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Review Article

Cosmetovigilance: Emerging safety trends

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ABSTRACT

The article offers an extensive evaluation of cosmetovigilance and its pivotal contribution to ensuring the safety and integrity of cosmetic products. It delves into the multifaceted cosmetics industry, encompassing segments like cosmeceuticals, nutricosmetics, and cosmetic devices, each tailored to enhance personal care. In addition to unveiling the details of cosmetovigilance, this article sheds light on a pressing concern – counterfeit beauty products. It underscores the hazards lurking within these deceptive imitations, emphasizing the necessity of consumer awareness and vigilance. The article equips readers with practical strategies to navigate the intricate landscape of cosmetics, evade harmful chemicals, and protect their well-being.

Above all, this article underscores the profound significance of cosmetovigilance as the sentinel of product safety and consumer welfare. It offers insights into the latest industry trends, regulatory adaptations, and the responsibilities entailed in reporting adverse events. Serving as an enduring reminder, it reinforces the enduring necessity for unwavering vigilance in the realm of cosmetics.

1. Introduction

Cosmetovigilance is a term that defines the surveillance activities carried out by the national competent authorities/health authorities and cosmetic industry bodies or manufacturers to address the safety of cosmetic products, like how pharmacovigilance focuses on the monitoring and understanding of adverse reactions associated with medications and pharmaceutical products.[1]

Cosmetics, as defined by the Federal Food, Drug, and Cosmetic (FD&C) Act, encompass a wide range of articles intended for application to the human body to enhance appearance, promote attractiveness, or alter physical appearance.[1]

In addition to cosmetics, there are other related categories that are worth mentioning. *Cosmeceuticals* are products that possess both cosmetic and therapeutic effects, targeting skin health and beauty. These products contain active ingredients that can influence the functioning of skin cells. Examples of cosmeceuticals include skin lightening agents, sunscreens, moisturizers, and anti-wrinkle/aging creams.[2]

Nutricosmetics, on the other hand, are dietary supplements consumed orally with the aim of improving the health and appearance of specific body parts. These supplements contain nutrients such as vitamins, minerals, amino acids, antioxidants, and other compounds that contribute to maintaining the body's health and beauty. Nutricosmetics can be classified as oral nutricosmetics, which are ingested as pills for anti-aging and skincare purposes, and drinkable nutricosmetics, which come in liquid form or are added to products like yogurts to enhance skincare and overall body health.[3,4]

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Cosmetic devices, also known as aesthetic devices, are used in cosmetic procedures for beautification purposes. This category includes aesthetic fillers and implants that are employed to enhance various aspects of appearance.

The field of cosmetics and personal care products can be further subdivided into categories such as oral care, skincare, sun care, hair care, decorative cosmetics, body care, and perfumes. Each category serves specific purposes in enhancing beauty and personal care.[5]

2. Materials and Methods

A systematic approach was employed to gather information and analyze it to identify emerging patterns in cosmetovigilance. The following steps were undertaken:

Literature search: A comprehensive search was conducted to identify relevant research articles, review articles, regulatory documents, guidelines, and other online resources related to cosmetovigilance. Databases, such as PubMed, Google Scholar, and regulatory agency websites, were utilized to obtain a wide range of scholarly and authoritative sources.

Data extraction and analysis: The selected publications, articles, and reports were meticulously reviewed and analyzed. The content of each source was carefully examined to extract pertinent information, including statistical data, case studies, adverse event reports, regulatory updates, and emerging concerns. Comparative analysis was performed to identify commonalities, discrepancies, and emerging trends within the collected data.

Data validation: To ensure accuracy and reliability, a rigorous process of cross-referencing and verification was employed. The extracted information was validated by comparing it with multiple sources and corroborating it with established scientific knowledge and regulatory guidelines in cosmetovigilance.

Pattern identification: The validated information was further analyzed to identify emerging patterns in cosmetovigilance. This involved scrutinizing the data for recurring adverse reactions/undesirable effects, safety concerns, emerging risks, and regulatory gaps. Patterns were recognized through the observation of consistent trends or associations within the collected data.

Documentation: The findings obtained from the analysis were carefully documented, including the identified patterns, relevant statistical data, and supporting evidence. The documentation served as a comprehensive record of the study's results, allowing for transparency, reproducibility, and future reference.

This systematic procedure ensured a thorough examination of the available literature and online resources related to cosmetovigilance. The careful analysis of collected information facilitated the identification of emerging patterns, thereby contributing to the understanding and improvement of cosmetovigilance practices.

