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Regulatory Compliance of Cosmetic Products in Kenya: A Narrative Review on Quality and Safety

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ABSTRACT

This study reviews the regulatory compliance of the cosmetic products in Kenya, with a focus on consumer risks and potential public health impact. A narrative review study design was employed and a literature search conducted using government reports, publications, academic databases and other relevant sources. Keywords such as cosmetic industry challenges and cosmetic regulation in Kenya were employed to search the literature for papers. Data focusing on regulatory frameworks, enforcement mechanisms, adverse reactions, and industry challenges was then extracted and discussed in form of a narration. The growth of the cosmetic industry, fueled by urbanization, a rising middle class, and increased grooming awareness, has attracted both local and international investors, presenting challenges in maintaining product quality and safety standards. Seven cases of adverse reactions related to cosmetics were reported by Pharmacy and Poisons Board between 2018-2023. Current study identifies noteworthy challenges by examining Kenya's regulatory framework, led by the Pharmacy and Poisons Board and the Kenya Bureau of Standards. Enforcement disparities within international standards, variance in regulations on prohibited ingredients, inconsistent labeling requirements, industry dynamics, counterfeiting, compounded with the complex nature of safety assessments raise concerns for cosmetic regulators, distributors and manufacturers. The study highlights existing gaps in regulatory oversight emphasizing the necessity of robust enforcement mechanisms. Compliance assessments by KEBS and PPB encompass evaluation of ingredients, formulations, microbial contamination, packaging and labeling. Factors contributing to regulatory noncompliance include poor product quality aggravated by supply chain complexities in the vast and diverse sector. The cosmetic cottage industry inadvertently presents a quality risk to consumers due to limited process and testing capacity. Reported adverse reactions, particularly to mercury-containing skin-lightening products, raise concerns about public health implications. This study advocates for continuous product monitoring and heightened vigilance. The review proposes improvement strategies, emphasizing a dynamic regulatory approach, periodic ingredient reviews, a centralized product approval system, and alignment with global manufacturing standards. Targeted consumer education initiatives focusing on product quality attributes, adverse reaction reporting, label reading and counterfeit awareness are recommended.

Keywords: *Cosmetics, Quality, Regulatory, Risks, Safety, Standards*

INTRODUCTION

Cosmetics are integral to daily grooming routines, encompassing a diverse range of products intended to enhance personal appearance. Within the global market, cosmetics play a crucial role as a thriving industry shaped by evolving trends and consumer demands (Rocca et al., 2022). They refer to substances or products designed for use on the human body, aiming to beautify, cleanse, alter appearance, or promote attractiveness without impacting the body's structure or functions (Baki, 2022). The term "cosmeceuticals" has emerged within this field, signifying products with bioactive ingredients claiming therapeutic benefits beyond traditional cosmetics (Goyal et al., 2022). The historical roots of cosmetics trace back to ancient civilizations, where diverse cultures employed natural substances for aesthetic purposes (Bioworks, 2023). In contemporary times, cosmetics are formulated using a combination of natural and synthetic ingredients, catering to an extensive array of consumer needs. These encompass various types, ranging from skincare and haircare products to makeup and fragrances (Krutika, 2023). The societal integration of cosmetics is deeply ingrained, serving both functional and aesthetic purposes, allowing individuals to nourish and protect their skin, enhance features, express personal style, and boost self-confidence. Cosmetic products are either therapeutic or non-therapeutic.

The dynamic nature of the cosmetic industry mirrors the evolving preferences and expectations of consumers globally. Exponential growth in the global cosmetics market is attributed to factors such as rising disposable incomes, evolving lifestyles, and the influence of social media (Rebel, 2023). This market, inclusive of multinational conglomerates and niche brands, was valued at USD 262.21 billion in 2022, with continuous projected expansion (Grand View Research, 2022). Therefore, regulatory oversight is critical for ensuring the safety and quality of cosmetic products. In the Kenyan market, international and local brands, produced either locally or imported, are available, ranging from large-scale production to cottage cosmetic industries. Some of these brands, particularly from cottage industries, may be unregistered and without a comparator product yet accessible in the market. Comprehensive exploration of this facet is essential to assess the regulatory landscape effectively.

