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A COMPARATIVE STUDY OF THE REGULATORY FRAMEWORK FOR COSMETICS IN SOUTH AFRICA, EUROPE, THE UNITED STATES OF AMERICA AND INDIA

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A Research Report submitted to the Faculty of Health Sciences, University of the Witwatersrand, Johannesburg, in partial fulfilment of the requirements for the degree of Master of Science in Medicine (Pharmaceutical Affairs).

Johannesburg, 2021

Declaration

I, Sohana Sukhnandan, declare that this Research Report is my own, unaided work. It is being submitted for the Master of Science in Medicine (Pharmaceutical Affairs) at the University of the Witwatersrand, Johannesburg. It has not been submitted before for any degree or examination at any other University.



Sohana Sukhnandan _____

Name of candidate Signature of candidate

7th day of March 2021 in Johannesburg, South Africa.

Dedication

To my husband and daughters, for their unwavering support and encouragement. Thank you for believing and inspiring me

To my parents for instilling in me the will to succeed and desire to continue learning

To my sister, nieces and nephew for their encouragement from afar

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Abstract

Globalisation has resulted in the world becoming interconnected. The alignment of regulatory frameworks is therefore important to ensure consumer safety and quality products without compromising international trade. As the South African cosmetics market is the largest on the African continent, the South African government has recognised that an improved legislative framework is required and therefore proposed amended regulations to the Foodstuffs, Cosmetics and Disinfectants Act of 1972. This study followed a qualitative, deductive approach utilising a framework analysis and aimed to compare the proposed amended cosmetic regulatory framework for South Africa (SA) to the European Union (EU), United States of America (USA) and India. The results have shown that SA is aligning to the EU cosmetics framework, adopting the positive and negative lists of ingredients, the use of universal INCI (International Nomenclature of Cosmetic Ingredients) terms for ingredient labelling and aligning on product claims which will facilitate harmonisation and reduce trade barriers but has adopted a passive post marketing surveillance system similar to the USA and India. It is recommended that an active surveillance system should be utilised as this will recognise safety trends faster.

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List of Abbreviations

ARB:	Advertising Regulatory Board
BIS:	Bureau of Indian Standards
CDSCO:	Central Drug Standard Control Organisation
CIR:	Cosmetic Ingredient Review
CTFA:	Cosmetic Toiletry and Fragrance Association
D&C:	Drugs and Cosmetics Act of 1940
dtic:	Department of Trade, Industry and Competition
EU:	European Union
FDA:	Food & Drug Administration of the United States of America
FCD:	Foodstuffs, Cosmetics and Disinfectants Act, Act 54 of 1972
FD&C:	Food, Drug and Cosmetic Act of 1938
FPLA:	Fair Packaging and Labelling Act
GMP:	Good Manufacturing Practice
ICCR:	International Cooperation on Cosmetics Harmonisation
INCI:	International Nomenclature of Cosmetic Ingredients
ISO:	International Organisation for Standardisation
MCC:	Medicines Control Council of South Africa
NDOH:	South African National Department of Health
NRCS**:**	National Regulator for Compulsory Specifications
PCP:	Personal Care Products
REACH:	Registration, Evaluation, Authorisation and Restriction of Chemicals
SABS:	South African Bureau of Standards
SANS:	South African National Standard
SAHPRA:	South African Health Product Regulatory Authority
SCCS:	Scientific Committee for Consumer Safety

VCRP: Voluntary Cosmetic Registration Program

USA: United States of America

Chapter 1

1. Introduction

1.1. Background

Cosmetic products are defined as formulations of ingredients or mixtures of substances that are applied externally to the human body by being “rubbed, poured, sprinkled or sprayed on or otherwise applied”, “for purposes of cleansing, perfuming, correcting body odours, conditioning, beautifying, protecting, promoting attractiveness or improving or altering the appearance, and includes any part or ingredient of any such article or substance” (Government Notice 30822, 2008). Examples of such products include skin-care creams, lotions, powders and sprays, perfumes, lipsticks, fingernail polishes, eye and facial makeup, permanent waves, hair colours, deodorants, baby products, bath and shower oils and creams, toothpaste and sunscreens. The safety of these products has become an increasing concern globally as the sales of these products increase. In South Africa (SA), the cosmetics sector has been growing annually by 6% and is the largest on the African continent, recording almost USD (United States Dollars) 3.2bn in revenue in 2018 (dtic, 2018; dtic, 2020). The global cosmetics market is expected to overtake the markets for antiretrovirals (ARVs) and regenerative medicines, reaching USD 430 billion by 2022 (Pastrana, et al., 2018), with household spending on personal care products also expected to grow by 25% from 2018 to 2023 (the dtic, 2020).

Although advances in scientific knowledge, innovation and technology have seen significant progress in the commercial production of cosmetics, this has also brought with it numerous concerns about their safety (Kumar, 2005; Nohynek et al., 2009; Cornell et al., 2019).

Through the ages, cosmetics have been used to modify the appearance and care for the skin, with the first documented case of lead poisoning, being Mary Stuart of Scotland reported in 1760, as a result of using skin lightening preparations. (Gonzalez-Minero and Bravo-Diaz, 2018; Mohiuddin, 2019). Since then, there have been numerous other documented cases. In the early 1930’s, depilatory products containing

thallium acetate were reported to cause serious nervous system toxicity and alopecia (Cornell et al., 2019; Meadows, 2006). In 1933, in the United States of America (USA), sixteen cases of blindness and possibly one death was linked to an eyelash dye, “Lash Lure”, containing p-phenylenediamine (Meadows, 2006; Cornell et al, 2019). In 1972, following the death of several infants in France from exposure to baby powder contaminated with high levels of hexachlorophene, the USA’s Food and Drug Administration (FDA) recalled more than 600 products. From 2014 to 2017, the FDA received several reports of rashes, blistering and cracking from a lip balm product and investigations later revealed that these were due to violations of Good Manufacturing Practices (GMP) and the presence of contaminants in the product (Cornell et al., 2019). More recently, Johnson and Johnson’s Baby Powder received significant media attention with a possible link to ovarian cancer associated with asbestos contaminated talcum powder (McGinley, 2017). An analysis of all product recalls of cosmetics and personal care products in the USA from 2002 to 2016 showed that baby products accounted for 24% of all recalls (Janetos et al., 2018).

People are living much longer today and both men and women want to maintain their youthful appearance which has caused an increase in demand for anti-ageing products that treat and prevent the signs of ageing. This has thus encouraged innovation in the cosmetic industry. Cosmetic products have thus grown beyond just enhancing the appearance of skin but also offering functional improvement with products that claim to “renew, restore and rejuvenate” (Lupo, 2001; Bellad et al., 2017).

The area of nanocosmetics, which incorporates nanomaterials into cosmetics, has become a key technology for the development of cosmetics in the past 20 years. Today there are over 200 cosmetics containing some form of nanomaterials (Pastrana et al., 2018). Nanoparticles are less than 100 nanometres in size, resulting in a larger surface area that allows better delivery of the cosmetics to the skin. For example, titanium dioxide nanoparticles are commonly used in sunscreens where they act as effective blockers of UV radiation but allow the formulation to be transparent at the same time and therefore more aesthetically acceptable to the consumer (Fytianos, et al. 2020). However, the possible absorption of nanomaterials through the skin has raised potential safety concerns (Mihranyan et al., 2012; Fytianos, et al. 2020.)

As modern technology and science is applied to developing cosmetics, the distinct differences between cosmetics and therapeutic products are becoming increasingly blurred. Some products are classed as 'borderline' and many regulatory agencies are of the view that it is the intended purpose of the product that determines its classification (Medicines Control Council, 2017). "Cosmeceuticals" are defined as cosmetic products that have or claim to have medicinal properties on the skin (Cornell et al, 2019; US FDA, 2018) and are examples of borderline products The term "cosmeceutical" is said to have been penned in the 1960's by dermatologist Arthur Kligman, when he developed a formula for photoaged skin (Cornell et al., 2019; US FDA, 2017). According to the "Global Cosmeceuticals Market Analysis", the global cosmeceuticals market was valued at USD 46.93 billion in 2017 and expected to reach a value of USD 80.36 billion by 2023 at a compound annual growth rate (CAGR) of 9.38% (MarketWatch, 2020). As the fastest growing segment of the personal care market (Lohani et al., 2014), cosmeceuticals are considered as "hybrids between cosmetics and pharmaceuticals, intended to enhance the health and beauty of skin" (Amer & Maged, 2009) and are marketed and sold as cosmetics but with medical claims e.g. the reduction of skin imperfections (Bellad et al, 2017). Nanotechnology has also been incorporated into the development of cosmeceuticals, with the smaller particles facilitating absorption and allowing repair to the damaged skin such as in antiaging creams, hydrating moisturisers and sunscreens (Lohani, et al., 2014).

There is also increasing demand for cosmetic products that are natural, organic and environmentally friendly and cosmetic production has thus shifted its focus accordingly (Gonzalez-Minero & Bravo Diaz, 2018; the dtic, 2018). South Africa has a rich biodiversity and is rich in natural ingredients such as aloe ferox, buchu, marula, baobab, honey bush, rooibos, and devil's claw and the growth in the market for these products has been identified as an area of opportunity for the local cosmetics and toiletries industry (the dtic, 2020). In order to promote investment and encourage export of South African cosmetics, the Department of Trade, Industry and Competition (dtic) has identified the need for South Africa to align with global standards that are critical for both local and export markets.

Quality standards are designed to ensure that producers of cosmetics meet the expectations of consumers for quality products as well as ensure the safety of consumers and implementing a quality system is an important aspect of regulatory

compliance. GMP is that part of quality assurance which ensures that products are consistently produced and controlled to the quality standards appropriate to their intended use. The fundamental principle of GMP is that the product should “do no harm” to the end user and it is therefore designed to minimise the main risks of contamination of products, inappropriate labelling and incorrect quantities of ingredients. GMP is applied to assure product quality and implementation of a quality system is therefore a crucial part of regulatory compliance. Cosmetics are unfortunately less strictly regulated than medicines and do not have the same global requirement for GMP as that of medicines. The International Standards Organisation (ISO) has developed guidelines regarding Good Manufacturing Practices for cosmetic products - ISO 22716:2017 provides specific guidance to the cosmetic industry for the production, control, storage and shipment of cosmetic products. Compliance to GMP can reduce the risk to adulterated or misbranded cosmetics (US FDA, 2013).

The growing number of counterfeit and misbranded products in the marketplace is a major concern and may be the result of the lack of effective regulatory frameworks in the cosmeceutical industry. The European Union (EU) is a global leader in the cosmetics market and was the first to harmonise its cosmetic regulations [Regulation (EC) 1223/2009 of the European Parliament and of the Council of 30 November 2009 on cosmetic products] across the Member States. Safety assessments are one of the key features of the EU regulatory framework which sets out to strengthen “*in-market control*”.

The Food and Drug Administration (FDA) of the USA regulates cosmetics under the Federal Food, Drug and Cosmetics Act of 1938 (FD&C Act) but, unlike in the EU, cosmetic manufacturers in the USA are not required to register their products with the FDA or report product complaints.

In South Africa, unlike pharmaceutical products that are subject to regulatory control, cosmetics are not required to be registered before they are marketed. Although the South African Foodstuffs, Cosmetics and Disinfectants Act, Act 54 of 1972 provides a basic framework for regulating cosmetics, there have been few amendments to the Act to ensure alignment with international best practices, including with cosmetic regulations in the EU and USA. The South African cosmetics industry remains self-

regulated with a variety of bodies and associations involved in enforcement of standards.

The need for effective and efficient regulatory processes and requirements to ensure the safety and quality of cosmetic products and the protection of consumers has led to the development of a global regulatory environment over the last two decades (Janetos et al., 2018).

1.2. Problem Statement

History has shown that when there is insufficient regulatory control, consumers are generally exploited (Califf, 2017). The fundamental concern of all regulatory authorities is that of the safety of the consumer.

