories according to one or more of these characteristics. A comprehensive list of this categorization is included in the actual directive so as to better guide the industry towards achieving compliance.

Following the product criteria of the definition, for any cosmetic, be it a single substance or mixture, the ingredients that can be included into its composition have been incorporated into the directive. Due to the vast and ever-growing amount of ingredients being discovered, designed or repurposed, a complete positive list of ingredients is not manageable from a regulatory point of view. Instead, several lists have been included into the annexes of this directive that together aim to control the safety of the cosmetic product for the consumer population. The lists are as follows:

**Prohibited substances:** Including all substances which cannot be part of the composition of a cosmetic product. This list constitutes Annex II of the cosmetics directive.

**Regulated substances:** Composed of several lists in which restrictions are set for certain allowed substances in regards to the concentration in the finished product relating also to their function.

The lists include:

- Substances included in Annex III
- Colouring agents included in Annex IV
- Preservatives included in Annex VI
- UV filters included in Annex VII

All ingredients which are deliberately introduced into a cosmetic product must appear in INCI nomenclature on the label as per Article 6 of the regulation, in decreasing order of concentration for those over 1% and in any order for those under 1%. For the particular

cases of perfumes the word “parfum” or “fragrance” is accepted, and in colorants, the code by which they are known.

Labelling requirements for every cosmetic product the following items must appear on the label:

- Name and address of the manufacturer or responsible person.
- The nominal content at the time of packaging, in weight or volume.
- The minimum durability date of the product. This can appear as an actual date, as a month/year or, for products with a shelf life of over 30 months, as what is called a PAO (period after opening), which is an indication of the period of time in which the product can be used without harm to the consumer.
- Particular precautions, which may have to do with the presence of a certain ingredient, such as the ones in the regulated lists, a specific presentation or the packaging.
- The batch number of manufacture. This assures traceability of the finished product and is deeply related to the exercise of good manufacturing practices.
- The function of the product, unless it is clear from the presentation.
- The list of ingredients

The Directive itself clearly indicates that each member state must assure the implementation of the standards provided in it, and it does so in Article 3, in which it grants each of these members the supervision over the market control of cosmetics in their country, and full compliance of the industry and final products. Furthermore, in Article 7a the directive gives the instruction that the competent authority must be notified of the manufacturing of the cosmetic product and that a certain amount of information regarding the cosmetic product must be kept available at the address stated as the responsible person’s address. Being a process left to the disposition of each country, places like Spain adopted a Registration System, by which the product was revised by the authorities and once it was deemed to be compliant with the directive, it would then be authorized for commercial distribution.

A part of the information to be kept and to be reviewed by the authorities is a GMP assessment, in which the method of production must be explained and it must follow the good manufacturing practices.

Last but not least, a matter of much ethical debate and animal testing. In the old directive, animal testing was not expressly banned, but rather adjusted itself to the good laboratory practices. Animal testing should be limited to practices and tests approved by the health authorities and carried out in the same manner.

### **The new Regulation EC 1223/2009**

After the new Regulation EC 1223/2009 [7] was entered into force in 2009, it fully replaced the old Directive 76/768/EEC from 2013. Issued as a Regulation, member states do not need to exercise a transposition of the actual Regulation or its contents, further helping

the harmonization process by direct application of the European legal text. With it, some crucial and significant changes were made to the cosmetic sector with the aim of making compliance easier and safer for the consumer at the same time. In this section we will highlight these changes and discuss their implications in order to grasp an understanding of the current framework set around cosmetic products and its industry.

Following the same order as with the previous directive, the new regulation does not introduce any significant changes to the definition of the cosmetic product. It still includes the triple positive definition of composition, area of application and function. The fact that the definition has not been changed means that there has been no need for a product reclassification which would entail that certain products would be under the scope of another regulation.