The Kenyan cosmetics industry is thriving, driven by urbanization, a rising middle class, and an increased awareness of personal grooming and hygiene (Statista Market Insights, 2024). Despite the industry's growth in the last decade, literature on the number of cosmetic manufacturers in Kenya is limited. The industry, valued at approximately KES 20 billion, presents an attractive opportunity for investors and key players, both local and international (Cosmetics Kenya Limited Institute, 2023). Consumers in Kenya are increasingly seeking beauty and personal care products that address specific skincare and haircare needs, with a growing preference for natural and organic formulations (Statista, 2023). This growth has led to the introduction of new products in the market, whose standards and regulations are still in the process of being fully drafted and implemented. Additionally, the Kenyan cosmetic cottage industry is rapidly expanding, particularly after the disruptions caused by the COVID-19 pandemic.

Cosmetics contain various ingredients that provide the intended rheological properties and efficacy. These Ingredients are broadly divided into two categories; functional ingredients which are necessary for the product to function as intended and performance ingredients which provide the specific benefits. The ingredients can be natural or synthesized chemically. Common ingredients include active ingredient, base, solvents, preservatives, colors, surfactants, humectants, texturizers etc. Solvents include water, alcohols and ketones, ethers, esters and other aromatic organic compounds. Cosmetics should not contain any ingredient that makes the product harmful when it is used according to directions on the label. The United States Food and Drug Administration (US FDA) has prohibited the following cosmetic ingredients: Bithional, Vinyl chloride, Certain halogenated salicylanilides, Zirconium in aerosol products, Chloroform, Methylene chloride, Chlorofluorocarbon propellants (Block, 2021; US FDA, 2022). However, the use of compounds such as mercury and hexachlorophene have been restricted by the FDA (US FDA, 2022). Generally, the manufacturers have a legal responsibility to ensure product safety. According to the European Commission database for information on cosmetic substances and ingredients, only those ingredients listed in Cosmetic Regulation No 1223/2009 are authorized for use. Risks associated with these ingredients in general include allergic reactions, skin sensitization, eye irritation, carcinogenic concerns, endocrine disruption, environmental impact and residue accumulation (Barbaud & Lafforgue, 2021)

[Table 1]. Correspondingly, even though marketing trends suggest that ingredients of herbal origin are safe, it is still necessary to evaluate and prove their safety for consumers according to comprehensive specifications since some of these products contain pharmacologically active ingredients.

Table 1:
Documented Probable Risks of a Few Known Cosmetic Ingredients

Ingredient	Use	Probable Risk	Ref
Parabens	Preservative	Allergic reactions, endocrine disruption	(Nowak et al., 2018)
Fragrance	Scent enhancement	Allergic reactions, skin sensitization	(Amerongen et al., 2021)
Phthalates	Plasticizers in fragrances, nail polish	Endocrine disruption, reproductive toxicity	(Young et al., 2018)
Formaldehyde	Preservative	Skin irritation, respiratory issues	(Asare-Donkor et al., 2020)
Sodium Lauryl Sulfate	Surfactant in cleansers	Skin irritation, eye irritation	(Bondi et al., 2015)
Retinol	Anti-aging ingredient	Skin irritation, photosensitivity	(Mukherjee et al., 2006)
Titanium Dioxide	Sunscreen, pigment	Inhalation risk, potential nanoparticle effects	(Skocaj et al., 2011)
Oxybenzone	UV filter in sunscreens	Hormone disruption, environmental impact	(Wang et al., 2016)
Talc	Absorbent in powders	Respiratory issues, possible contamination	(Borm, 2022)

Ensuring regulatory compliance for cosmetic products is imperative for safeguarding consumers and upholding market integrity. The quality and safety system for these products spans the entire product life cycle, from manufacturing to post-market surveillance. The term cosmetovigilance, introduced in 1997 refers to surveillance carried out to address the safety of cosmetics products during or after the use. Regulatory authorities play a vital role in evaluating products before market entry and maintaining a robust post-marketing safety surveillance program to monitor potential unexpected health risks associated with the use of marketed products. Cosmetic products adhere to the Good Manufacturing Practice (GMP) standard, ensuring both quality and safety. The European Union regulation ISO 22716:2007 provides specific guidelines for the production, control, and shipment of cosmetic products. These guidelines cover aspects such as premises design, machine and equipment qualification, operational and material control, personnel training, personnel hygiene, as well as maintenance and sanitation. Regulatory bodies in the United States, Canada, and the European Union also incorporate elements of the ISO standard for cosmetic GMPs when formulating or updating guidelines and measures related to GMPs. However, hitches arise due to differing restrictions on the use of ingredients and regulatory frameworks among markets or countries. The lack of harmonization in finished product standards and regulations is a deterrent to international trade, hinders innovation, and limits market growth for a broader population, as noted by Ferreira et al. (2022).