As the global conditions change and more countries are trading with each other, it has become important to compare how they align their regulatory frameworks to ensure safety of consumers and quality products yet still facilitate globalisation and international trade of cosmetics. The South African government has proposed an amendment to the Foodstuffs, Cosmetics and Disinfectants Act 1972 (Act 54 of 1972), introducing updated cosmetics regulations, “Regulations: Labelling, Advertising and Composition of Cosmetics”.

Multinational companies want to achieve economies of scale and therefore differences in regulatory frameworks may act as a barrier to trade. The Department of Trade, Industry and Competition (dtic), established as a result of the merger of the Department of Trade and Industry and the Economic Development Department of South Africa, has identified the cosmetics industry as an opportunity for growth for the country, to increase local manufacture and export. The regulatory environment in South Africa has, however, been identified as a hurdle to compliance, global alignment and market access. (dtic, 2018; IDC & InvestSA, 2019)

Harmonisation of South Africa’s cosmetic regulations with that of recognised international agencies, like the EU and USA, and global best practice will reduce the duplication of regulatory effort for industry, allow international trade in cosmetics

without compromising consumer safety, and establish improved systems for safety surveillance on a global level.

1.3. Aim and Objectives

This research study will therefore:

1. Examine the proposed regulations for cosmetics in South Africa
2. Compare the proposed regulations in South Africa to the cosmetic regulatory frameworks of the European Union (EU), United States of America (USA) and India and understand whether these meet the requirements for international harmonisation

The objectives of this research are:

1. To examine and review the proposed legislation and regulatory framework for cosmetics in South Africa and compare it to the cosmetic regulatory frameworks of the EU, USA and India.
2. To analyse the safety regulations and practices for cosmetic products being used in each market and investigate the considerations in controlling safety of cosmetic products.
3. To review and compare the labelling requirements for cosmetic products in SA, the EU, USA and India. It is important to understand the labelling requirements in each of these markets as labelling has become a primary tool for regulating cosmetics, as it promotes safety.
4. To describe how each market regulates borderline products and cosmeceuticals – new and emerging technologies in the cosmetic industry that pose a risk to the safety of consumers.

1.4. Overview

This research report consists of six chapters, outlined as follows and depicted in Figure 1.1.

Chapter 1 outlines the introduction to the research and is divided into 4 sections. These are the background to the research, problem statement, aims and objectives of the research and this outline of the chapters.

Chapter 2 reviews the literature in 3 sections viz. the cosmetic regulatory framework, product labelling and nanotechnology. The cosmetic regulatory framework is further subdivided into 3 sections providing insight into the regulatory framework in the EU, USA and India, the regulatory framework in South Africa and harmonisation.

Chapter 3 details the methodology used to conduct this research, detailing the study design, the procedure used in carrying out the research, the ethical considerations and data analysis. The data analysis step involves the steps in developing the coding framework and thereafter organising the data into the framework to facilitate the comparative analysis of the regulations of the EU, USA, India and SA.

Chapter 4 reviews the results and is divided into 2 sections. The first section examines the proposed South African Regulations and the second section then gives the comparative analysis of the EU, USA, India and South Africa.

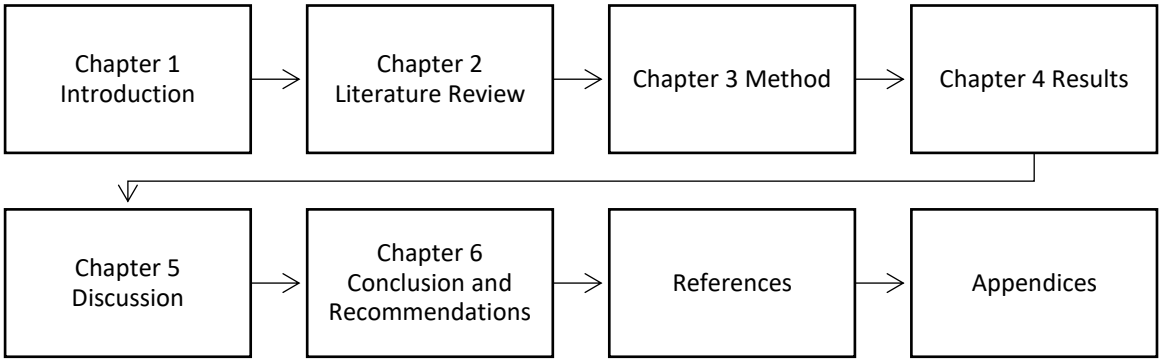


Figure 1.1 Outline of Research Report

The results are analysed and discussed in 7 sections in Chapter 5, in line with the framework analysis. The first examines market surveillance – understanding market control of cosmetics in each of the 4 markets; the second examines good manufacturing practices and standards required for quality assurance in cosmetics; the third describes and analyses the safety practices in each market; the fourth looks

at any actions taken by the regulations against animal testing; the fifth reviews the labelling requirements; the sixth examines the regulations on new technologies and the seventh section looks at the similarities and the differences in cosmetic regulations of the 4 markets. Chapter 6 is the concluding chapter of the Research Report detailing the conclusions and recommendations.

Chapter 2

2. Literature Review

Regulatory frameworks reflect the cultural differences and legislative environments between markets. In this chapter, a literature review was performed of government reports, policy reports, peer reviewed journal articles and data from other similar research projects and media coverage to assist in understanding the regulatory frameworks of the countries that are the topic of this research. These also assisted in understanding the social, political and economic context and obtaining a balanced account of the experiences and challenges currently faced with regulatory frameworks for cosmetic products.

2.1. The Regulatory Framework for Cosmetics

2.1.1. The Regulatory Framework in the EU, USA & India

The central role of any regulatory framework is to protect the consumer from misleading claims of cosmetic products. Vernon & Nwaogu, (2004) and Nobile (2016) have identified 2 types of cosmetic regulations.

The first type of regulatory framework is the approach that is utilised by the EU. Their regulatory framework model has a broad definition of cosmetics, requires safety data to be available and uses lists which specify the allowances and restrictions on the use of specific ingredients. The EU was the first market in the world to have harmonised their cosmetic regulations across member states and is considered to be at the forefront in regulating the safety of cosmetics. In 1976, the Member States of the European Economic Community (now called the European Union – EU) issued Directive 76/768/EEC that established a set of guidelines for cosmetics to ensure consumer protection and that would allow the free trade of cosmetics between member states. This Directive was replaced in 2013 by the EU Regulations on Cosmetic Products 1223/2009 and is the primary regulatory framework for finished cosmetic products placed on the EU market. Its purpose is “to ensure the safety of cosmetics, better harmonise compliance within the Member States, simplify procedures and streamline terminology” (SCCS/1564/15, 2016). As a Regulation, the updated

legislation provides the EU greater enforcement powers as opposed to the former Directive. Safety is the main objective of Regulation 1223/2009 and its objective is to strengthen “in-market control with a view of ensuring a high level of protection of human health” (2009/1223/EC). The ultimate responsibility for ensuring the safety of a cosmetic product though resides primarily with the cosmetics industry.

The second regulatory framework has a narrow definition of cosmetics, fewer restrictions regarding ingredients and fewer requirements regarding the availability of safety data and is the model that is utilised by the USA. The USA’s Food, Drug & Cosmetic Act of 1938 (FD&C Act) is the oldest law on cosmetics, and the Fair Packaging and Labelling Act (FPLA), provide the frameworks through which the Food and Drug Administration (FDA) regulates cosmetics, and is centred on self-regulation. Cosmetic manufacturers in the USA are still not required to register their products with the FDA or report product complaints, unlike in the EU. Cosmetic companies may voluntarily register their products with the FDA's Voluntary Cosmetic Registration Program (VCRP), which then assists the FDA in carrying out its responsibility to regulate cosmetics and the FDA then uses the information to evaluate cosmetic products on the market. This voluntary process is unique to the USA (US FDA, 2017). It is therefore the responsibility of cosmetic manufacturers to ensure products that are marketed are safe, properly labelled, use no prohibited ingredients and adhere to limits on restricted ingredients. Depending on the claims made, or on the ingredients in the cosmetics, many products classified as a cosmetic in the first framework may now be classified as an over the counter (OTC) pharmaceutical product according to the second regulation framework, as in the case of sunscreens in the USA, due to the narrow definition of a cosmetic. The second type of regulatory model, that is utilised in the USA, is therefore more restrictive on innovation and does not increase consumer safety. Vernon & Nwaogu, concluded that this framework is less likely to be acceptable in markets outside of the USA and Canada, e.g. in emerging markets, as this model has limited controls and requires effective in-market surveillance in order to provide adequate consumer protection.

In India, the Central Drug Standard Control Organisation (CDSCO) has integrated the drugs and cosmetics framework and regulates cosmetics through the Drugs and Cosmetics Act (1940) and Rules 1945, amended in December 2016, and the Bureau of Indian Standards (BIS) issues standards for ingredient usage. Although, the Indian

cosmetics regulatory framework has the same narrow definition of cosmetics as the USA, it has adopted some features of the EU regulations, for example, its lists of regulated ingredients. As of 1 April 2013, it is a requirement to register and obtain approval for cosmetics being imported before marketing and sale of such cosmetics in India and an online system is available to assist importers. Locally manufactured cosmetics in India do not require such registration but cosmetic manufacturers are required to be inspected and licensed prior to manufacturing and these licenses are valid for a period of 5 years. (Raj & Chandrul, 2016).

Of the five major emerging global economies, Brazil, Russia, India, China and South Africa, (BRICS), India is a developing country like South Africa and has a cosmetics market that is growing twice as fast as the USA and Europe (Singh et al., 2018).

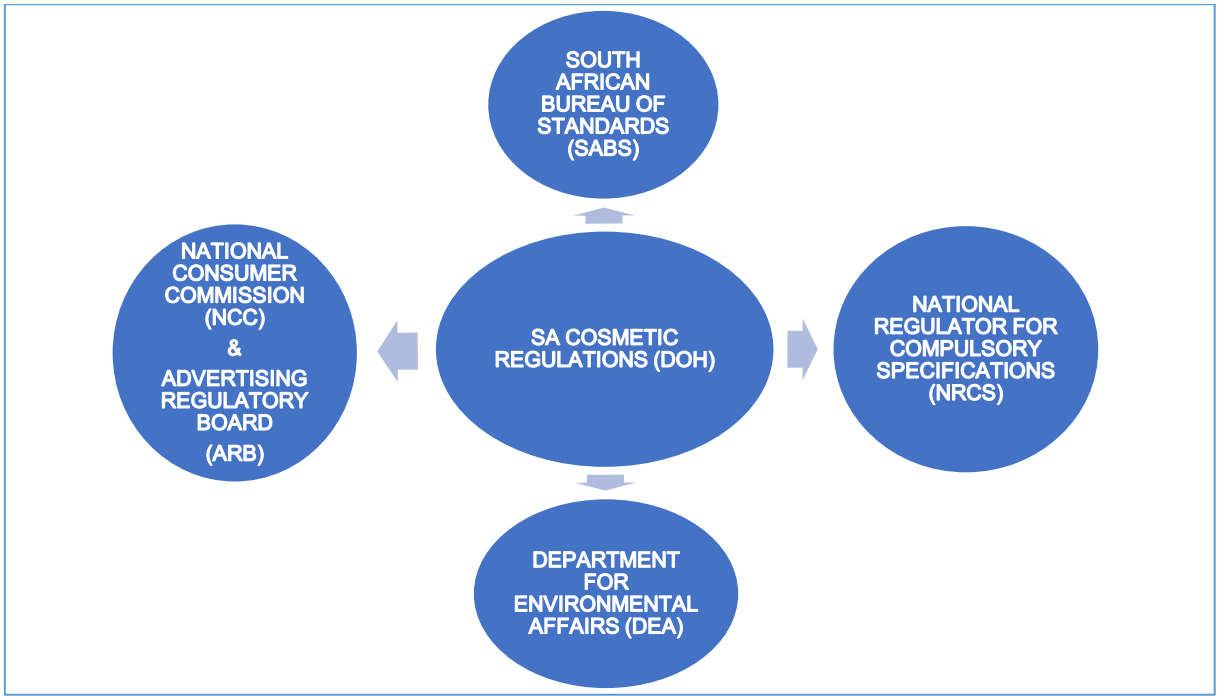
2.1.2. The Regulatory Framework in South Africa