3. Cosmetovigilance: Need of the Hour

In today's fast-paced world, the cosmetics industry stands at a unique juncture of innovation, diversity, and increasing consumer demand. With a constant stream of novel products and evolving consumer preferences, the realm of beauty and personal care has never been more dynamic. Yet, within this dynamic landscape, the obligation for cosmetovigilance emerges as a cornerstone of responsible product stewardship. Cosmetovigilance, at its core, represents the vigilant surveillance and monitoring of adverse events and potential risks associated with cosmetic products. In this section, we delve into the pivotal practice of cosmetovigilance, unravelling the multifaceted factors that underscore its necessity in the modern era.

Several key factors converge to emphasize the pressing need for cosmetovigilance in today's landscape:

3.1. Consumer safety and adverse reactions

Consumer safety stands as the foremost motivation behind cosmetovigilance. Cosmetic products intimately interact with the skin, hair, nails, and various body areas. Although most cosmetics maintain a high safety standard, the potential for adverse reactions and other safety issues exists. Cosmetovigilance plays a pivotal role by systematically gathering and scrutinizing data on adverse reactions, discerning patterns, evaluating the seriousness and frequency of incidents, and uncovering underlying causes. This meticulous analysis serves to enhance product safety and pre-emptively mitigate risks, ultimately safeguarding consumers from potential harm.

3.2. Regulatory compliance

Regulatory authorities enforce safety standards and regulations to protect consumers. Cosmetovigilance data is crucial for assessing compliance with these regulations, identifying gaps, and taking appropriate actions to ensure that cosmetic products meet the required safety standards. It helps in developing and updating regulations to address emerging risks.

3.3. Rapidly evolving industry

The cosmetic industry is dynamic, with new ingredients, formulations, and products constantly being introduced. Cosmetovigilance is necessary to keep up with these changes and assess the safety of new ingredients and products before they are marketed; it helps identify potential risks associated with emerging trends or innovations in the cosmetic industry.

3.4. Scientific advancements and research

Ongoing scientific research and advancements in dermatology, toxicology, and other related fields contribute to the need for cosmetovigilance. New findings, studies, and evidence regarding the safety and efficacy of cosmetic ingredients or products may necessitate the monitoring and evaluation of their impact on consumer health. Cosmetovigilance ensures that scientific knowledge is translated into practical measures for consumer safety.

3.5. Global market and supply chains

Cosmetics are often produced and distributed on a global scale, with ingredients sourced from various regions. Cosmetovigilance ensures that potential risks associated with cosmetics are monitored throughout the entire supply chain, including the identification of unsafe ingredients, detection of counterfeit products, and addressing safety concerns related to manufacturing, packaging, or distribution processes.

3.6. Public awareness and consumer expectations

Increasing consumer awareness and concerns about product safety have also fueled the need for cosmetovigilance. Consumers expect transparency, accurate labeling, and safe products. Monitoring adverse events and implementing measures to ensure safety help build consumer trust in cosmetic products and the industry.

4. Safety Recalls in the Cosmetics Industry

The safety and efficacy of cosmetic products are paramount to the well-being of consumers worldwide. To uphold these standards, regulatory agencies such as the Food and Drug Administration (FDA) in the United States of America (USA) and the European Medicines Agency (EMA) in Europe play pivotal roles in monitoring, assessing, and when necessary, recalling cosmetic products. In recent years, these agencies have undertaken several recalls, significantly impacting the cosmetics industry and consumer safety.

This comprehensive evaluation delves into the notable cosmetic product recalls initiated by the FDA and EMA, shedding light on both the products affected and the compelling reasons that necessitated these recalls. These cases are characteristic of the vigilant oversight exercised by regulatory authorities to ensure that cosmetics meet stringent safety and quality standards.

4.1. Asbestos contamination (FDA)

4.1.1. Recalled product

Talc-based powders and cosmetics

4.1.2. Reason for recall

Asbestos contamination poses a significant health risk as it is a known carcinogen when inhaled. Cosmetic products contaminated with asbestos can lead to long-term health issues, including lung cancer and mesothelioma.[6]

4.2. Microbial contamination (FDA and EMA)

4.2.1. Recalled products

Various cosmetics, including creams, lotions, and skincare products.

4.2.2. Reason for recall

Microbial contamination can result in skin infections and other health issues when applied to the skin. The recall aims to prevent consumer harm and ensure product safety.[7–9]

4.3. Allergic reactions (FDA)

4.3.1. Recalled product

Certain cosmetic products, such as face creams and serums.

4.3.2. Reason for recall

Reports of severe allergic reactions, including redness, swelling, and itching, prompted these recalls. Allergic reactions can lead to discomfort and may necessitate medical treatment.[10]

4.4. Unsafe ingredients (FDA and EMA)

4.4.1. Recalled products

Cosmetic products containing unsafe levels of heavy metals or prohibited substances.