In Kenya, regulatory bodies oversee the cosmetic industry to ensure compliance with established standards, proper labeling, and the absence of prohibited or harmful substances. The Pharmacy and Poisons Board (PPB) is tasked with regulating therapeutic cosmetics, while the Kenya Bureau of Standards (KEBS) and the East African Standards (EAS) set standards for nontherapeutic cosmetic products. The EAS Standard for cosmetics (DEAS 346:2021) aims to harmonize cosmetic product labeling requirements in the East African region. The KEBS guidelines specify requirements for non-medicated cosmetic products, encompassing attributes like pH, microbial contamination and limits for heavy metals. Adherence to the KS ISO 22716 GMP standard for cosmetics is also recommended. The diverse cosmetics sector in Kenya includes large-scale, small-scale, and household producers and has the obligation of adhering to regulatory GMP quality standards. The quality of finished products is influenced by the manufacturing process, production equipment, and the quality of raw materials, including water.

Given the high demand for cosmetics in Kenya, these products are distributed widely, from manufacturing sites to home stores, utilizing innovative channels

such as wholesalers, retailers, department stores, drug stores, professional channels, online retailers, and direct customer sales. The intricate distribution network necessitates a robust post-surveillance system to continuously ensure the safety and efficacy of products in the market. Despite the regulatory efforts, problems exist, and some cosmetic products may not adhere to national quality standards due to the use of unreliable inputs and unqualified processes (Mpungu, 2019). This article critically examines the current state of safety and regulatory compliance in the Kenyan cosmetic industry, aiming to evaluate potential risks to consumers and the resulting impact on public health.

REGULATORY REQUIREMENTS FOR COSMETICS IN KENYA

Globally, industries adhere to regulations and standards to ensure consumer safety and facilitate international trade. The cosmetic industry is no exception, and while major international markets share common regulatory elements, existing differences impact and restrict market growth. This has led to significant growth in the production of innovative products and generic brands in Kenya. Various international organizations, including the International Organization of Standards (ISO) and the Organization for Economic Co-operation and Development (OECD), work to harmonize cosmetic regulatory frameworks globally (Ferreira et al., 2022). Different regions worldwide, such as the European Union (EU), Association of Southeast Asian Nations (ASEAN) and MERCOSUR (Mercado Común del Sur), the Southern Common Market, that is, Argentina, Brazil, Uruguay and Paraguay have their specific set of standards alongside international ones. In Africa, organizations like Common Market for Eastern and Southern Africa (COMESA), Economic Community of West African States (ECOWAS), and the EAC are working toward harmonizing standards for cosmetics to facilitate regional trade (United Nations, 2019).

In Kenya, regulatory bodies, including the PPB and KEBS, oversee different aspects of cosmetic products to ensure safety and quality. The PPB regulates therapeutic cosmetics, while KEBS sets and enforces standards for nontherapeutic cosmetics. Kenya has implemented the Pre-Export Verification of Conformity (PVoC) program through KEBS to ensure that goods imported into Kenya comply with the relevant Kenyan standards and regulations (International Trade Administration, 2022). Under the PVoC program, certain imported products, including cosmetics, undergo a conformity assessment before they are allowed entry into the Kenyan market. This assessment verifies that the products meet the specified standards and quality requirements. The regulatory bodies have in place the appropriate enforcement mechanisms to ensure quality and safety of products as guided by relevant laws. Effective enforcement of these regulations is critical for ensuring compliance with legal requirements and standards. Key elements of implementation include product registration and licensing, inspections and audits, market surveillance, and public awareness and education.