Cosmetic products have been historically self-regulated in South Africa with the marketing communication industry voluntarily regulating the content of advertising and a variety of bodies and associations involved in ensuring a minimum level of compliance as depicted in Figure 2.1. This has made the consumer vulnerable to unsafe products. The Foodstuffs, Cosmetics and Disinfectants Act 54 of 1972 has provided some regulatory control for cosmetics, but with few amendments since its inception, it has not kept pace with evolution of the cosmetics market. A resolution by the Medicines Control Council (now called the South African Health Products Regulatory Authority), Resolution 172.08.06 of October 1997, in respect of cosmetics recommended that all advertising requirements for cosmetics conform to the provisions of the Standards Act (Act 8 of 2008) and the Advertising Standards Authority of South Africa (ASA) Code of Advertising Practice. In this resolution, the Cosmetic Toiletry and Fragrance Association (CTFA) also received approval from the MCC and in so doing, became responsible for regulating the advertising of cosmetics

The CTFA is the industry body in SA that is responsible for compiling and managing the Cosmetic Advertising Code of Practice which is based on the EU Cosmetic Regulations and submitted to the Advertising Regulatory Board (ARB), established in 2018 after liquidation of ASA, for inclusion into the Advertising Code of Practice. The

CTFA has thus aligned the Cosmetic Advertising Code of Practice Africa to the EU cosmetic regulations, with the exception of the requirement to register these products.

The ARB is an independent body responsible for administering the Code of Advertising Practice and regulates product advertising, to ensure that the system of self-regulation that protects the consumer is effective. However, as a self-regulatory body, the Code of Advertising Practice is not binding and only consulted for guidance on certain specific issues.



(Pimental, A., 2018)

Figure 2.1 South African Regulatory Influences

The South African Bureau of Standards (SABS) is the national standards and accreditation authority that is responsible for maintaining and developing standards and technical specifications (called South African National Standards – SANS), such as product labelling requirements in the cosmetics industry. These standards and specifications are also used as guidelines but the use of these are voluntary and make no impositions on the industry. The National Regulator for Compulsory Specifications (NRCS), which is independent of the SABS was established to promote public health and safety, environmental protection, and ensure fair trade. The NRCS has a mandate to develop and administer compulsory specifications and technical regulations as well

as conduct market surveillance to ensure compliance with compulsory specifications and technical regulations.

The proposed updated SA cosmetics regulations, “Regulations: Labelling, Advertising and Composition of Cosmetics” was first published by the South African Department of Health in the Government Gazette as a draft amendment in August 2016 and after a 3-month comment period, a revised version was published in December 2017 with a further comment period (Government Notice 1469, 2017). Since then there has been no further revisions and this Regulation is now awaiting promulgation.

2.1.3. Regulatory Harmonisation

As the EU and the USA are the largest cosmetic markets and yield worldwide economic and political influence, the regulatory frameworks in these markets are often used as models by other countries to mirror their regulatory framework, particularly in resource constrained settings.

Lindenschmidt, et al. (2001), employed in the cosmetics industry, provide insight into the regulatory obstacles encountered for cosmetic products and the progress made by some markets (USA, EU, Latin America, and Asia) in their paper titled “Global cosmetic regulatory harmonization” in 2001. They provided some of the common strategies used by these markets to achieve harmonisation and agreed that harmonisation would foster global competition whilst allowing consumers to obtain the latest products with safety data.

Whilst the US has taken the lead and shaped international markets on pharmaceutical regulation, the EU has shaped cosmetic regulation with approximately 30 countries using the EU model as a means of harmonising their cosmetics legislation. These include the Association of South East Asian Nations (ASEAN), Mercosur (Argentina, Brazil, Paraguay and Uruguay) and the Andean Community (Colombia, Peru, Bolivia, Venezuela and Ecuador). Some countries have only adopted some features from the EU Regulations into their national legislation, particularly the definition of a cosmetic product and the lists of the regulated ingredients, viz. China, Algeria, India, Israel, Morocco and Saudi Arabia (Vernon & Nwaogu, 2004). The aspects that these regions/countries have adopted are the definition of a cosmetic, the manufacturers’

responsibility for cosmetic products, the restricted and prohibited ingredients lists and the in-market surveillance systems to monitor compliance and safety.

As markets evolve and countries seek to amend regulations to ensure that they align to international standards whilst still ensuring economic viability, comparison studies provide insight into the similarities and differences of regulatory approaches. Vernon & Nwaogu (2004) recommended that working towards common or similar guidelines and procedures would provide an efficient and effective way to harmonise the regulatory practices and remove the barriers to trade whilst still enabling innovation and ensuring patient safety. These authors undertook a comprehensive study for the EU Commission Director General Enterprise, entitled a “Comparative study on cosmetics legislation in the EU and other principal markets with special attention to so-called borderline products”. The analysis was conducted to “explore the different approaches taken to the regulation of cosmetics in different markets, identify the similarities and divergences at the international level, analyse the impacts associated with these and to make recommendations on the prospects and advantages of a harmonised approach”. The major markets to which the EU was compared were the USA, Japan and Canada, and the study involved various stakeholders, including regulatory authorities, industry and consumers. The authors concluded that although the alignment of the regulatory frameworks in these different countries was increasing, there were significant differences that created barriers to trade. This study also suggested the measures to enhance the alignment of regulations as a:

- common definition of cosmetics;
- common positive lists of ingredients;
- common approaches to safety testing;
- greater alignment in labelling and packaging rules; and
- increased use of international guidelines

Vernon & Nwaogu found that differences in regulatory frameworks result in enforcement problems for regulators as a result of imported products not complying with the local regulations, market delays and reduced ranges available to consumers and loss of sales for manufacturers and importers. This negatively affects global trade of products and products focus on meeting the regulatory processes of countries as opposed to focusing on safety of the products.

Blaschke (2005) also compared the cosmetic regulatory framework of the EU, USA and Japan to assess the state of cosmetic harmonisation and compared the definitions, regulations for ingredients, labelling and the registration or notification requirement in each market. There has been a lot of cooperation and communication between markets to harmonise regulations, e.g. the creation of an ingredient listing system and the International Nomenclature of Cosmetic Ingredients (INCI). However, product categorisation and registration were still key differences between these markets and Blaschke concluded that the language requirements on labels and the restrictions on ingredients, primarily preservatives and colourants, “continued to be the biggest challenges facing the cosmetic industry.”

Zakaria (2014) described how the EU regulatory framework had been adopted, using Malaysia as a case study. The EU shared its harmonisation experiences with the ASEAN countries allowing for a smoother and faster transition and additional requirements were made based on cultural and regional differences of the countries. Although Malaysia did not adopt the entire EU framework, it did adopt the fundamentals allowing it to achieve a safer more efficient cosmetic regulatory system benefiting consumers and reducing trade barriers amongst the ASEAN.

With the Indian cosmetic market becoming increasingly important and showing a high growth potential, there have been a quite a few papers examining the Indian Cosmetic Regulations, with a focus on comparing different aspects of the framework to the EU & USA and are listed below.

Authors	**Year of study**	**Objective**
Srikanth, et al	2011	Examined and compared the legislation and manufacture of cosmetics, licensing requirements, labelling aspects, ingredient restrictions, safety aspects and stability data requirements across the three markets
Suhag and Dureja	2015	Compared the premarket approval, ingredients control, labelling, testing, and safety requirements of the cosmetic regulatory environment of the EU, USA and Japan to the Indian framework

Raj and Chandrul	2016	Compared the cosmetic regulations of the USA, Europe, Australia, India and ASEAN Countries. The regulations affecting each market were collected and a framework was developed for the requirements in India. The key features of market control (notification versus registration), ingredient lists, labelling/packaging, safety testing and safety and efficacy data requirements were compared. The authors also reviewed the regulatory frameworks for the consideration of borderline-products.
Ravi, et al	2016	Compared the regulations that directly affect the manufacture and sale of cosmetics in the USA, EU and India
Singh, et al	2108	Compared the cosmetic regulations of the USA, EU and India to understand the differences between the markets and their implications.
Ruhela, et al	2018	Compared the regulatory framework and market scenario of the US and India.

These authors all established that India's regulations are influenced by EU regulations and have adopted the restricted and prohibited ingredient lists, but there are differences in labelling requirements and premarket approval for imported cosmetics. With the ultimate goal of all countries being "to protect the consumer by ensuring safe cosmetic products" and because of increased globalisation, all the authors agreed that there was a need to enhance the regulations for safety information in India and therefore a greater need to harmonise the regulations.

The first cosmetic international organisation that was established, was the Cosmetic Harmonization and International Cooperation (CHIC) in 1999 with the regulatory authorities of Canada, the European Union (EU), Japan and the United States of America (USA) being members. The intention of this group was "to introduce the different partners of international regulatory schemes, to seek areas of commonality for regulatory alignment and to develop a memorandum of cooperation" (US FDA, 2019). However, in 2005 CHIC disbanded as a result of not achieving their goals and

established the International Cooperation on Cosmetics Regulation (ICCR) in 2006, with Brazil joining as a member in 2014. They meet annually with the purpose “to maintain the highest level of global consumer protection, while minimizing barriers to international trade” (ICCR, 2017; US FDA, 2019) and discuss common issues on cosmetic safety and regulations, including recommendations and alternatives to issues such as animal testing and use of nanotechnologies. Regulatory agencies in other countries have also attended ICCR meetings as observers viz. Argentina, Chile, Columbia, Israel, South Africa, South Korea and Taiwan (US FDA, 2019). However, the recommendations of this group are non-binding on members and therefore have a limited effect on international trade.

2.2. Product Labelling

Globally harmonised packaging and labelling requirements are important as countries place emphasis on consumer protection. Product labelling and claims are paramount as this is the information available to consumers to understand the intended use of the cosmetic product.

Klaschka and Rother, 2013, assessed whether the information provided on personal care product (PCP) labels to consumers in the EU and SA was effective to allow consumers to make an informed risk assessment of the product and whether the information was presented in a manner that could be easily understood. They concluded that providing ingredient lists on labels, placed too much responsibility on the consumer to determine the risk of a product. Whilst acknowledging that there was a trend to harmonise labelling of products containing hazardous chemicals, they concluded that the “general public were not all able to read the ingredient lists on the labels nor understand the implications of these in order to use the products safely”. The paper proposed risk mitigation strategies that included increased enforcement of legislation, mandatory labels clearly indicating the PCPs health risks, educating consumers on how to read labels and pictograms on labels.

In order for consumers to be protected from misleading claims, appropriate testing of cosmetic products should be performed to substantiate the claims. The EU regulation CE 655/2013 specifies that “Claims for cosmetic products, whether explicit or implicit, shall be supported by adequate and verifiable evidence regardless of the types of

evidential support used to substantiate them". Although proving efficacy was a legal requirement for cosmetic products, the differing regulatory requirements in countries affected the testing of cosmetics. There was minimal standardisation of the technical requirements of cosmetic efficacy testing in humans and no clear guidelines to achieve this.

Nobile, (2016), reviewed the main ethical, technical and regulatory requirements affecting the design of efficacy studies of cosmetic products. In comparing the various regulatory frameworks, Nobile found that the EU, employed a restricted list as well as positive and negative list of ingredients, required safety data to be included in the Product Information File (PIF) at the time of launch and all claims needed to be fully substantiated. The USA on the other hand, employed fewer restrictions regarding ingredients and safety data but claims had to be reasonably substantiated. The Indian cosmetic regulatory market was part of the drug regulatory market and followed a cosmetic regulatory framework similar to that of the USA. The author concluded that lack of alignment of the main regulatory frameworks created challenges for testing and innovation and prevented the free trade of cosmetic products. Despite similarities being identified between the various regulatory frameworks the author concluded that there were, however, no global guidelines or standards for efficacy testing in humans and improved communication between regulators was needed to ensure standardised technical requirements for cosmetic efficacy testing.