4.4.2. Reason for recall

Heavy metals like lead or mercury in cosmetics can accumulate in the body over time, leading to health issues such as neurological damage and developmental problems.[11–15]

4.5. Mislabelling or misbranding (FDA and EMA)

4.5.1. Recalled products

Cosmetics that falsely claimed to be "natural" or "organic" while containing synthetic ingredients.

4.5.2. Reason for recall

Misleading labeling can misinform consumers and lead them to believe they are using safer or more natural products than they actually are. The recalls aim to enforce accurate product labeling and prevent consumer deception.

4.6. Counterfeit beauty products (FDA and EMA)

4.6.1. Recalled products

Imitation cosmetics bearing counterfeit branding and packaging.

4.6.2. Reason for recall

Counterfeit cosmetics often contain unknown and potentially harmful ingredients, posing serious health risks to consumers. Regulatory agencies take action to protect consumers from these fraudulent products.[16–18]

4.7. Quality control and batch testing issues (FDA and EMA)

4.7.1. Recalled products

Various cosmetic products, including skincare and haircare items.

4.7.2. Reason for recall

Recalls may occur when specific batches of cosmetic products fail quality control tests, or deviations from established quality standards are identified. These measures ensure that only safe and effective products reach consumers.

5. Diving Deep: The Ever-Present Challenge of Chemicals in Cosmetics

Cosmetics, an integral part of our daily routines, contribute to our sense of well-being, self-expression, and personal grooming. These products are formulated to enhance our appearance and boost our confidence. However, beneath the appeal of the beauty industry lies a complex world of chemicals and ingredients, some of which can have significant implications for our health.

While most cosmetics are rigorously tested and proven safe for use, a subset of these products contains chemicals and harmful agents that can potentially impact our health. In this section, we delve into the realm of cosmetics and their ingredients, shedding light on the various chemicals and agents that have raised concerns in recent years.

5.1. Sulfates

Sulfates, which are formed through the reaction of sulphuric acid (H_2SO_4) with other substances, can be derived from petroleum or plant sources such as coconut and palm oil. These salts are commonly used as surfactants in cosmetics to create lather. However, sulfates can cause irritation to the skin and eyes, prematurely fade hair dye, and pose a toxic threat to aquatic life when washed away.[19–21]

5.2. Parabens

Parabens are preservatives used to maintain the freshness and hygiene of skincare and makeup products. They can be found in various items such as soaps, lotions, and cosmetics. Studies have indicated that parabens can increase estrogen production and interfere with reproductive and brain functions. Some research suggests that parabens can penetrate the skin and mimic estrogen, leading to excessive cell division in breast tissue and ultimately contributing to the development of breast cancer.[14,22]

5.3. Phthalates

Phthalates are chemicals used to enhance the spreadability of cosmetic products and are commonly found in items like nail polishes, perfumes, and lotions. Additionally, they serve as softeners in shampoos. However, phthalates are known to be reproductive and developmental toxins.[23]

5.4. Triclosan

Triclosan is a common chemical found in antibacterial soaps, and deodorants. While it is effective against microbes, it is also an endocrine disruptor and can cause skin irritation. Some studies have reported that triclosan can lead to gut inflammation and tumor growth in mammals. Due to its slow breakdown, triclosan poses a potential threat to the environment and can be harmful to aquatic life, like sulfates.[24]

5.5. Toluene

Toluene, a petrochemical solvent, is commonly found in hair dyes and nail polish. It can have adverse effects on the immune system and carries a risk of birth defects and blood cancer. Pregnant women are advised to avoid using hair dyes and nail polish containing toluene, as it can harm the developing fetus. Toluene can also affect the central nervous system, leading to symptoms such as fatigue, headaches, nausea, and drowsiness.[19,21,23]

5.6. Talc

Talc is often used to absorb moisture and is found in products like baby powders, eye shadows, blushes, deodorants, and certain soaps. However, talc has been directly linked to ovarian cancer. Inhalation of talc can also cause lung tumors.[6]

5.7. Lead

Lead is a heavy metal present in lipsticks, eyeliners, foundations, and whitening toothpastes. Although lead is not directly added to lipsticks, it is a significant contaminant in the colorants used. Since lead is naturally found in the earth's crust and humans are already exposed to it

through air, food, and water, regulatory bodies such as the U.S. FDA allow its presence in cosmetics within a range of 0 to 20 parts-per-million (ppm). Lead ingestion or absorption through cosmetics can have detrimental effects on health.[11,12,15]

5.8. Polyethylene glycol (PEG)

PEG is commonly used as a thickening agent in skincare products like lotions, sunscreens, and shampoos. However, it has the potential to cause cancer and respiratory disorders. PEG can also strip the natural oils (sebum) from the skin, triggering the sebaceous glands to produce excessive sebum, resulting in greasy skin.[14]