The PPB plays a pivotal role in evaluating and approving therapeutic cosmetic products before they enter the market, ensuring they meet specific safety and quality standards. The approval process is designed to ensure that cosmetic products meet specific safety and quality standards before they are introduced to the market. Manufacturers must submit detailed information about their products, including ingredient composition, manufacturing processes, and safety data. The Pharmacy Board evaluates this information to ensure compliance with national regulations outlined in acts such as the Pharmacy and Poisons Act (Cap 244) and the Food, Drugs, Chemical Substances Act (Cap 254) and Guidelines on Evaluation and Registration of Medicines. The acts empower the PPB to regulate the importation, manufacture and distribution of therapeutic cosmetics. The approval process is a critical step to safeguard consumer health and ensure the integrity of the cosmetic market in Kenya. In addition, regular inspections and audits of manufacturing facilities, distribution channels, and retail outlets are performed to verify that cosmetic products align with established standards, contributing to consumer safety and confidence. These products are distributed through retail stores, supermarkets, beauty salons, and increasingly through online platforms. The diverse nature of the cosmetics sector in Kenya and the complexity of distribution channels utilized to bring products to consumers necessitates a comprehensive regulatory enforcement mechanism to ensure compliance.

The KEBS cosmetics standard KS 2937:2021 prescribes the general safety requirements for non-

medicated cosmetic products, emphasizing quality attributes such as pH, microbial contamination, and heavy metal limits, and in addition, the production process, packaging and labeling requirements. The cosmetics should be manufactured as per the ISO 22716:2007 GMP standard. Despite the notable regulatory efforts, there is a likelihood of proliferation of substandard cosmetics products on the market in Kenya, mainly due to the complex distribution channels and diverseness within this sector. For small capacity producers, risk factors include inadequate quality control measures, substandard manufacturing processes, and the use of unqualified product inputs and packaging materials.

The process of ensuring compliance with cosmetic regulations is a multifaceted approach, involving regulatory bodies, customs officials, law enforcement agencies, and other stakeholders. Non-compliance with established standards may lead to penalties, including product recalls and fines. Regulatory bodies, including the PPB and KEBS work closely with customs officials, law enforcement agencies, and other stakeholders to identify and address any illegal or substandard cosmetic products in circulation. This collaboration extends to both the prevention and response phases of the regulatory process.

Customs officials play a critical role in the prevention phase by scrutinizing incoming shipments of cosmetic products to ensure they comply with established regulations. They work in tandem with regulatory bodies to prevent non-compliant products from entering the market in the first place due to rampant imports. Law enforcement agencies, such as the police, collaborate with regulatory bodies in the response phase. In cases where non-compliant or substandard cosmetic products are identified in the market, these agencies may be involved in executing product recalls, conducting investigations, and imposing fines on the responsible parties. This collaboration improves efficiency in handling issues related to non-compliance and protects consumers from potential harm. Consumer feedback and complaints can be valuable sources of information for regulatory bodies, aiding in the identification of problematic products. They also engage in public awareness campaigns to educate consumers, manufacturers, and other stakeholders about the importance of using regulated and compliant cosmetic products. This helps create a more informed and vigilant consumer base. However, information concerning cosmetics consumer feedback and public awareness campaigns is scanty or not documented.

QUALITY ASSESSMENT OF COSMETIC PRODUCTS IN KENYA

As noted above, enforcement of regulatory frameworks ensure that cosmetic products comply with specified quality standards. The catalogue of East African Standards for harmonizing requirements governing quality of products and services in East Africa contains specifications for some of the cosmetics in the EA market. The KEBS continues to develop standards for cosmetic products to ensure that the cosmetics marketed in Kenya have the required identity and content. In 2020, eleven standards for cosmetics (KEBS/TC163) were developed for use by the cosmetic industry. The aim is to control critical parameters such as raw material requirements, and the level of heavy metal and microbiological contaminants. In addition, the KEBS has a list of ingredients that are prohibited in cosmetics in Kenya such as hydroquinone, mercury and its compounds. A cosmetic product must be labeled according to cosmetic labeling regulations. Often, during routine monitoring and surveillance, KEBS and PPB conduct product quality assessments to determine whether products stocked by distributors and retailers conform to standard specification in regard to the label claim and presence of prohibited ingredients. This entails physical, chemical and microbial evaluation using numerous standard testing methods.