2.3. Nanotechnology

Product innovation is a major growth driver for the cosmetic industry and nanotechnology is being used more and more in dermatology today as it has shown to change the way cosmetics deliver their benefits. Despite the fact that nanotechnology in cosmetics is growing rapidly, concerns about their safety have been well documented.

As early as 2004 the UK's Royal Society and Royal Academy of Engineering raised questions about the safety of nanocosmetics, in a report commissioned by the UK Government. Since then there have been various papers and reviews on this topic.

Nohynek et al, (2009) summarised the information available on the use of nanoparticles in cosmetics focusing particularly on the safety aspects. The authors concluded that although there is contradictory evidence of the risks of using nanomaterials, the available evidence suggested that nanomaterials used in cosmetics applied to the skin posed little or no risk to humans but that, depending on the nanoparticles used, further safety testing may be required.

Falkner et al, (2009) wrote a briefing paper comparing the status of consumer labelling of nanomaterials in cosmetics in the EU and the US. The authors concluded that the differences in consumer labelling between the two countries posed a potential challenge to transatlantic regulatory cooperation and international trade.

Mihranyan et al, (2011), in a review paper on research and development trends in nanotechnology in Europe and the USA from 2000 – 2010, suggested that the safety and toxicity of nanotechnology remains a concern to both humans and the environment. They argued that penetration of the protective skin barrier by nanoparticles, particularly in diseased or injured skin, may result in widespread distribution to organ systems and possible harm to the individual. The review highlighted the importance of understanding potential interactions between nanoparticles and tissue and organ systems of the body. Similarly, manufacturing methods, including distribution and degradation of nanoparticles, have the potential to adversely affect the environment. The review paper also considered public opinions and attitudes to nanotechnology, and suggested that, although the public do not fully understand nanotechnology, it is their opinions and attitudes that will likely determine the future of these products.

Pastrana et al. (2018) reviewed the gaps between the commercialisation process and the regulatory frameworks of the USA, Europe, Japan and Latin America for nanotechnology-based cosmetics. They concluded that only the EU had developed specific regulatory requirements for nanomaterials in cosmetics and that may be a barrier to harmonising regulations. In addition, due to the lack of information, constant debates and contradictory results on nanomaterials, it was difficult to make a conclusive risk assessment on their inclusion in cosmetics. They concluded that “any additional delay in creating and implementing a common regulatory framework

involuntarily exposes consumers to products whose risks have not yet been determined."

Fyntianos, et al. (2020) wrote a review paper on the updates on the use of nanomaterials in cosmetics focusing on (1) the different types of nanomaterials and advances in development, production and characterisation; (2) the process of safety assessments and the regulations in Europe and the USA. Nanomaterials have unique characteristics that result in their varied functions. Inorganic nanoparticles of titanium dioxide and zinc oxide in sunscreens are examples of commonly used nanoparticle ingredients in cosmetics today. Other nanoparticle ingredients used in cosmetics include gold, silver, carbon black, tris-biphenyl triazine and hydroxyapatite. Additionally, nanocapsules, nanoliposomes, solid lipid nanoparticles and nanostructured lipid carriers are examples of the types of formulations used in nanocosmetic products. With the development in nanomaterials, safety testing has therefore become important to understand their potential toxic effects. In the USA, although there is no formal regulation for nanoparticles, the FDA has developed guidelines for safety assessments. The EU, on the other hand, has developed a catalogue of nanomaterials that may be used in cosmetic products intended for consumer information. Although inclusion of nanomaterials in this catalogue does not mean they are authorised, safety assessments are mandatory for all cosmetic products marketed in the EU, including those containing nanoparticles. The major conclusion from this review: "The cost is not the only important issue, safety and the application of alternative testing methods for toxicity are of crucial importance as well". They identified the requirements for the assessment of the potential hazard of nanomaterials taking their properties into consideration.

In the pharmaceuticals market, regulators and industry have worked together to develop best practice regulatory standards and guidelines for the development and manufacture of medicines. Unlike with pharmaceuticals, the literature on best-practice regulatory approaches for cosmetic products is limited and there appears to be little or no data comparing the South African cosmetics regulatory framework with those of other countries. Although the literature provides extensive and comprehensive coverage of the different types of regulatory frameworks and cosmetics safety regulations in the EU & USA, and there are comparisons of these regulations with other markets, there is no literature comparing the South African cosmetic regulatory

framework with regulatory frameworks of other countries. This study has therefore sought to compare the cosmetic regulatory framework in South Africa with that in the EU, USA and India.

Chapter 3

3. Methods

3.1. Study Design

The aim of this research was to compare the proposed cosmetic regulatory framework for South Africa to the EU, USA and India and to understand whether it meets the requirements for international harmonisation. This study followed a qualitative, deductive approach utilising a “Framework” analysis, developed by the National Centre for Social Research (Ritchie & Spencer, 1994).

Because of the nature of the comparison, a structured approach was needed to ensure consistency and that the framework method supported the thematic content analysis and offered a systematic way of analysing the data sets. A content analysis method involves summarising and classifying the data within a thematic framework in order to analyse and compare data by theme, thereby facilitating the aim of this research (Green & Thorogood, 2018; Flick et al., 2014).

3.2. Procedure

A document analysis was undertaken and involved identifying the cosmetics regulations of the four different markets viz. USA, EU, India and South Africa. Data were obtained from the websites of the respective country governments and Regulatory Authorities and formed the primary data sources to address the research objectives i.e. the comparative analysis of the data sets. (Table 3.1).

Pubmed, Science Direct, Ebsco Host and Google Scholar were used to obtain secondary data sources i.e. Government reports, Policy Reports, peer reviewed journal articles and primary data from other similar research projects and media coverage. These were used to assist in understanding the social, political and economic context and obtained a balanced account of the experiences and challenges faced in implementing cosmetic regulations.

Table 3.1 Primary Data Sources

	Title of Document	Source
South Africa	Proposed Regulations Relating to the Labelling, Advertising, and Composition of Cosmetics Act 54 of 1972.	https://www.greengazette.co.za/notices/foodstuffs-cosmetics-and-disinfectants-act-54-1972-regulations-relating-to-the-labelling-advertising-and-composition-of-cosmetics_20171222-GGR-41351-01469
European Union	Regulation (EC) 1223/2009 of the European Parliament and of the Council of 30 November 2009 on cosmetic products	https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32009R1223&qid=1601217877587&from=EN
United States of America	Title 21-Food and Drugs, Chapter 9 - Federal Food, Drug, And Cosmetic Act Subchapter VI-Cosmetics Title 15-Commerce and Trade Chapter 39-Fair Packaging and Labelling Program	https://www.fda.gov/regulatory-information/federal-food-drug-and-cosmetic-act-fdc-act/fdc-act-chapter-vi-cosmetics
India	Drugs and Cosmetics Act,1940 and Rules, 1945	https://cdsco.gov.in/opencms/opencms/en/Acts-Rules/

3.3. Ethical Considerations

This Research Report is a comparative analysis examining publicly available legislative and regulatory data viz. the laws, regulations and guidelines of four markets. No animal or human participants were involved, and an Ethics Waiver was obtained, Ref W-CBP-2005 14-05, included in Appendix A.

3.4. Data Analysis

This method of qualitative content analysis was used to analyse the data from the selected documents utilising the framework method. The data analysis steps involved data collection by becoming familiar with the data, identifying a thematic framework (and developing a coding frame), systematically indexing the data sets (applying codes systematically to the data) and then organising the codes and themes by charting the data into a matrix to facilitate the comparison between data sets, using Microsoft Excel®.

The themes were deductively identified before starting the analysis in line with the aims and objectives. As the South African CTFA developed the Cosmetic Compendium that

it utilises as the approach for self-regulation, and which is aligned to the EU Cosmetic Regulations, the EU Regulations were therefore used to develop the analytical "Framework" against which the data sets was compared to address the research objectives. Some inductive coding was also performed when going through the data sets in detail to identify all themes. The framework was then used for the comparative analysis to identify similarities and differences. Table 3.2 lists the themes, codes, and code descriptions used to compare the framework in each country.

Table 3.2 Coding Framework

Themes	Codes	Code descriptions
Quality	GMP	Manufacturing practices, manufacturing standards, manufacturing certification
Market Surveillance/ Control of Product	Definition of cosmetic	How a cosmetic is defined
	Notification or Registration Requirement	Registration requirement with the Authority
	In-market control	Product Information File, Authority requests information, control of product, information on cosmetics, traceability system
Safety	Ingredients & Composition	Environmental safety, specifications, prohibited substance, restrictive substances, consumers right to access information, annexes
	Safety assessment	Responsible person, Compliance, safety report
	Post Marketing Surveillance	Regulatory checks/changes, recording of complaints, recording/reporting of adverse events, sampling and analysis, responding to significant changes of the product, recall
Labelling Requirements	Requirements for labelling	Packaging, statements as per Annexes, name and address, warnings, precautions, expiry date, nominal content, lot number
	Claims	Consumer information, indications, warnings, logos
Animal Testing	Requirement by legislation	Is it allowed?
	Labelling on tests	Logos, claims
New Technologies	Definition of new technologies	nanotechnology, cosmeceutical, borderline products
	Requirements for new technologies	Specific requirements for the nanotechnology, cosmeceuticals, borderlines products

Chapter 4

4. Results

4.1. Examination of the Proposed Changes to the SA Foodstuffs, Cosmetics and Disinfectants Act

The proposed amendment to the Foodstuffs, Cosmetics and Disinfectants Act: *Regulations: Labelling, advertising and composition of cosmetics,* published for comment on 22 December 2017, introduces the regulations for the labelling, advertising and composition of cosmetics in South Africa. With the cosmetics industry currently being self-regulated in South Africa and guidance being provided by the CTFA in its Cosmetics Compendium on the Codes of Practice and Standards, these proposed new regulations, demonstrate the intention of the South African government to regulate this industry and focus on the critical areas of labelling, composition, advertising and post marketing surveillance that require enforcement. This amendment has been divided into 13 regulations and 6 Annexes.

4.1.1 Regulation 1: Definitions

The proposed regulations include definitions for words or expressions that are referred to but does not contain a definition for a cosmetic. The Foodstuffs, Cosmetics and Disinfectants Act, Act 54 of 1972, provides the definition for a cosmetic as "*any article, preparation or substance (except a medicine as defined in the Medicines and Related Substances Act, 1965 (Act No. 101 of 1965)) intended to be rubbed, poured, sprinkled or sprayed on or otherwise applied to the human body, including the epidermis, hair, teeth, mucous membranes of the oral cavity, lips and external genital organs, for purposes of cleansing, perfuming, correcting body odours, conditioning, beautifying, protecting, promoting attractiveness or improving or altering the appearance, and includes any part or ingredient of any such article or substance*"; in other words, defining a cosmetic according to its intended use and the product achieves its effect without being systemically absorbed.

4.1.2 Regulation 2: Category of Cosmetics

Seventeen categories of cosmetics are listed, although this list is not exhaustive. Whilst Regulation 1 does not specifically provide a definition for a cosmetic, this regulation specifically states that "*Substances or mixtures intended to be ingested, inhaled, injected or implanted into the human body shall not be considered to be a cosmetic*", thereby suggesting that if the product/product's composition is used for treating, diagnosing, preventing, monitoring, alleviating disease or injury; or restoring, correcting or modifying somatic, psychic or organic functions in human beings, it is considered to be a medical device or a medicine, as per their definitions in the Medicines and Related Substances Act, Act 101 of 1965, and thus regulated by a different set of Regulations.