5.9. Formaldehyde

Formaldehyde is a colorless gas often used as a preservative in skincare products. It helps prevent bacterial growth and can be found in items such as nail polishes, hair straightening treatments, hair gels, nail hardeners, shampoos, deodorants, lotions, and makeup. Formaldehyde has been associated with developmental toxins, hair loss, scalp burns, asthma, and neurotoxicity. Inhalation of formaldehyde can cause dizziness and suffocation.[1,25–28]

5.10. Diethanolamine

Diethanolamine is a foaming agent commonly present in body washes, shampoos, cleansers, and bubble baths. It is classified as a cancer-causing agent and a respiratory toxin.[10,19,29]

5.11. Alcohol

Alcohol is frequently used as a solvent in skincare products. While it aids in product absorption and is suitable for certain creams and lotions, alcohol can be harmful to the skin. Drying alcohol can leave the skin dry and flaky, disrupting the skin renewal process.[30]

5.12. Hydroquinone

Hydroquinone is utilized in skincare products for its skin lightening properties, targeting pigmentation issues such as acne scars, freckles, melasma, age spots, and post-inflammatory hyperpigmentation. However, hydroquinone is a known carcinogen. Prolonged use can result in skin whitening as it significantly reduces melanocytes, the cells responsible for producing melanin.[31]

5.13. Petrolatum

Petrolatum is known for its softening effect and is commonly found in lip balms and moisturizers, recommended for dry skin. While it forms a barrier to prevent water loss, it also hinders the absorption of moisture from the air. This can lead to dry skin, necessitating frequent lip balm reapplication. Furthermore, if not refined properly, petrolatum may retain harmful chemicals like polycyclic aromatic hydrocarbons (PAHs).[14,32]

5.14. Synthetic colors

Synthetic colors, derived from petroleum or coal tar, are used in cosmetics, particularly lipsticks, where the concentration of coal tar can be higher. These colors have been linked to skin irritations, cancers, acne breakouts, and even attention deficit hyperactivity disorder (ADHD).[21]

5.15. Fragrance

Fragrances are present in skincare products such as perfumes, moisturizers, shampoos, cleansers, and conditioners. These fragrances are composed of chemicals that have been associated with respiratory disorders, skin allergies, dermatitis, and adverse effects on the reproductive system. The lack of regulations requiring manufacturers to disclose the ingredients used in fragrances makes them potential carcinogens, irritants, and endocrine disruptors.[14]

6. Counterfeit Cosmetics and Safety Risks

Counterfeit cosmetics are fraudulent or imitation beauty products that are designed to mimic genuine and reputable brands. These counterfeit products are often produced and distributed without the authorization or approval of the original brand or regulatory authorities. They are sold with the intent to deceive consumers into believing they are purchasing legitimate and safe cosmetics.

The problem of counterfeit cosmetics has grown significantly in recent years, and it poses several substantial challenges:

6.1. Safety concerns

Counterfeit cosmetics often contain harmful and undisclosed ingredients. These substances can range from toxic heavy metals like lead and mercury to harmful allergens and microbial contaminants. The use of such products can lead to serious health issues, including skin reactions, allergies, infections, and even long-term health risks like organ damage or cancer.

6.2. Consumer deception

Counterfeit cosmetics are packaged to closely resemble genuine products, making it difficult for consumers to distinguish between real and fake items. Consumers may inadvertently purchase counterfeit cosmetics, believing they are buying genuine, safe products.

6.3. Economic impact

Counterfeit cosmetics can cause financial losses for legitimate cosmetic brands. They erode the market share of authentic products, leading to reduced revenues and profitability for genuine manufacturers.

6.4. Regulatory challenges

Regulatory bodies and law enforcement agencies face challenges in tracking and prosecuting those involved in the production and distribution of counterfeit cosmetics, often due to the global nature of the counterfeit cosmetics trade.

6.5. Consumer health risks

The use of counterfeit cosmetics can lead to adverse health effects, which can strain healthcare resources and have long-term implications for public health.

The extent of the counterfeit cosmetics problem varies by region and market, but it is a significant and growing issue globally. Counterfeit cosmetics can be found in physical retail stores, as well as online marketplaces, making them easily accessible to consumers. To combat this issue, regulatory authorities, brand owners, and consumers must work together to raise awareness, enhance product authentication measures, and enforce strict penalties for those involved in the production and distribution of counterfeit cosmetics.