At times, these assessments are done by PPB owing to a surge in reported cases of adverse reactions by the consumers (Barry et al., 2020). The PPB and KEBS have made provisions for approved cosmetic ingredients which manufacturers are mandated to adhere to and comply with. These provisions outline the type of ingredient, i.e. in terms of colorant, stabilizers, perfumery etc., and their permissible levels of concentration in different formulations. Should an ingredient be found to be out of the permissible concentration level, the product is recalled or withdrawn from the market and a corrective and preventive action report should be submitted to the regulatory authority by the manufacturer. For instance, in 2022, The Kenya Cosmetics Standards Body banned 131 cosmetic brands over their

contamination with mercury and hydroquinone. It is estimated that counterfeit cosmetics, or poor quality raw materials, are nearly 30% of all products, on the EA cosmetics market (Borgna, 2017). A study conducted by KEBS found that a substantial number of skin-lightening creams contained high levels of mercury, a toxic substance with adverse health effects, including damage to the kidneys and nervous system (Wanjiru, 2022). Fortunately, KEBS has been robust in nabbing and banning counterfeit products such as: skin lightening lotion, creams and gels containing hydroquinone and mercury and also, soaps containing mercury and its compounds.

CONSUMER SAFETY AND PUBLIC HEALTH IMPACT

Cosmetic product formulations range from those that contain traditional ingredients to modern skin care products developed with the intent to alter the structure and function of human skin for aesthetics purposes. Potential risks associated with the use of cosmetics products are well documented (Barbaud & Lafforgue, 2021; Pereira & Pereira, 2018). Cosmetovigilance is a part of pharmacovigilance system for cosmetics that addresses the safety of cosmetic products. Despite safety assessment measures, reported cases of adverse reactions to cosmetics do occur. The PPB has a system in place to monitor and investigate such incidents. Adverse reactions can range from mild skin irritation to severe allergic reactions. The reporting system allows consumers, healthcare professionals, and manufacturers to notify the PPB of any adverse reactions they encounter. Adverse reactions to cosmetic products, such as skin conditions and allergies, have a direct impact on public health. Hydroquinone, a skin-lightening agent, was prohibited from being used as an ingredient in cosmetic products after it was found to cause adverse effects such as skin irritation, ochronosis, and potentially carcinogenic properties (Pollock et al., 2021).

As the cosmetic industry in Kenya experiences rapid growth, it becomes imperative to assess the potential risks associated with these products and understand their broader impact on public health. The safety of cosmetic product ingredients is a primary concern. For example, skin-lightening products containing mercury have been identified as a significant risk in Kenya. Some cosmetic ingredients may have systemic effects, impacting internal organs or contributing to chronic health conditions. Also, some hair dye ingredients have been shown to potentially have systemic effects emphasizing the need for thorough safety assessments to prevent adverse health outcomes (He et al., 2022). Moreover, disposal of cosmetic products and their packaging contributes to environmental pollution. Plastics and other non-biodegradable materials in cosmetics may find their way into water bodies, affecting ecosystems and potentially harming human health through the food chain (Yuan et al., 2022). All in all, consumer risk and public health impact of cosmetic products is and can be more significant if concerned parties do not adhere to stipulated regulations.

In Kenya, the prevalence of counterfeit cosmetics, including falsified version of popular brands, has been reported (Meneses & Pereira, 2023; Mpungu, 2019). Some of these products have been reported to contain substandard or toxic ingredients, leading to adverse effects such as skin irritation, allergies, or even more severe health issues. Upon inquiry, retailers of substandard products retort that the noncompliance is caused by unawareness of ingredient requirements in cosmetic products and their potential health implications; resulting in the inadvertent use of products containing allergens or harmful substances.