Regarding the composition, another thing that has remained is the classification of cosmetic ingredients into corresponding lists according to whether they are prohibited, regulated based on maximum allowed concentration and function, and allowed substances for specific functions, like colouring agents or UV filters. However, there are two new additions to the ingredient considerations: CMR substances and Nanomaterials. CMR substances are those that can be carcinogenic, mutagenic or reprotoxic when used, and their inclusion is initially prohibited. Exceptions could however be made if the scientific reviews deem it safe for human use in cosmetic form and there are no possible alternatives to their use. In the case of nanomaterials, the corresponding authorities need to be expressly notified of their presence in the cosmetic product formula and enough data must be available that ensures its safety in human cosmetics. They must also be listed as such in the label so as to inform the consumer of their presence and allow for an informed decision.

No significant changes have been made to the minimum labelling requirements either, the information to be included in it remains the same, but the description and indications given in the Regulation are clearer and more elaborate. As before, the language in which the label must bear the relevant information must be determined by the member states, although it is generally accepted that the label must be in the main language of each country in which the cosmetic product wants to be marketed. While all this has not varied much, there is one element that is becoming increasingly important in the cosmetic industry which is featured in this Regulation in its Article 20, Product claims. This article clearly states that there must be no kind of implication that the cosmetic product bearing the claims has characteristics or functions that they do not have. This concept is further explored in the Commission Regulation (EU) No 655/2013 of 10 July 2013 [8], dedicated to cosmetic claims in which, among

other things, it states that claims are an information tool for the end consumer, and as such, any claim that is included must be proved or substantiated and based on six distinct principles: legal compliance, truthfulness, evidential support, honesty, fairness and informed decision-making. In this way, product assertions are regulated specifically from a health authority standpoint and not only from a publicity and advertisement point.

Product control in the new Regulation is now not only a question for each member of the European Union to decide upon. Rather, responsibilities have been shared out and now each part bears an equal load in regards to product compliance with the Regulation. The figure of the Responsible Person is still present, but the concept has been slightly expanded to include the preparation and custody of what has been deemed a "product information file" or PIF. This PIF is similar to the information dossier that needed to be done under the old Directive 76/768, and it includes a safety assessment report as a main part of it. This PIF must be kept at the premises given for the responsible person and be available upon request of the health authorities for a period of 10 years after the last batch has been placed in the market. The next level of control, the one exercised by the corresponding authority of each member state has also been shifted from the market authorization, which has disappeared, to a market surveillance scheme as described in Article 22, where it gives each country the right and responsibility to check the products that are being sold in their territory through the PIF and any testing they deem necessary, as well as monitoring compliance with the principles of good manufacturing practices. Lastly, the now extinct market authorization (which was basically a registration process) has been substituted by a Notification scheme by which, through electronic means, the responsible person or notifier shall submit a certain degree of information such as the category, name and address of the responsible person, member state in which it was first placed in the market, etc. All this information is enough to identify without a shadow of a doubt the product, the responsible person and the degree of health-relevance that the product might carry.

GMP compliance is a key issue in this regulation. The production method must be described in the PIF, and it should reflect the GMP principles. As seen, inspections can be carried out by the authorities of the member states to assure that the facilities and processes are adapted to the GMP indications. According to the relevant article of the Regulation, Article 8, these GMP shall be drawn from the corresponding harmonized standard, which is to mean, that ISO 22716 is the reference guide to GMP implementation and assessment, and it is this standard by which all manufacturers and distributors must abide by in their activity. Since it is an international standard, local

health authorities cannot certify compliance to the ISO 22716, which can be done through private entities, but it is expected upon inspection to be able to prove full observance and when found not to, there could be liability or administrative repercussions.

Finally, and as the first regulation to introduce this worldwide, this directive expressly bans all animal testing from cosmetic products and ingredients, and for any testing to be done within the European Union. Instead, valid *in vitro* methods are to be used for product and ingredient assessment. All previous ingredients and products that in order to fulfil compliance with the previous Directive had carried out animal testing, could still be placed in the market, however, no further testing can be done. All new ingredients and products must be sure to ascribe to the valid alternative testing methods in order to complete the respective Material Safety Data Sheets and Safety Evaluation Reports.