4.1.3 Regulation 3: Responsible Person

This new cosmetics regulation introduces the requirement for a Responsible Person (RP). The RP, defined as a "natural or juristic person (manufacturer, importer or distributor) responsible for making the cosmetic available on the market" places the responsibility for ensuring the quality and safety of the cosmetic product in the hands of the manufacturer/importer/distributor. Thus, it is the responsibility of the manufacturer/importer/distributor to ensure compliance of the cosmetic product that is placed on the market to these cosmetic regulations. Every manufacturer/importer/distributor has to have a nominated RP and Figure 4.1 clearly outline outlines their obligations as referred to throughout the Regulations:

- Responsible for making the product available on the market
- Responsible for compliance of the product on the market
- Ensuring the cosmetic product has undergone safety assessments of both its finished product and ingredients
- Keep a Product Information File (PIF)
- Post marketing surveillance

4.1.4 Regulation 4: Safety

Along with the Responsible Person introduced earlier, Regulation 4 introduces the components to achieve the safety of cosmetics. No cosmetic can be sold,

manufactured or imported if the presentation, composition, labelling, instructions for use and any other information is likely to cause harm. A cosmetic safety assessment report must also be performed by an appropriately trained person, on the finished product and its ingredients and the minimum requirements that must be considered in the risk assessment are listed.

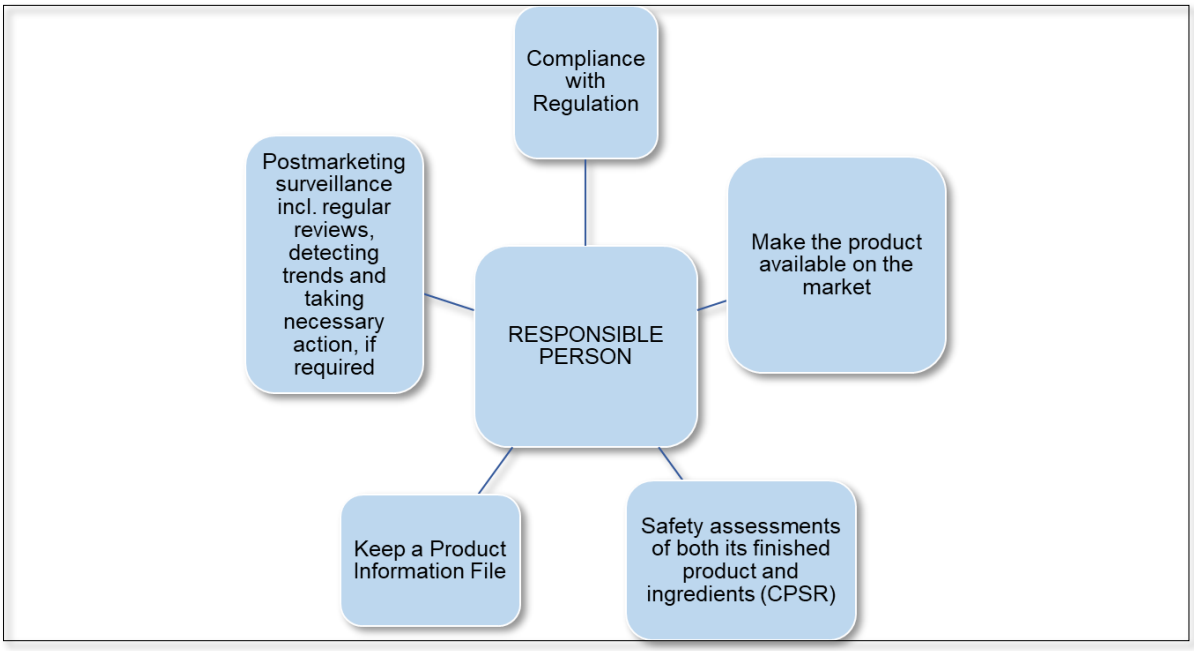


Figure 4.1 Responsibilities of the Responsible Person

4.1.5 Regulation 5: Good Manufacturing Practice

Currently there is a national standard, SANS 22716:2011- "*Cosmetics - Good Manufacturing Practices (GMP) - Guidelines on Good Manufacturing"* that is based on the international guideline, ISO 22716:2007. As the use of SANS are merely voluntary and not mandated by law, this is only a guideline for GMP implementation. The proposed regulations therefore now compel the cosmetic manufacturers to either ensure GMP certification or be aligned with the relevant SANS and ISO standards which will then infer compliance and thus recognising internationally accepted standards of GMP.

4.1.6 Regulation 6: Product Information File (PIF)

The requirement for a PIF is also new to the SA Cosmetic Regulatory framework. When a product is marketed, the responsible person is required to keep a product information

file for each cosmetic, for control purposes. The PIF is an information dossier, required to contain minimum information on the description of the cosmetic, methods of manufacture and compliance with GMP, the cosmetic safety report, scientific substantiation of the claims and efficacy and data on any animal testing. The PIF must be available when a product is placed on the market and be made available to the Authority when requested at any time. It is kept for a period of 10 years after the last batch of product is placed on the market. The safety assessment report is a major part of this document and is a means of product control by the Authority. The regulations also specify the minimum requirements for the safety report.

4.1.7 Regulation 7: Product Composition

The composition of cosmetics is important, and this regulation makes reference to the list of prohibited substances, restricted substances with conditions of use and warnings, colourants, preservatives and UV filters for cosmetics stipulated in the Annexes and which have all been adopted from the EU regulations. The current Cosmetics Compendium, developed by the CTFA, have adopted the EU Annexes in the self-regulatory framework. These will therefore become mandatory once the regulations are signed into law.

4.1.8 Regulation 8: Labelling

Currently labelling is regulated by the Legal Metrology Act of 2014 and the SANS 289:2013 - *Labelling Requirements for pre-packaged goods (pre-packages) and general requirements for the sale of goods subject to legal metrology control* provides the guidance to ensuring the requirements of the Act are met. This is a compulsory standard for all products marketed in South Africa that focuses on technical requirements on the packaging of products and falls under the ambit of the National Regulator for Compulsory Specifications. There is a SANS guideline, SAN 98:2012 – *Ingredient Labelling of Cosmetics Products*, but once again this is not compulsory. The proposed regulations make provisions for regulating the labelling requirements for cosmetics specifically and proposes that the primary and secondary container of every cosmetic for sale must have a label that “must be visible, legible and indelible” and

shall not be obstructed by pictorial or any other matter, printed or otherwise and be in at least English, with at least the following information:

- name of the cosmetic.
- name and business address (i.e. manufacturer, importer or distributor)
- country of origin for imported cosmetics
- The nominal content at the time of packaging in accordance with the Legal Metrology Act 2014 although there are certain exemptions
- Date of minimum durability i.e. expiry date, to be preceded by the symbol or the words “best before the end of…” and be clearly expressed
- Precautions and warning statements where applicable, and at least those listed in the Annexes
- The batch or lot number
- Declaration of ingredients according to INCI nomenclature including fragrances, hair colourants, colouring agents in cosmetics, in decreasing order of concentration. Ingredients present in the form of nanomaterials to be followed by the word “nano” in brackets
- The function of the cosmetic
- Any pressurised container must contain a warning statement indicating that the container is pressurised, be protected from direct sunlight and temperatures exceeding 50 °C and should not be pierced, punctured, burnt or incinerated, even after use.

4.1.9 Regulations 9 & 11: Product Claims & Advertising

The Cosmetic Code of Advertising Practice for South Africa, administered by the Advertising Regulatory Board (ARB), provides specific guidance to the marketing and advertising of cosmetics in South Africa. It provides the requirements for claims being made and advertising of particular products however, it is a self-regulatory code. The proposed Regulation 9 regulates the claims being made on cosmetics – prohibited claims, in words or pictorials, unless they can be scientifically substantiated like “clinically proven” and “recommended by doctors”; claims, either by text, pictures or symbols, that imply characteristics or functions that a product do not have or that the cosmetic contains medicinal properties, are also prohibited. Currently and as per Government Notice, No. R. 1227 of 24 June 1988, Regulations Prohibiting the Use of

Any Active or Potentially Active Depigmenting Ingredient, Lead and Its Salts, Mercury and its Salts and the Cosmetic Category Skin Bleacher, Skin Lightener or Skin Whitener, any product claiming to be a skin bleacher, skin lightener or skin whitener is prohibited. There is no change to this regulation in the proposed amendment.

Regulation 11, on advertising, is an extension of Regulation 9 by stipulating that advertisements can only contain information that is allowed on the label of the cosmetic.

4.1.10 Regulation 10: Post Marketing Surveillance

There is no post marketing surveillance requirement for cosmetics currently in South Africa. The regulations thus propose the manufacturer have a process in place to conduct post marketing surveillance. This will involve investigating and recording undesirable and serious undesirable events, recording these in the PIF and regularly reviewing the undesirable and serious undesirable events to detect trends and to act when required.

4.1.11 Regulations 12: Penalties

In a self-regulated market, the industry association would be responsible for providing guidance to compliance on guidelines. Regulation 12 provides the penalties for failure to adhere to the regulations – a fine, imprisonment or both with the severity depending on the number of times of being convicted as well as destruction of the products that do not comply with the proposed regulations.

4.1.12 Regulation 13: Amendment of Annexes

The following are the Annexes in the regulations

Annex I List of substances which must not form part of the composition of cosmetics

Annex II List of substances which cosmetics must not contain, except subject to restrictions laid down

Annex III List of colouring agents allowed for use in cosmetics

Annex IV List of preservatives allowed in cosmetics

Annex V List of UV Filters allowed in cosmetics

Annex VI Symbols used on packaging / container

Regulation 13 provides for the Authority to amend/adapt the Annexes when it assesses there is potential risk to human health as a result of substances used in cosmetics. These annexes are aligned to the EU Regulation and thus this regulation allows the annexes to be amended in line with amendments in the EU when they occur without further consultation with the SA cosmetics industry.

4.2. Comparative Analysis of the proposed Cosmetic Regulations in South Africa to the EU, USA, and India.

The final framework consists of thirteen codes, clustered into six themes, each with a brief explanatory description of their meaning and examples of what ideas or elements might be summarised under that code. The coding framework is shown in Table 3.2 and the Comparative Results of the Cosmetic Regulations for the four markets is shown in Table 4.1.

1 **Table 4.1 Comparative Analysis of Cosmetic Regulations in SA, EU, USA & India**

THEMES	SOUTH AFRICA	EUROPE	UNITED STATES OF AMERICA	INDIA
Regulation / Guideline	Foodstuffs, Cosmetics and Disinfectants Act, 1972 (Act No. 54 of 1972) Proposed “Regulations Relating to the Labelling, Advertising, and Composition of Cosmetics”	Regulation (EC) No 1223/2009	Federal Food, Drug and Cosmetic Act (FD&C Act). Fair Packaging and Labelling Act (FPLA)	Drugs and Cosmetics Act, 1940 and Rules, 1945 Labelling Declarations by Bureau of Indian Standards (BIS) The Legal Metrology Act 2009
Definition of a Cosmetic	”Any article, preparation or substance (except a medicine as defined in the Medicines and Related Substances Act, 1965 (Act No. 101 of 1965)) intended to be rubbed, poured, sprinkled or sprayed on or otherwise applied to the human body, including the epidermis, hair, teeth, mucous membranes of the oral cavity, lips and external genital organs, for purposes of cleansing, perfuming, correcting body odours, conditioning, beautifying, protecting, promoting attractiveness or improving or altering the appearance, and includes any part or ingredient of any such article or substance."	”Any substance or mixture intended to be placed in contact with the 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, protecting them, keeping them in good condition or correcting body odours.”	”Articles 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 articles intended for use as a component of any such articles; except that such term shall not include soap.”	”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.”