The cosmetic cottage industry in Kenya, comprising small-scale and home-based producers exposes the consumer to several risks that demand careful management to ensure product safety and quality, as well as the protection of consumer well-being. These small-scale producers often grapple with some issues that pertain to manufacturing that can impact the integrity of their cosmetic products. One significant risk stems from the potential lack of robust quality control measures in small-scale operations. Limited resources may hinder the implementation of standardized processes, leading to variations in product quality and, in some cases, the production of substandard cosmetics. The absence of stringent regulatory oversight is another concern, as cottage industry producers may not be subject to the same level of scrutiny as larger manufacturers. This regulatory gap presents a potential risk to product safety and quality. Further, ingredient safety is a notable consideration, with small-scale producers possibly facing difficulties in accessing a broad range

of safe and approved cosmetic ingredients. The use of unauthorized or substandard substances is a threat to consumer health. Furthermore, inadequate labeling practices may result in insufficient information about the ingredients used in the products, limiting consumers' ability to make informed choices. Hygiene and sanitation concerns may also arise in home-based production environments, where adherence to industry standards may not be as rigorous as in larger manufacturing facilities. Poor hygiene practices and use of potable water during the manufacturing process can lead to microbial contamination, potentially causing adverse skin reactions or infections among consumers.

Packaging and labeling compliance are additional intricacies faced by cottage industry producers. Inadequate packaging may expose products to contamination, while insufficient or inaccurate labeling can fail to provide consumers with essential information about product ingredients, usage instructions, and potential allergens. Limited capability for ensuring accuracy in measurements, standard procedures and process documentation is another risk associated with small-scale operations. These producers may lack the resources for comprehensive product testing, including quality control analysis, stability testing, storage of retention samples and safety assessments. This increases the likelihood of introducing products with inadequate shelf life or potential safety risks into the market.

To address these risks, regulatory bodies such as the PPB in Kenya are obligated to play a crucial role in providing guidelines and support for small-scale cosmetic producers. Training programs, resources on GMPs, and initiatives to enhance awareness of regulatory requirements can contribute to safer cosmetic products and a more robust regulatory framework. Additionally, consumer awareness is a crucial factor in mitigating these risks. Consumers may be less informed about the potential hazards associated with products from the cottage industry. Limited awareness and education can contribute to a lack of understanding regarding the importance of using safe and regulated cosmetic products.

CHALLENGES IN REGULATORY COMPLIANCE

Cosmetic manufacturers encounter numerous obstacles when striving to comply with regulatory requirements. One significant hurdle is the complexity and variability of ingredient safety assessments. The process of identifying and evaluating the safety of cosmetic ingredients involves intricate scientific considerations, often requiring specialized knowledge. Small manufacturers, in particular, may grapple with financial and technical resources needed to conduct thorough safety assessments, leading to delays in product market entry. Furthermore, the fast-paced nature of the cosmetic industry presents a challenge in itself. Constant innovation and the introduction of new ingredients and formulations necessitate an agile regulatory approach. Manufacturers must adapt quickly to changes in regulations, and regulatory bodies need to stay abreast of emerging trends to ensure that safety standards remain effective. The failure to synchronize regulatory frameworks with industry advancements can result in outdated standards and potential safety risks for consumers. Supply chain complexities also contribute to complications in regulatory compliance for cosmetic manufacturers. The globalization of supply chains means that manufacturers source ingredients from various regions, each with its own regulatory requirements. Ensuring that every component complies with diverse international standards can be logistically impractical, particularly for smaller manufacturers with limited resources. Additionally, the issue of counterfeiting is a menace to regulatory compliance. Counterfeit cosmetics are falsified products which often infiltrate the market, bearing fake labels and are potentially harmful formulations. The clandestine nature of counterfeiting makes it difficult for regulatory bodies to trace and eradicate such products, putting consumers at risk and manufacturers who may unwittingly source counterfeit ingredients.

Despite regulatory efforts, there exist gaps in the frameworks designed to govern cosmetic products. One prominent gap lies in the regulation of unique categories of cosmetic products such as cosmeceuticals, which are intersection products between cosmetics and pharmaceuticals. These products may contain ingredients with medicinal properties but may be licensed as nontherapeutic cosmetics. In this category, only seven adverse reaction cases were reported by PPB between 2018-2023, most probably due to underreporting (PPB, 2022; PPB, 2023). Labeling requirements also

present a regulatory gap, as inconsistent standards may confuse both manufacturers and consumers. The absence of standardized international labeling conventions for cosmetic products contributes to variations in how ingredients are listed, hindering cross-border trade and consumer understanding. Manufacturers may find it difficult to comply with diverse labeling requirements, impacting their ability to access different markets seamlessly. Furthermore, the oversight of online sales of cosmetic products currently remains a regulatory nuisance due to lack of regulatory framework specific to e-sales . The rise of e-commerce has led to a proliferation of cosmetic products sold through online platforms, often operating beyond the direct reach of traditional regulatory mechanisms. Monitoring and enforcing compliance for products sold online become intricate tasks, requiring regulatory bodies to adapt and develop strategies that encompass the digital landscape. Inadequate post-market surveillance is another regulatory gap that compromises the effectiveness of cosmetic regulation. Once products enter the market, continuous monitoring is essential to identify and address any emerging safety concerns promptly. A lack of resources including trained personnel to perform post-market surveillance can result in delayed detection of adverse reactions or substandard products, prolonging potential risks to consumer health.