It is clear that both the old European Directive and the new European Regulation are intricate texts which present the opportunity for a more in-depth review and examination of the repercussions, interpretations and implications of all the wording set in place. However, the key points which arise when examining any regulatory text have been identified, weighed and compared in order to give the intended bird's-eye view, which will be necessary in order to be able to envision a global regulatory framework in place.

#### UNITED STATES OF AMERICA LEGISLATION

The Food and Drug Administration (FDA) is the health authority in charge of the regulation and control of cosmetic products. Through the regulatory texts and guidance documents which interpret laws, the FDA sets the standards which are to be followed and exercises its own kind of control over compliance with them.

According to the Federal Food, Drug, and Cosmetic Act (FD&C), cosmetics are "*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 their appearance, and articles intended for use as a component of any such articles*".<sup>[9]</sup>

Regarding product and market control, the FDA does not pre-approve a cosmetic product for its marketing and distribution. Compliance with the standards and regulations lies within the responsible person, be it a physical or judicial, for the product being on the market. However, the fact that no pre-market approval exists does not mean that the FDA exercises no control, but rather that products on the market can be tested or examined and anything that might be a risk to human health will have the corresponding consequences of product withdrawal and possibly administrative sanctions. For imported products, these are examined upon entry to the US, and deemed as fit to be granted access or a Notice of Action or Warning Letters will be

issued in order to address any non-compliance that might have arisen.<sup>[10-11]</sup>

There is, nonetheless, a Voluntary Registration Program (VCRP) to which products and manufacturers can endorse. Only cosmetic products which are already on the market can be registered, and it does not grant an approval by the authorities, but rather it is a means for the manufacturer/distributor to keep the FDA informed of the cosmetics he has brought to the market.<sup>[12]</sup> While the registration procedure is common to many countries, the fact that it is voluntary is a unique characteristic of the US and FDA. As stated before, manufacturers can also register through the VCRP, and inform the FDA of their activity, and this extends both to local and foreign manufacturers. Any manufacturer that has a cosmetic product in the US market can be inspected at any given time if the FDA deems it appropriate with prior warning. Upon inspection, the manufacturer is expected to be able to prove that the conditions in which cosmetic products are produced assure quality and safety. Regarding GMP compliance, the FDA has published "Draft Guidance for Industry: Cosmetic Good Manufacturing Practices"<sup>[13]</sup>, which was last reviewed in 2013. This guide was published and as a Draft, it is not compulsory to follow it, however, the FDA strongly encourages it and fully expects it to be adopted.

With respect to assuring the safety of the cosmetic product for human health through its composition, the FD&C Act gives a definition in Section 361 of an Adulterated Cosmetic as that "*which bears any poisonous or deleterious substance which may render it injurious to users under the conditions of use prescribed or are customary or usual*". This definition, in all its ambiguity will be used as a basis for ingredient regulation. A list of specific ingredients which are prohibited from being included into a cosmetic product has been issued by the FDA and is included in the Federal Regulations<sup>[14]</sup>, but it is a small list, with only 12 items, in comparison to the ones established by the European Commission. Once again, the responsibility that the ingredients included are safe and that the labelling gives the appropriate indications lies solely on the person who has made the cosmetic available in the market, be it manufacturer, importer or brand. Nanomaterials can be used, but a full safety assessment is encouraged before its use. The FDA also encourages manufacturers to inform when using a new nanomaterial and to provide the scientific proof of its safety beforehand.<sup>[15]</sup>

In keeping with including enough information on the label about ingredients and the intended use of the cosmetic product, there are other pieces of information that need to be included. Failure to do so or to do it in an incorrect manner might render the cosmetic product "misbranded" according to the FD&C Act. A misbranded cosmetic is so when the "*labelling is false or misleading in any particular*", or "*if in package form unless it bears a label containing the name and place of business of the manufacturer, packer, or distributor, and an accurate*

statement of the quantity of the contents in terms of weight, measure or numerical count”.