Themes	South Africa	Europe	United States of America	India
Market Surveillance	No registration requirement for cosmetics	Notification requirement to the notification portal (CPNP) Sampling and analysis of the cosmetic product	Cosmetics are not subject to pre-market approval. Manufacturers / Distributors may voluntarily register information on the FDA's Voluntary Cosmetic Registration Program (VCRP)	Approval is required for imported cosmetics. Locally manufactured cosmetics do not require registration, but certain categories of cosmetics require licenses prior to manufacturing.
Quality	• The manufacture of cosmetics must comply with GMP. • Compliance with GMP shall be presumed where the manufacture of a cosmetic is in accordance with the relevant SANS and ISO standards.	The manufacturer must state compliance with principles of GMP and adopt similar practices with ISO 22716 being the recognised standard.	No GMP regulations	The CDSCO (Central Drug Standard Control Organisation) refers to cosmetics complying with standards of quality and safety but does not prescribe a standard.
Safety	• The Responsible Person: ✓ is responsible for making the product available on the market, ✓ is responsible for compliance of the product on the market ✓ must compile/keep a PIF ✓ must have a process to record and investigate undesirable and serious undesirable events from consumers ✓ must conduct regular reviews of the reported undesirable and serious undesirable events, to detect trends and respond if required – record in the PIF	• The Responsible Person is legally responsible for ✓ ensuring safety and compliance. ✓ Compiling a Product Information File (PIF) ✓ Checking ingredients used are of suitable grade and quality ✓ Producing a Cosmetic Product Safety Report (CPSR) & safety assessment by a qualified person is a premarket obligation • General prohibition on materials classified as Carcinogens,	• Short list of prohibited or restricted ingredients including biothionol, hexachlorophene, mercury compounds (except under certain conditions as preservatives in eye cosmetics), vinyl chloride and zirconium salts in aerosol products, halogenated salicylanides, chloroform and methylene chloride. • Colour additives are regulated & must be tested for safety and approved for their intended use by the FDA before they can be marketed	• Schedule S – 28 categories of cosmetics allowed if it meets with compliance under BIS. If the cosmetic is not included in Schedule S, it must meet with specifications under the rules and standards applicable to it in the country of origin. • Dyes, Colours & Pigments are prohibited unless they are specified by the BIS in the Standard 4707 (Part 1) and Schedule Q (Drugs &Cosmetics Rules, 1945)

	• Safety assessments of cosmetic products for both the finished product and ingredients and included in the PIF • Post marketing surveillance • Regulation of ingredients is based on lists (negative & positive lists) of: ✓ List of prohibited substances ✓ List of restricted substances ✓ Positive list - colouring agents ✓ Positive list – preservatives ✓ Positive list - UV filters	Mutagens or Reproductive Toxins (CMRs). • Regulation of ingredients is based on lists of: ✓ List of prohibited substances ✓ List of restricted substances ✓ Positive list - colouring agents ✓ Positive list – preservatives ✓ Positive list - UV filters • Traces of 'prohibited materials' are permitted as impurities if technically unavoidable and determined to be at a safe level. • Post Marketing Surveillance • Recording of complaints • Notify Authority of SUES (Serious Undesirable Effects) • Ongoing due diligence Information must be made readily available to poison centres	Voluntary Cosmetic Ingredient Review recommendations are followed by industry • Prohibited cattle materials • Sunscreens in cosmetics - Use of the term "sunscreen" or similar sun protection wording in a product's labelling generally causes the product to be subject to regulation as a drug (/drugs) or a drug/cosmetic, depending on the claims • FDA routinely monitors cosmetics for: ✓ Microbial contamination ✓ Other contamination ✓ 1,4 dioxane ✓ Lead ✓ Asbestos in talc ✓ Parabens ✓ Phthalates ✓ Nitrosamines, Diethanolamine and pesticide residuals have previously been monitored • Ethyl alcohol in cosmetics must be denatured	• Indian Standard, Classification of Cosmetics Raw Materials and Adjuncts Part 2 - List of Raw Materials Generally Not Recognized as Safe for Use in Cosmetics. Ingredients in this standard have been classified as per the following four lists: Annex A - List of substances which must not form part of the composition of cosmetic products. Annex B - List of substances which cosmetic products must not contain except subject to the restrictions and conditions laid down. Annex C - List of preservatives which cosmetic products may contain. Annex D-List of UV filters which cosmetic sunscreen products may contain • Cosmetics with Hexachlorophene, Lead or Arsenic compounds and mercury compounds are prohibited to be manufactured and imported

Themes	South Africa	Europe	United States of America	India
Animal Testing	• The secondary container label or any notice, document, label referring to the cosmetic, may refer that no animal tests have been performed only if the manufacturer and suppliers have not carried out or commissioned any animal tests on the finished cosmetic or any of the ingredients or used any ingredients that have been tested on animals • PIF must contain data on any animal testing performed by the manufacturer, his agents/suppliers relating to development or safety assessments or any animal testing performed to meet the legislative or regulatory requirements of other countries	It is the responsible person's obligation to ensure products comply with animal testing regulations. A complete ban is set for cosmetics which have been tested on animals, be it the finished product or their ingredients.	No cosmetic shall be manufactured from, processed with, or otherwise contain, prohibited cattle materials.	Cosmetics that are tested on animals are not allowed for import in India.
Labelling Requirements	• Minimum requirements for the label of a cosmetic container: ✓ name of the cosmetic ✓ name and business address ✓ country of origin for imported cosmetics ✓ The nominal content at the time of packaging in accordance with the Legal Metrology Act 2014	• Requirements for the label of a cosmetic container: ✓ name and business address of the responsible person ✓ country of origin for imported cosmetics. ✓ The nominal content at the time of packaging	• Requirements for the label of a cosmetic container: ✓ Name and address of manufacturer, packer or distributor ✓ Country of origin for imported products ✓ Identity ✓ Net quantity of contents	• Every product imported into India with the following mandatory labelling on the outer packaging ✓ Name of cosmetic ✓ name and address of the importer/distributor ✓ net quantity in terms of standard unit of weights and measures

	✓ Date of minimum durability i.e. expiry date, to be preceded by the symbol or the words “best before the end of…” and be clearly expressed ✓ Precautions and warning statements where applicable, and at least those listed in the Annexes ✓ The batch or lot number ✓ Declaration of ingredients according to INCI nomenclature including fragrances, hair colourants, colouring agents in cosmetics, in decreasing order of concentration. ✓ The function of the cosmetic ✓ Language: English ✓ No product claims are allowed on a cosmetic product’s label unless it can be scientifically substantiated	✓ Best before date or period after opening symbol ✓ Precautions ✓ Batch number ✓ Function of product ✓ List of ingredients - INCI names, correct order, nanomaterials identified • Claims either by text, names, trademarks, pictures and figurative or other signs shall not be used to imply that these products have characteristics or functions which they do not have.	✓ The label shall include the name of each ingredient in descending order of predominance listed by their INCI names ✓ Directions for safe use ✓ Warnings & caution statements ✓ Information must be stated prominently, with conspicuousness so that it can be read and understood by ordinary consumers under normal conditions of purchase and use ✓ Must be in English ✓ If safety has not been substantiated “Warning – The safety of this product has not been determined” ✓ Applicable warning statements for aerosols, feminine deodorant sprays, foaming detergent bath products	✓ Production date: month and year of packing ✓ Expiry date ✓ Net contents • On the inner label: ✓ Directions for safe use, ✓ Any warnings, caution or special direction required to be observed by the consumer, ✓ Statement of the names and quantities of the ingredients that are hazardous or poisonous. ✓ Names of ingredients in the order of percentage of content.
New technologies	• Definition for nanomaterial means an insoluble or biopersistant and intentionally manufactured material with one or more external dimensions, or an internal	• Contains definition for nanotechnology - means an insoluble or biopersistant and intentionally manufactured material with one or more external dimensions, or an	• No definition provided for nanotechnology and not recognised in the regulations	• No definition provided for nanotechnology and not recognised in the regulations

	structure, on the scale from 1 to 100 nm; • Labelling requirement: Ingredients present in the form of nanomaterials to be followed by the word “nano” in brackets	internal structure, on the scale from 1 to 100 nm; • Cosmetic containing nanomaterials need to be notified to the Commission 6 months prior to placing on the market providing the following information: o Identification (IUPAC name) o Specification (particle size; physical and chemical properties) o Estimated quantity contained in cosmetic product per year o Toxicological profile o Safety data o Reasonably foreseeable exposure conditions • Exception applies for nanomaterials used as colorants, UV-filters or preservatives. • All ingredients present in the form of nanomaterials shall be clearly indicated in the list of ingredients. The names of such ingredients shall be followed by the word ‘nano’ in brackets.		

2

Chapter 5

5. Discussion

The comparative results are discussed in six main sections, in line with the themes identified in the framework analysis. The first section examines market surveillance – understanding market control of cosmetics in each of the 4 markets; the second examines good manufacturing practices and standards that are required for quality assurance in cosmetics; the third describes and analyses the safety practices in each market; the fourth looks at regulations regarding animal testing; the fifth reviews the labelling requirements and the sixth examines the regulations on new technologies.

5.1. Market Surveillance

Whilst the EU regulation utilises a notification system prior to placing cosmetic products on the market, the South African cosmetics regulations do not require pre-approval to enter the market. This has been maintained from the current self-regulatory model and is the same as the USA, except colour additives in the latter that must be preapproved. The FDA does, however, have a Voluntary Cosmetic Registration Program (VCRP) where USA cosmetic companies may voluntarily register their products, unique to the USA. As of 1 April 2013, compulsory approval is required in India to import cosmetics while locally manufactured cosmetics do not require registration, but certain categories of cosmetics require licenses prior to manufacturing. Although the EU Notification system does not require the registration of cosmetics prior to launching on the market like for medicines, the advantage of this system is that it allows the health authorities and poison centres of the different member States to access the portal to acquire information about the products and intervene when necessary. It also mandates companies to develop some sort of internal controls and ensure that manufacturers are in control of and take responsibility for the product they are launching by ensuring they have already a PIF in place. India, on the other hand, requires cosmetic products that are imported, through specified ports of entry, to be registered with the CDSCO the registration for which is then valid for a period of three years with re-registration required thereafter. The authority must also be informed beforehand of any changes

any changes in the product specifications, ingredients or variants after being granted the registration. A fee of USD 2000 is also paid for the registration of each cosmetic category and USD 50 for each variant. This is possibly a mechanism to ensure that the Indian market is not flooded with spurious cosmetics and thus protect the consumer. For cosmetics manufactured in India, registration of the cosmetic product is not required but manufacturing licenses are required and issued by the State Licensing Authorities.

5.2. Quality

There has been a national standard in South Africa that has served as a guideline for GMP implementation, SANS 22716:2011 - *Cosmetics - Good Manufacturing Practices (GMP) - Guidelines on Good Manufacturing*. This is the same as the global guideline ISO 22716:2007. The SA regulations propose that the manufacturing of cosmetics must be in line with GMP Standards but does not make it prescriptive as the regulation further recognises and accepts other standards - “compliance with GMP shall be presumed if manufacture of cosmetics is in line with relevant ISO and SANS standards”. This is in line with EU Regulations where the manufacturer must state compliance with principles of GMP and adopt similar practices with ISO 22716 which is the recognised standard. In contrast, the USA’s FDA has no formal GMP regulations for cosmetics but has developed a draft Guidance Document on Cosmetic GMP, dated 2013, called “Guidance for Industry: Cosmetic Good Manufacturing Practices” that describes their thinking on the topic without establishing legally enforceable responsibilities. The CDSCO in India refers to cosmetics complying with standards of quality and safety. The implementation of a quality system is a crucial part of regulatory compliance because it is designed to minimise risks like contamination of products, incorrect labelling and incorrect quantity of ingredients. Whilst all markets make some sort of reference to quality standards required for manufacturing practices, they do not prescribe which standard is to be adopted.