This section reveals the danger of counterfeit cosmetics, filled with undisclosed and unregulated chemicals. From toxic heavy metals to allergens, we unveil the risks these hidden chemicals pose to health.[16–18]

6.6. Lead

One of the more common ingredients found in counterfeit cosmetics at 5 to 19 times above the legal level. Health effects are reported to be human developmental toxicity, reproductive issues, and organ system toxicity within the kidneys, liver, sensory organs, and the cardiovascular system.[11–15]

6.7. Arsenic

This dangerous ingredient can show up due to the contamination of other ingredients if not added directly. This used to be a common ingredient in cosmetics in the 1800s. Health effects are reported to be organ toxicity and bioaccumulation, which means arsenic can build up to dangerous levels over time. Concerns are especially high for pregnant women or breastfeeding moms. This product leads to cancer at the highest level.[13,33]

6.8. Copper

Classified as toxic or harmful by the Environment Canada Domestic Substance List. Persistence and bioaccumulation with enhanced skin absorption of other chemicals.[13]

6.9. Mercury

Mercury is a possible human development toxicant, can lead to nervous system toxicity, as well as immune and respiratory toxicity. This is recognized by many institutions as a toxic chemical. Mercury is particularly hazardous during fetal development and is readily absorbed by the skin. The presence of mercury in any cosmetic is a concern and should not be treated lightly.[13,14]

6.10. Beryllium

A heavy metal that hasn't been the subject of extensive research but has been found in counterfeit cosmetic products. Suspected areas of health concen[13] are in reproductive, immune, and nervous systems where it can cause toxicity.[13]

6.11. Cadmium

Cadmium is toxic in moderate doses and is a potent antagonist of several essential minerals including calcium, iron, copper, and zinc.[13]

6.12. Aluminum

Aluminum-based compounds vary in their toxicity. Some are linked to neurotoxicity, developmental & reproductive toxicity, and cancer. To find the effects of aluminum in your cosmetics, you need to find the specific type of aluminum and the concentration level.[13]

6.13. Microbial Contamination - Bacteria

Different kinds of bacteria have been found in counterfeit cosmetics and they are causing infections, skin rashes, and allergic reactions. One more common type of bacteria that has been found in counterfeit cosmetics is E. Coli (Escherichia coli) which can cause severe diarrhea, kidney failure, and anemia.[7–9]

7. Guidelines to Safeguard Yourself from Harmful Chemicals

1. *Review product labels:* Before purchasing skincare products, always take the time to read and examine the labels. Pay attention to the listed ingredients and remain cautious of any potentially harmful chemicals.
2. *Avoid sulfates:* Be on the lookout for sulfates such as SLS (sodium lauryl sulfate) and SLES (sodium laureth sulfate) in shampoos and other personal care items.

These substances can be harsh on the skin and strip away natural oils.

3. *Exercise caution with parabens:* Chemicals like methyl, butyl, and propyl parabens are commonly used as preservatives in cosmetics. Due to potential health concerns, it's advisable to avoid products containing these ingredients.
4. *Be wary of toluene:* Toluene is often listed under alternative names such as benzene, phenylmethane, toluol, or methylbenzene. As a solvent, it can be harmful, so it's best to steer clear of products that include it.
5. *Stay alert to PEGs:* Polyethylene glycols (PEGs) are often identified by numerical values like 100, 120, 14M, 30, 32, 40, 75, and so on. These ingredients can potentially cause irritation, so it's wise to avoid them.
6. *Watch out for formaldehyde:* Skincare products may contain formaldehyde, which might be listed as formalin, formaldehyde, glyoxal, or bronopol. These ingredients indicate the presence of a known irritant and allergen.
7. *Avoid DEA:* Diethanolamine (DEA) is frequently utilized in cosmetic products, but it's best to avoid it as it can cause skin and eye irritation.
8. *Steer clear of drying alcohols:* Ingredients like ethanol, methanol, denatured alcohol, and ethyl alcohol are drying alcohols that can strip moisture from the skin. It's better to choose products without these ingredients, particularly if you have dry or sensitive skin.
9. *Be cautious of petrolatum ingredients:* Petrolatum ingredients encompass mineral oil, benzene, paraffin wax, and compounds ending in "-eth." These ingredients have the potential to clog pores and suffocate the skin, so it's advisable to opt for products without them.
10. *Avoid artificial colours:* Be mindful of ingredients labelled as FD&C (food, drug, and cosmetic) or D&C (drugs and cosmetics) since these indicate the presence of artificial colours. Sometimes, these colours can cause skin sensitivities or allergies.
11. *Select transparent brands:* Look for beauty brands that prioritize transparency and openly disclose all their ingredients. This allows you to make informed decisions about the products you choose to use.
12. *Consider natural brands:* Explore the option of using natural beauty brands that not only avoid harmful chemicals but also incorporate powerful and beneficial ingredients derived from plants. However, keep in mind that natural ingredients can still cause skin irritation in some individuals, so it's crucial to be aware of your own sensitivities and allergies.

By adhering to these procedures, you can enhance your knowledge regarding the components present in your skincare products and make decisions that prioritize your overall health and well-being.