So here we have at least two requirements as to the content of the label: name and address and net content declaration, as well as a reference to any possible borderline claims. Furthermore, if we align both adulterated and misbranded definitions, we reach the conclusion that the label must also feature indications on the function/use instructions if deemed necessary and also any particular precautions regarding safety, whether it is because of an ingredient or the end product. Additional instructions are given as to the size and visibility of the label contents, which are not relevant to the current review.

Finally, on the subject of animal testing, the FDA does not support or condone the use of animals in order to test security or efficacy of cosmetics. It is once again left to the judgement and responsibility of the manufacturer/brand. It does insist that any testing required ensuring the safety of the cosmetic product must be used, while at the same time urging for alternative validated testing methods to be used. It also fully advocates for the use of the minimum animals needed to obtain the maximum amount of scientific information possible. [16]

We have seen three major countries regulatory frameworks and examined good and valid examples of different aspects included in the laws that control and limit the cosmetic industry.

Product classification is a major issue when dealing with different regulations and countries. What is a cosmetic in one place might be a drug in another or a borderline product in yet another.

Another possible source of confusion is product control. There are a set number of product control processes from the authorities, and a set number of names, but the combinations of both used are plentiful. Products can be freely manufactured and sold, they may have to be communicated the authorities of their intended production/commercialization or they may need to apply for an authorization on the cosmetic product. These are the three possibilities to which product control is limited. Confusion derives when the term “notification” is used in any other meaning than the communication to the authorities, and “registration” is not used to indicate product approval. In Europe, you notify the cosmetic product but the product is not approved or rejected, and in India the product must be registered in a process that involves product and information review.

The next three elements, ingredients, labelling and GMP, do not present much room for confusion. European composition lists are exhaustive, India is following the same while US is in contrast quite thrifty, leaving ample room to move around in. Labelling requirements do not vary that much, leaving the same information to be added in all countries. For GMP, all

regulatory texts agree that product safety is the main concern and reflect that in the publishing or acceptance of a GMP Standard. It is understood that for a product to be safe it needs to be manufactured in adequate and hygienic conditions. However, there does not seem to be any kind of consensus as to how these GMP are verified. In Europe, ISO 22716 is in force as the standard, but there is no requirement for certification and the authorities do not always inspect for compliance. In other countries, a license of operations must be obtained for which inspections are carried out in order to assure GMP compliance before the manufacturer begins commercial activity.

Finally, animal testing is an important topic from a legal and ethical point of view. Europe and India has proved that the cosmetic industry can be safe without the use of animals for testing, and opting instead for in-vitro methods. However, while most countries lean towards the use of in vitro alternatives, they do not introduce a ban on animal testing and so it continues to be a common practice throughout the world. While the interest for cruelty-free cosmetics increases, the authorities are more interested in introducing a ban also is at a rise, but to this moment, most of the regulatory world is still in neutral ground and will not take a step either way.

Throughout this review there has been a conscious effort to scale down a subject which is far from being brief, and all the effort has been put into being able to provide a wide vision of what the global scheme of regulations that affect directly or indirectly all cosmetic products.

There is the need for regulatory experts to work hand in hand with all the areas of the industry, either with research in order to determine the allowed composition, with the design team in order to design compliant labels or with the sales department to see which countries are available for distribution.

A law is a law after all, and it is mainly based in the abilities and competences derived from the Legislation and Deontology scope. However, there is a background theme that carries along the review which is related to the Pharmaceutical Management area. After all, the direct application of the analysis of these laws correlates perfectly with the private sector and cosmetic industry, both with its merits and challenges.

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