5.3. Safety

One of the key elements of the SA Cosmetic Regulations of safety is the Product Information File (PIF) as it provides the evidence that the manufacturer has met the

responsibility for ensuring safety of the cosmetic product. The Cosmetic Product Safety Report (CPSR) is a key report included in the PIF as the manufacturer must show safety before marketing a cosmetic and South Africa has aligned to the EU regulations in this regard. Neither USA nor India has requirements for a PIF in their regulations. For cosmetics that are marketed in the USA where safety has not been proven, the product must carry the statement “Warning – The safety of this product has not been determined”. India requires approval for all imported cosmetics by their Authority, and information that is submitted to the CDSCO includes the labels (original or copies), product specification and testing protocol, information about the brand, product and manufacturer and package insert if any. Locally manufactured cosmetics in India do not require approval before launching in the market although they require a licence to manufacture.

The EU cosmetic regulations regulate the composition of cosmetic products through a set of Annexes that it has developed. These are lists of ingredients (positive or negative), that it either allows, prohibits or restricts within specific concentrations to be used in the formulation of cosmetics. The risk of assessment of these cosmetic ingredients in the EU is performed by the SCCS (Scientific Committee on Consumer Safety). The SCCS also provides guidance to authorities and the cosmetic industry to improve harmonised compliance. One of the responsibilities of the SCCS is to recommend guidelines in developing safety studies to be used in the evaluation of cosmetic substances to the cosmetic and raw material industry.

India has a Standard Classification of Cosmetics Raw Materials and Adjuncts that is essentially aligned to the EU legislation with the BIS (the statutory body responsible for raw material controls in India) following the EU REACH’s (Registration, Evaluation, Authorisation and Restriction of Chemicals) compliance and any update in EU legislation is followed by an update in the BIS in India. There are marginal differences in line with restrictions given in Drugs and Cosmetics Act, and Rules 1945. India also has a list of Dyes, Colours and Pigments that are permitted to be included in cosmetics (Schedule Q of the Drugs and Cosmetics Rule, 1945).

The USA on the other hand only has a short list of 9 prohibited or restricted ingredients for cosmetics and these have not been subject to regular review. However, reviews of ingredient safety are undertaken by the Cosmetics Industry Review (CIR), a committee

of experts organised by the CTFA and supported by the FDA, and its recommendations are generally followed by the industry. The USA does not have a positive list of ingredients and one of the reasons is possibly because many of the ingredients on this list would require pre-approval e.g. UV Filters in sunscreens are regulated as over-the-counter (OTC) medicines in the USA and therefore require pre-approval. Colour additives also require pre-approval in the USA. The responsibility for ensuring safe of cosmetic products in the US lies with the manufacturer, supported by an in-market surveillance system. The FDA is authorised to conduct unannounced inspections to ensure compliance with the regulations. 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.

There is therefore a disconnect between the 2 biggest markets, EU and USA, on prohibited and allowed ingredients and the way they are regulated.
The CTFA in South Africa currently aligns with the Cosmetic Compendium to the EU and the proposed regulations have also adopted the EU ingredient lists with the following Annexes in the Regulations:

- Annex I List of substances which must not form part of the composition of cosmetics – Negative list
- Annex II List of substances which cosmetics must not contain, except subject to restrictions laid down - Negative list
- Annex Ill List of colouring agents allowed for use in cosmetics – Positive list
- Annex IV List of preservatives allowed in cosmetics – Positive list
- Annex V List of UV Filters allowed in cosmetics - Positive list

Despite the regulatory controls of cosmetic ingredients and finished products, and the safety assessment of finished products, some consumers may still experience adverse reactions to cosmetic products. Post marketing surveillance is therefore paramount. Cosmetovigilance is the ongoing and systematic monitoring of the safety of cosmetics in terms of human health with the aim being to detect adverse effects of cosmetic products, and to be proactive and try and prevent adverse effects by taking appropriate measures when necessary (Vigan, M. & Castelain, F. 2014).

Of the 4 markets under review, only the EU has an active post marketing surveillance system where manufacturers are legally obliged to forward serious undesirable effects (SUEs) to the Authority. The USA and India practice a passive surveillance system and South Africa is also proposing a passive post marketing surveillance system with the responsibility to record and investigate undesirable and serious undesirable events lying with the RP but no reporting system to the Authority is proposed. This is possibly due to the lack of resources in SA and although, this surveillance system places the responsibility of in-market control on the manufacturer, a more active surveillance system by the Authority will allow safety trends to be detected. The South African Health Products Regulatory Authority (SAHPRA) already has an active system in place for medicines and medical devices and cosmetics could easily be incorporated into this.

5.4. Animal Testing

Animal testing is an important topic. With the EU having taken the lead and introducing the ban on animal testing on finished products in 2004 and completely banning all animal testing on both finished products and ingredients from 2009, they have become a leader in this area and many countries have followed suit - including India, which did so in 2013. The EU and the Indian regulations expressly ban all animal testing on cosmetic products and their ingredients, and these products are not allowed for import. They have instead allowed for *in vitro* methods to be used for product and ingredient assessment. With SA aligning to the EU on many aspects in the regulations, it is therefore noticeable and odd that the South African regulations do not align with regards animal testing in cosmetics. The regulation does however refer to animal testing twice in the regulations. Firstly, it makes allowance for the PIF to contain information on animal testing if it was conducted relating to safety assessments of the finished product or its ingredients to meet the legislative requirements of other countries. Secondly, in Regulation 8(13) on Labelling, it allows for the label of secondary containers to contain information if no animal tests were conducted by both suppliers of ingredients and the manufacturer of the cosmetic product. Whilst the USA does not implicitly request animal testing it also does not explicitly prohibit animal testing. It does however prohibit the use of cattle materials in the manufacture of cosmetics, with the exception of tallow that is used in soaps. This is to protect against bovine spongiform encephalopathy (BSE) or commonly known as “mad cow disease”.

5.5. Labelling Requirements

Proper labelling is an important aspect of marketing a cosmetic product and ensuring consumer safety. Regulation 4 of the proposed SA Regulations specifies that no cosmetic product that is made available for sale in South Africa "*may cause damage to human health when used under normal or reasonably foreseeable conditions of use"* and *"taking account, in particular, of the following:*

a) *product presentation;*
b) *product composition;*
c) *labelling;*
d) *instructions for use and disposal; and*
e) *any other indication or information provided by the responsible person.*

In other words, cosmetics must be safe when used under normal conditions. In order for consumers to do so, they must be able to make an informed decision on the purchase. Hence labelling must be transparent and easily understood.

The ideal packaging for most multinational companies is to create a single packaging version that can be sold worldwide, a "one-size-fits-all" concept that achieves economies of scale. However, there are many issues in global packaging to consider before a company can develop one label that can be used and sold in every country in the world. Apart from the differing languages, the differing regulations in countries do not always align making having a single packaging unit very difficult to achieve. Customs officials also prevent the entry of the cosmetics into the country if the packaging does not meet the local regulations. Thus, packaging regulations can be a trade barrier for entry into a market e.g. all the markets require the expiry date to be included on the product except the USA. This makes sharing the label with the USA or exporting product to the USA difficult.

One of the key elements that affects the packaging and marketing of a cosmetic is the definition as this clearly distinguishes a drug and a cosmetic. Essentially a cosmetic's action is superficial, to improve the external appearance whilst the effects of drugs are physiological in nature i.e. to affect the structure and function of the body. Whilst the proposed SA Regulation has not included the definition of a cosmetic in its list of definitions, the FCD Act has defined a cosmetic and this definition is similar in all 4 markets, with the following exceptions:

- the USA's definition also explicitly excludes soap (a "soap" is defined differently in the USA and is regulated by a different set of regulations) and
- the EU definition is worded differently, making specific reference to "a substance or mixture intended to be placed in contact with the 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". The definition includes products such as skin moisturisers, perfumes, lipsticks, eye and facial makeup, cleansing shampoos, hair dyes, and deodorants.

It is therefore the intended use that defines a product as a cosmetic. According to the regulations in SA, EU & India, a product can either only be a drug or cosmetic, however the USA regulation states that a cosmetic is legally also a drug if it is intended to exert a physical as well as a physiological effect. The FD&C Act provides that the categories of "drug" and "cosmetic" are not mutually exclusive, e.g. sunscreens in the USA are regulated as OTC medicines because they are intended to prevent disease - marketed to prevent sunburn and skin cancer – even though their primary use is cosmetic, whilst the other 3 markets consider sunscreens to be cosmetics.

South Africa aligns with the EU in terms of substantiation of claims for the product - "Claims in respect of the nature, effects and quality of the cosmetic is prohibited, unless scientifically substantiated". The SA regulation is also prohibiting the use of the words "clinically proven" unless scientifically substantiated or "recommended by doctors" or any other words or pictures that imply that medical practitioners or scientific specialists recommend its use. The definition of a cosmetic is once again important as claims that convey the impression that the cosmetic possesses medicinal properties are prohibited.

Topical skin lightener products are popular on the African continent having become a part of life in African communities although their health consequences have been highlighted (Davids, et al. 2016; Dlova, et al. 2015). There is inconsistent regulation across the African continent but one of the few amendments made to Act 54 of 1972 was in 1988 with the "Regulations Prohibiting the Use of any Active or Potentially Active Depigmenting Ingredient, Lead and its Salts, Mercury and its Salts and the Cosmetic Category Skin Bleacher, Skin Lightener or Skin Whitener". This is included in the proposed regulations where the words "skin bleacher", "skin lightener" or "skin whitener" or claims that convey such impressions are prohibited. This is one of the

regulations that is culturally specific to South Africa and therefore none of the other markets have any such regulation in place for this category of cosmetics.

Another key element in labelling is that of ingredients. This is because ingredient labelling is an important attribute for the safe use of cosmetic products by consumers. As products are traded internationally it is necessary therefore that uniformity is used in the listing of cosmetic ingredients. The names for most cosmetic ingredients are based on the International Nomenclature of Cosmetic Ingredients (INCI), which is a universal list of ingredients that was established in the 1973 by the CTFA to harmonise ingredient names, and is used today by all countries including the USA, EU and others. Specifications for ingredient labelling in South Africa are currently listed in SANS 98:2012, Ingredient labelling of Cosmetic Products, which although being a national standard, is not compulsory. Although this Standard specifies that as a general requirement “Ingredient labelling for all cosmetic products shall comply with the relevant national legislation”, to date there has been no such regulation. The only mandatory requirement has been that all cosmetic products sold in the South African, post December 2006, include the allergens that are found in the listing of the 26 allergens if they present in the product. The new regulations therefore propose the list of ingredients according to INCI nomenclature to be included on the secondary and/or primary packaging.

The guidelines for the labelling of the quantity of cosmetics in South Africa is found in SANS 289:2013, entitled “Labelling requirements for pre-packaged goods (pre-packages) and general requirements for the sale of goods subject to legal metrology control.” This is a compulsory standard and as such all products sold (both locally manufactured and imported) need to comply with this standard.

In the USA, irrespective of whether cosmetics are imported or manufactured in the USA, they must comply with the labelling regulations of the FD&C Act & the FP&L Act. The FP&L Act ensures that labelling provides consumers with accurate information about the quantity of contents whilst the FD&C Act prohibits the marketing of cosmetics that are adulterated or misbranded as well as their adulteration or misbranding. Legally cosmetic manufacturers are responsible for the labelling of their products in the USA because if a product’s labelling is false or misleading or does not contain the required labelling information or the container is made or filled deceptively, then it is considered

to be misbranded. The FDA thus issued “The Cosmetics Labelling Guide” to provide guidelines on cosmetic labelling in line with these Acts.

5.6. Regulation of Borderline Products and Cosmeceuticals

Whilst cosmetics are substances to “*cleanse, perfume, correct body odours, condition, beautify, protect, promote attractiveness or improve or alter the appearance”,* advances in technology has challenged the traditional definitions and characteristics of cosmetics and health products. There are sometimes overlapping characteristics between health products and cosmetics making it difficult to differentiate medicines, medical devices, cosmetics, food supplements or biocidal products. Figure 5.1 shows the overlapping areas of the different health products. Depending on their classification, different regulations apply.