Simplify choose for products that have simpler ingredient lists and avoid those that contain undisclosed "fragrance" ingredients. Be cautious of products labeled with "fragrance" or "parfum" as they may contain various ingredients associated with potential health risks. Instead, support companies that willingly disclose their fragrance ingredients.

Scrutinize Ingredient labels given the limited regulations in the beauty industry, it's essential to conduct your own research to identify the safest products. Claims such as "pure," "natural," or "organic" lack legal standards for personal care items. Therefore, it's important to look beyond marketing tactics and carefully read ingredient labels.

8. Navigating Evolving Cosmetics Safety Regulations

8.1. FDA: MoCRA: A Comprehensive overview

The Modernization of Cosmetics Regulation Act of 2022 (MoCRA) signifies a significant expansion of the FDA's regulatory authority, surpassing the provisions of the Federal Food, Drug, and Cosmetic (FD&C) Act of 1938. This newly enacted legislation is geared towards enhancing the safety of everyday cosmetic products widely used by consumers.

8.1.1. Key provisions of MoCRA include

1. *Records Access:* Under certain conditions, the FDA is empowered to access and make copies of specific records related to a cosmetic product, including safety records.
2. *Mandatory Recall Authority:* In cases where the FDA determines that a cosmetic product is adulterated or misbranded and its use poses a substantial risk of severe health consequences or even death, the agency can enforce a mandatory recall if the responsible party refuses voluntary compliance.

Additional Requirements Introduced by MoCRA for the Cosmetic Industry:

1. *Undesirable Effects Reporting:* Manufacturers or responsible parties are obliged to promptly report any Serious Undesirable Effects (SUE) associated with cosmetic products used in the United States to the FDA within 15 business days of receiving the report. Furthermore, they must provide additional information, including new medical findings, within one year of the initial report. The FDA will have access to these reports during inspections.
2. *Facility Registration:* Manufacturers and processors must register their facilities with the FDA and renew their registration every two years. The FDA has the authority to suspend the registration of a facility if it

determines that a cosmetic product manufactured or processed by that facility, and distributed within the United States, has a reasonable probability of causing serious adverse health consequences or death. This suspension prevents the distribution, sale, introduction, or delivery of cosmetic products from that facility within the United States.

3. *Product Listing:* Responsible parties must provide a comprehensive listing of each cosmetic product marketed in the United States, including a detailed list of ingredients. Updates to this listing must be submitted annually.
4. *Safety Substantiation:* Responsible parties must maintain records substantiating the safety of their cosmetic products.

Furthermore, MoCRA necessitates strict adherence to FDA regulations in the following areas:

5. *Good Manufacturing Practice (GMP) Requirements:* Facilities engaged in the manufacture of cosmetic products must adhere to GMP standards.
6. *Fragrance Allergen Labeling:* Compliance with fragrance allergen labeling requirements is mandatory.
7. *Asbestos Detection:* The act mandates the implementation of standardized testing methods for the detection and identification of asbestos in talc-containing cosmetic products.

When Should Undesirable Effects (UEs) be Reported?

For Fatal or Life-Threatening Undesirable Effects

Rapid reporting to the regulatory authority is mandatory.

Notification should occur as soon as possible, within 7 calendar days after first knowledge, utilizing methods such as telephone, facsimile transmission, email, or written communication.

Additionally, the Undesirable Cosmetic Effect Report Form should be completed within the subsequent 8 calendar days, accompanied by any requested information.

For Other Serious Undesirable Effects

Events that are not fatal or life-threatening should be reported promptly.

Notification should take place as soon as possible but no later than 15 calendar days after initial knowledge.

The MoCRA represents a pivotal step in ensuring the safety and integrity of cosmetic products, underscoring the importance of industry compliance and vigilance in safeguarding consumer health and well-being.

8.2. European cosmetic regulations: A comprehensive overview

Europe, a significant player in the cosmetics industry, has instituted Regulation (EC) No 1223/2009 of the European Parliament and of the Council, a multifaceted legislation enacted on 30 November 2009. This regulation serves as a cornerstone in harmonizing the cosmetics market within the European Union (EU) while prioritizing human health and environmental protection.

The objectives of this regulation are manifold, encompassing aspects crucial to both consumers and industry stakeholders. First and foremost, it is dedicated to enhancing the safety of cosmetic products available in the EU by enforcing rigorous safety standards. This prioritization of safety safeguards consumers from potential harm arising from product usage.

Beyond safety, the regulation seeks to streamline processes for companies operating within the cosmetics industry. By harmonizing regulations and procedures, it facilitates the seamless circulation of cosmetic products within the single market. This not only benefits manufacturers but also ensures a consistent quality standard for consumers across the EU.

Moreover, the regulation is forward-looking, incorporating the latest technological and scientific advancements. It embraces the potential utilization of nanomaterials, reflecting the ever-evolving nature of cosmetic ingredients and their impact on consumer well-being.