On a global scale, an important aspect is the need for international harmonization of cosmetic regulations. Divergence in regulatory requirements between different countries create a burdensome landscape for manufacturers seeking to enter multiple markets. International collaboration can streamline compliance processes, reduce costs for manufacturers, and enhance consumer safety by fostering consistency in safety standards. The EU regulatory framework for cosmetics serves as a benchmark for many countries by implementing a centralized system that requires cosmetic products to undergo a safety assessment by a designated responsible person before entering the market. Adopting a similar centralized approach could enhance regulatory efficiency in other regions, providing a standardized method for ensuring product safety. Moreover, the EU has banned the use of certain ingredients in cosmetics, setting a precedent for proactive risk management. Emulating such measures can help regulators anticipate potential risks associated with specific ingredients and take preventive actions, reinforcing consumer protection. In the realm of ingredient transparency, the US requires cosmetic manufacturers to comply with the Federal Food, Drug, and Cosmetic Act (FD&C Act), mandating the disclosure of ingredients on product labels. Implementing similar transparency requirements globally could empower consumers to make informed choices while encouraging manufacturers to uphold high safety standards.

CONCLUSION

The cosmetic industry in Kenya has seen substantial growth due to urbanization, an expanding middle class, heightened grooming awareness and COVID-19 pandemic disruptions. The regulatory framework involves PPB, KEBS and PVoC, yet enforcement and harmonization with international standards remain problematic. The quality and safety assessment process by KEBS and PPB covers ingredients, formulations, packaging, and labeling. Very few incidences of adverse reactions were reported by PPB. However, market surveillance reports raise concerns about the public health impact, with skin-lightening products containing mercury and counterfeit cosmetics being prominent risks. Also, products from the cosmetic cottage industry and home based producers can inadvertently pose a risk to consumers due to the potential lack of a robust process and quality control system. Regulatory gaps such as limitations on importation of certain products caused by divergence in regulatory requirements between different countries. Inconsistent labeling requirements is also an impediment for distributors and manufacturers. Addressing these problems necessitates a comprehensive approach, including periodic reviews of approved ingredients and centralized approval system. Industry collaboration through continuous dialogue and advisory boards, coupled with transparent communication channels, can enhance compliance. Consumer education initiatives on label reading, counterfeit awareness, adverse effects reporting and digital platforms to empower consumers and contribute to a safer marketplace.

RECOMMENDATIONS

Based on the above discussion and inferred conclusion this study proposes these recommendations. Firstly, it advocates for the enhancement of collaboration between the PPB and KEBS in the realm of market surveillance. This partnership will ensure a more robust and coordinated approach to identifying and addressing potential risks associated with substandard products, counterfeits and products containing prohibited and restricted ingredients. This collaborative reinforcement aims to elevate the effectiveness of market surveillance, ultimately safeguarding public health.

Secondly, the study recommends the development and implementation of comprehensive guidelines for manufacturing and testing within the cosmetic cottage industry. Recognizing the unique impediments to compliance by smaller producers, these guidelines would serve as a tailored framework, encompassing realistic regulations and standards. Additionally, the study suggests the provision of training and support programs to enhance compliance among cottage industry and home-based producers, promoting the production of safe and quality cosmetic products.

Lastly, the study advocates for consumer education initiatives to empower individuals in making informed choices. The recommendations include training of consumers on label reading, counterfeit awareness, and understanding the potential risks associated with specific cosmetic ingredients and adverse effects reporting. Leveraging digital platforms is proposed as a means to disseminate this information widely, fostering a well-informed consumer base and contributing to a safer and more transparent cosmetic marketplace in Kenya.

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