According to the WHO, borderline products “are generally medical products for which it is unclear which legislation applies”. In March 2017 the MCC issued a guideline for comment on Borderline Products. Although not finalized to date, it does however provide their insight into the regulation of this category of products. Borderline cosmetic products are products that could either be classified as medicines, medical devices or cosmetic products and would fall into an overlapping in Figure 5.1 would be considered borderline. Although differentiation between these is made according to 2 main factors – the composition and the claims made about the product, it is ultimately the intended purpose of the product that classifies the regulation that will apply.

Cosmeceuticals, being a hybrid between pharmaceutical and cosmetics products, is a type of borderline cosmetic product but have not been recognised by any of the regulatory policies that were examined and there is therefore no separate regulatory framework for such products. Examples of such products are said to improve appearance of the skin by delivering nutrients necessary for healthy skin. They most commonly claim to reduce wrinkles and to improve tone, texture and radiance of the skin (Lintner, 2009). Although the US regulatory framework recognises that a product can be both a drug and a cosmetic, the FDA has issued a statement that the “FD&C Act does not recognize any such category as cosmeceuticals." (FDA, 2018)

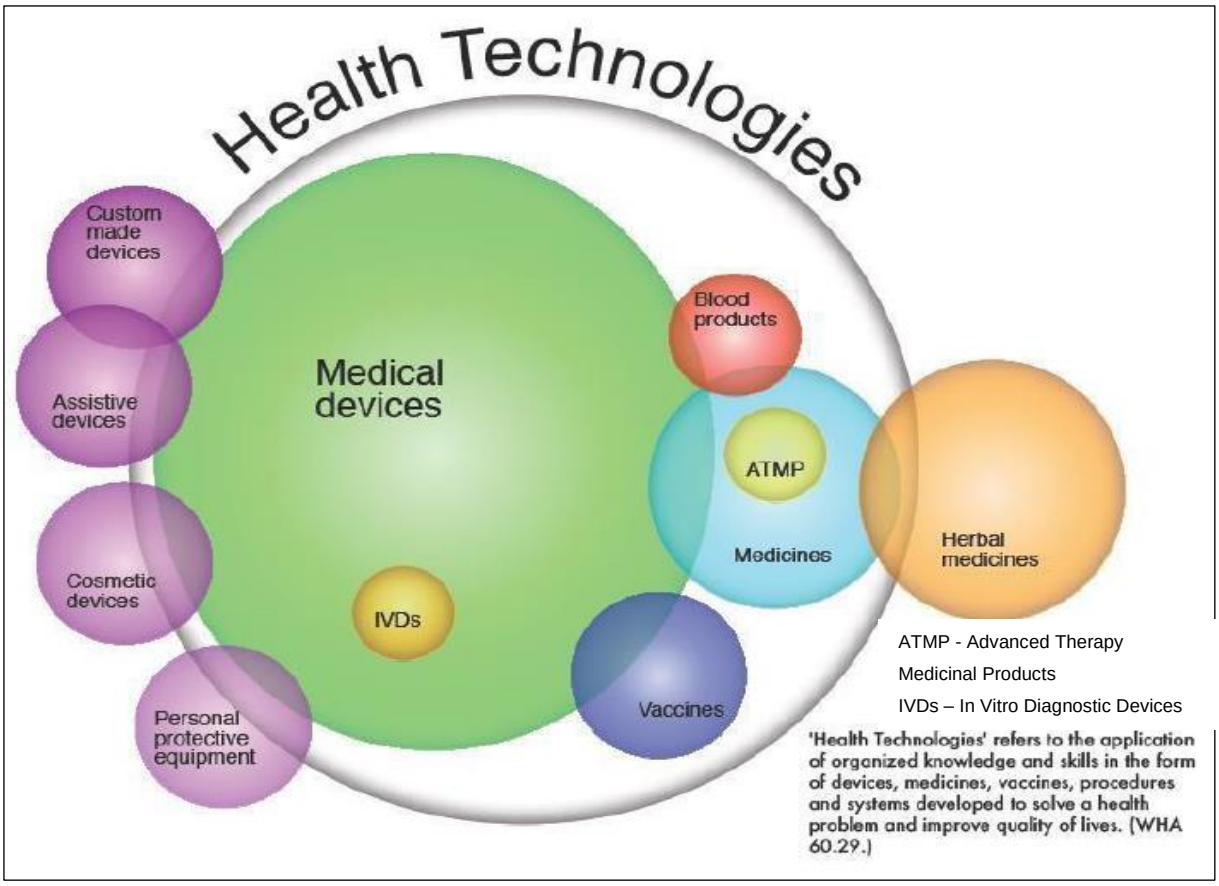


Figure 5.1 Inter-relation of (medical) products inside and outside healthcare (MCC, March 2017)

5.6.1 Regulation of Nanomaterials

Nanomaterials, as defined by both the SA and EU regulations, is “an insoluble or biopersistant and intentionally manufactured material, with one or more external dimensions, or an internal structure, on the scale from 1 to 100 nm”. They have biological, chemical or physical properties that are different from the conventional ingredients. Regulations are important for this new innovation to protect the environment and the consumer as the emerging risks are still fairly unknown. The nanoparticles titanium dioxide and zinc oxide are the most common products of nanotechnology present in sunscreens in the market today.

The only requirement in the SA regulation is that any nanomaterial must be indicated as such on the label of ingredients. The EU regulation addresses the concern of nanomaterials more in their regulations as it is a requirement to inform the Commission six months before a cosmetic product containing nanomaterials is placed on the market and providing information on identification, specification(particle size; physical and

chemical properties), quantity contained in the product, toxicological profile, safety data, and foreseeable exposure conditions.

The USFDA has not issued any definitions of nanomaterials or nanotechnology or legislation addressing nanotechnology, and thus regulates nanotechnology through their current framework for safety assessments. They have, however, issued a guidance document for the industry on the Safety of Nanomaterials in Cosmetic Products but ultimately the Industry remains responsible for ensuring that its products meet all applicable legal requirements, including standards for safety (US FDA, 2014).

Chapter 6

6. Conclusion and Recommendations

6.1. Conclusion

Regulation is key to ensuring consumer safety. The key principle for regulations across the four markets reviewed is that cosmetics must be safe but how they each go about trying to achieve this is different.

This study has examined the proposed amended regulations of South Africa and compared it to three major regulatory markets and found the four markets have the following similarities:

- The full responsibility of the cosmetic product placed on the market remains is that of the manufacturer i.e. quality, safety and surveillance
- Limited number of banned or restricted ingredients
- Scientific substantiation is required for claims
- Regulatory focus on safety as opposed to efficacy

The main differences in the cosmetic regulations of the markets reviewed include the following:

- Pre-market control mechanisms - registration vs notification systems or lack thereof
- Definitions of cosmetics which results in differing categorisation and as a result different regulation being adopted
- Post marketing surveillance (cosmetovigilance system) - Active vs passive system
- Labelling requirements – there are still differences in the information that is mandatory on the labels
- Controls over ingredients – the lists of prohibited and accepted substances
- No global consensus on animal testing of the finished product or the ingredients

- Although there is awareness of the risks of the newer technologies by the different regulatory authorities, there are limited control measures in place and the Authorities need to have more discussions on this topic. Labelling of nanomaterials is compulsory under the EU Cosmetics Regulations but not under the USA's FD&C Act. Although the Indian Drugs and Cosmetics Act makes no reference to nanotechnology, it does differentiate between the different systems of indigenous medicines.

With the differences in regulations between the 2 largest markets, the EU & USA, South Africa has, like India and many other countries, chosen to align its cosmetic regulations with that of the EU, who have shaped cosmetic regulations globally. In examining and comparing the differing regulations, SA has adopted the positive and negative lists of ingredients from the EU, there is improved alignment on product claims and labelling and the use of INCI terms for ingredient labelling. These changes will significantly reduce barriers to trade and constraints on innovation and will ensure safety of consumers and availability of quality products both locally and internationally. Although South Africa is aligning with many of the regulatory aspects of the EU model, it is however, choosing a passive post marketing cosmetovigilance system instead of an active in-market surveillance system like the EU. This is possibly due to resource and infrastructure constraints. However, without active surveillance and monitoring systems, it will be unable to identify safety signals for cosmetics or monitor and compare safety on a global level. South African framework should therefore borrow the systems and innovations being currently developed and utilised for medicines and medical devices which will provide oversight of cosmetics without burdening the regulatory process and ensure high levels of safety that consumers expect from the national Regulator. An effective in-market surveillance will assist in the reduction of trade barriers without compromising consumer safety.

Currently, there is no guidance regarding which administrative Authority in South Africa will assume responsibility for the implementation and administration of the Cosmetic Regulations. Whilst it is assumed that this responsibility may fall to SAHPRA, cosmetic products are currently not included in SAHPRA's formal regulatory mandate. Moreover, given SAHPRA's current resource constraints, it would be difficult for it to assume responsibility for enforcing these regulations as well. It is likely therefore that this will remain a regulatory mandate within the National Department of Health in terms

of the Foodstuffs, Cosmetics and Disinfectants Act of 1972. Furthermore, it is vitally important for South Africa to develop a monitoring and reporting system to ensure the safety and quality of cosmetic products in the marketplace. Such a vigilance system would need to enforce safety and quality reporting by manufacturers as well as encourage reporting by consumers. It may need to also include oversight by SAHPRA given its experience and key role in ensuring the safety of pharmaceutical and medical device products on the market.

Achieving a common cosmetic regulation will be impossible, due to cultural and legislative traditions, but the harmonisation of the South African Cosmetic Regulations with that of the EU is a step in the right direction to provide guidance to a currently unregulated industry.

This study has focused on comparing South Africa to international markets, but as trade within the African continent increases, it would be interesting to focus on regulatory comparisons with other African markets.

6.2. Limitations of the research

Regulations are quite complex, and within the confines of this Research Report, it was not possible to provide a detailed analysis of the laws of each market.

There was a vast amount of information and secondary data on the cosmetics regulatory frameworks of the EU, USA and India but the lack of studies on cosmetics regulations in South Africa provided a challenge in comparing these.

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Appendix A Ethical Clearance Certificate

UNIVERSITY OF THE WITWATERSRAND, JOHANNESBURG

HUMAN RESEARCH ETHICS COMMITTEE (MEDICAL)

Human Research Ethics Committee (Medical)

Research Office Secretariat:
Faculty of Health Sciences, Phillip Tobias Health Sciences Building, 3rd Floor, Office 301/2/4, 29 Princess of Wales Terrace, Parktown, 2193
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Website: www.wits.ac.za/research/about-our-research/ethics-and-research-integrity/

Ref: W-CBP-200514-05 14/05/2020

TO WHOM IT MAY CONCERN:

Waiver:	This certifies that the following research does not require clearance from the Human Research Ethics Committee (Medical)
Investigator:	Mrs S. Sukhnandan
Supervisor:	Prof. S. Banoo/Prof. M. Danckwerts
Department:	Pharmacy and Pharmacology
Project title:	A Comparative Study of the Regulatory Framework for Cosmetics in South Africa, Europe, United States and India.
Reason:	A review of publicly available legislative and regulatory data as applied to cosmetics. No human participants, human data or human tissues will be involved in the study.

CB Penny

Dr CB Penny

Chairperson: Human Research Ethics Committee (Medical)

Copy – HREC (Medical) Secretariat: Ms Zanele Ndlovu, Ms Mapula Ramaila and Mr Rhulani Mkansi

Appendix B Turnitin Report

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A COMPARATIVE STUDY OF THE REGULATORY FRAMEWORK FOR COSMETICS IN SOUTH AFRICA, EUROPE, THE UNITED STATES OF AMERICA AND INDIA

Sohana Sukhnandan

A Research Report submitted to the Faculty of Health Sciences, University of the Witwatersrand, Johannesburg, in partial fulfilment of the requirements for the degree of Master of Science in Medicine (Pharmaceutical Affairs).

Johannesburg, 2020

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