Perhaps one of the most notable and ethically progressive aspects of Regulation (EC) No 1223/2009 is its unequivocal prohibition of animal testing. This commitment to cruelty-free practices aligns with evolving societal values and reflects a conscientious approach to product development.

8.2.1. Key takeaways from european cosmetic regulations

1. *Cosmetic Product Safety Report (CPSR):* A cornerstone of the regulation is the requirement for all cosmetic products to undergo a rigorous assessment, resulting in the creation of a Cosmetic Product Safety Report (CPSR). This report, divided into two sections, contains comprehensive information about the cosmetic product, its composition, stability, and potential risks. Notably, the CPSR is an ever-evolving document, necessitating updates to incorporate emerging information and regulatory changes. Furthermore, it forms an integral part of the Product Information File (PIF), a dossier that must be retained for a decade from the final batch's introduction to the market.
2. *The Responsible Person:* Selling cosmetic products within the EU is contingent upon designating a 'responsible person.' This individual, whether natural or legal, residing in the Union, assumes the crucial responsibility of ensuring that the product complies with all safety standards outlined in Regulation (EC) No 1223/2009.
3. *Cosmetic Products Notification Portal:* Simplifying the administrative landscape, the regulation mandates the registration of all cosmetic products only once in the Cosmetic Products Notification Portal of the EU,

streamlining the regulatory process for market access.

4. *Serious Undesirable Effects (SUE) Reporting:* The regulation introduces a pivotal obligation to report Serious Undesirable Effects (SUEs). These effects encompass adverse reactions resulting from the typical or reasonably foreseeable use of a cosmetic product and include serious outcomes. Reporting of SUEs must occur within a strict timeframe, and responsible persons and distributors bear the responsibility of notifying national competent authorities. The sharing of such information among EU Member States is also mandated to facilitate a robust safety network.
5. *Packaging and Labeling:* Cosmetic product packaging is required to convey essential information, including the responsible person's identity, product contents, usage precautions, and a comprehensive list of ingredients. The labeling information must provide ingredient lists using common names to enhance transparency.

9. Conclusions

The field of cosmetics and personal care products has gained significant attention in recent years due to concerns about the safety of various ingredients and the proliferation of counterfeit products. The practice of cosmetovigilance, which involves the surveillance and monitoring of cosmetic products, has become increasingly important to ensure the safety and well-being of consumers.

This article has highlighted the negative impact of chemicals commonly found in cosmetics, such as sulfates, parabens, phthalates, synthetic colors, fragrances, triclosan, toluene, talc, lead, and others. These substances have been linked to various health issues, including skin irritation, hormonal disruption, reproductive and developmental toxicity, and even cancer and the presence of these harmful chemicals emphasizes the need for robust cosmetovigilance practices to detect and address potential risks associated with cosmetic products.

Furthermore, the article shed light on the alarming prevalence of counterfeit beauty products in the market. Counterfeit cosmetics pose significant safety risks as they often contain high levels of toxic substances such as lead, arsenic, mercury, and microbial contaminants. The consumption or use of counterfeit products can lead to serious health consequences, ranging from organ toxicity to cancer.

To protect themselves from these risks, consumers are advised to read product labels, avoid sulfates and parabens, be cautious of toluene, and stay vigilant against counterfeit products. By being informed and making conscious choices, consumers can prioritize their health and safety when it comes to cosmetic products.

Overall, the importance of cosmetovigilance cannot be overstated. Regulatory bodies, industry stakeholders, and consumers must work together to ensure the safety and integrity of cosmetic products. Continued research, stringent regulations, and public awareness are essential in safeguarding consumer well-being and promoting a healthy cosmetics industry.

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11. Conflict of Interest

None.

References

1. Vigan M, Castelain F. Cosmetovigilance: Definition, regulation and use "in practice. *Eur J Dermatol*. 2014;24(6):643–9.
2. Choi CM, Berson DS. Cosmeceuticals. *Seminars Cutaneous Med Surg*. 2006;25:163–8.
3. Dini I, Laneri S. Nutricosmetics: A brief overview. *Phytotherapy Res*. 2019;33(12):3054–63.
4. Nutricosmetics: Feeding the Skin; 2009. Available from: https://www.cosmeticsandtoiletries.com/research/tech-transfer/article/21834308/nutricosmetics-feeding-the-skin.
5. Tosti A, Guerra L, Vincenzi C, Piraccini BM, Peluso AM. Contact sensitization caused by toluene sulfonamide-formaldehyde resin in women who use nail cosmetics. *Dermatitis*. 1993;4(3):150–3.
6. Stoiber T, Fitzgerald S, Leiba NS. Asbestos contamination in talc-based cosmetics: An invisible cancer risk. *Environ Health Insights*. 2020;14:1178630220976558. doi:10.1177/1178630220976558.
7. Michalek I, John S, Santos F. Microbiological contamination of cosmetic products - observations from Europe. *J Eur Acad Dermatol Venereol*. 2005;33(11):2151–7.
8. Neza E, Centini M. Microbiologically contaminated and over-preserved cosmetic products according Rapex. *Cosmetics*. 2008;3(1):1–3. doi:10.3390/cosmetics3010003.
9. Wong S, Street D, Delgado SI, Klontz KC. Recalls of foods and cosmetics due to microbial contamination reported to the U.S. Food and Drug Administration. *J Food Prot*. 2000;63(8):1113–6.
10. Mertens S, Gilissen L, Goossens A. Allergic contact dermatitis caused by cocamide diethanolamine. *Contact Dermatitis*. 2016;75(1):20–4.
11. Al-Saleh I, Al-Enazi S, Shinwari N. Assessment of lead in cosmetic products. *Regul Toxicol Pharmacol*. 2009;54(2):105–13.
12. Ayenimo J, Yusuf A, Doherty WO, Ogunkunle OA. Iron, lead, and nickel in selected consumer products in Nigeria: A potential public health concern. *Toxicol Environ Chem*. 2010;92(1):51–9.
13. Brzóska MM, Sidorczuk MG, Borowska S. Metals in Cosmetics. *Metal Aller*. 2018;p. 177–96. doi:10.1007/978-3-319-58503-1_15.
14. Khan AD, Alam MN. Cosmetics and their associated adverse effects: A review. *J Appl Pharm Sci Res*. 2019;2(1):1–6.
15. Castiglioni ET, Barhoumi R, Mouneimne Y. Kohl and Surma eye cosmetics as significant sources of lead (PB) exposure. *J Local and Glob Health Sci*. 2012;12(1). doi:10.5339/jlghs.2012.1.
16. Morse BL, Repsha CL. Pretty poisonous: How counterfeit cosmetics can be toxic to student skin. *NASN School Nurse*. 2020;36(1):58–61.
17. Odiboh O, Olabanjo J, Ekanem T, Oyedepo T. Curbing counterfeiting and piracy with public relations tools: The case of Nigeria's beauty and cosmetics industry. *J Afr Res Business Technol*. 2022;p. 1–16. doi:10.5171/2022.651081.
18. Sachs R. Fake' makeup isn't so pretty: Revising the vicarious liability standard for consumers injured by counterfeit cosmetics. *SSRN Electronic J*. 2019;Available from: https://papers.ssrn.com/sol3/papers.cfm?abstract_id=3519965.
19. Alessandrini A, Piraccini B. Essential of hair care cosmetics. *Cosmetics*. 2016;3(4):34. doi:10.3390/cosmetics3040034.

20. Fiume M, Bergfeld WF, Belsito DV, Klaassen CD, Marks JG, Shank RC, et al. Final report on the safety assessment of sodium Cetearyl sulfate and related alkyl sulfates as used in cosmetics. *Int J Toxicol*. 2010;29(3):115–32.
21. Guerra E, Llompart M, Jares CG. Analysis of dyes in cosmetics: Challenges and recent developments. *Cosmetics*. 2018;5(3):47. doi:10.3390/cosmetics5030047.
22. Cherian P, Zhu J, Bergfeld WF, Belsito DV, Hill RA, Klaassen CD, et al. Amended safety assessment of Parabens as used in cosmetics. *Int J Toxicol*. 2020;39(1):5–97.
23. Koo HJ, Lee BM. Estimated exposure to phthalates in cosmetics and risk assessment. *J Toxicol Environ Health*. 2004;67:1901–14.
24. Lee JD, Lee JY, Kwack SJ, Shin CY, Jang H, Kim HY. Risk assessment of Triclosan, a cosmetic preservative. *Toxicol Res*. 2019;35(2):137–54.
25. De Groot A, Veenstra M. Formaldehyde-releasers in cosmetics in the USA and in Europe. *Contact Dermatitis*. 2010;62(4):221–4.
26. De Groot A, White IR, Flyvholm M, Lensen G, Coenraads P. Formaldehyde-releasers in cosmetics: Relationship to formaldehyde contact allergy. *Contact Dermatitis*. 2010;62(1):2–17.
27. Malinauskiene L, Blaziene A, Chomiciene A, Isaksson M. Formaldehyde may be found in cosmetic productseven when unlabelled. *Open Med*. 2015;10(1):323–8. doi:10.1515/med-2015-0047.
28. Tosti A, Guerra L, Vincenzi C, Piraccini BM, Peluso AM. Contact sensitization caused by toluene sulfonamide-formaldehyde resin in women who use nail cosmetics. *Am J Contact Dermatitis*. 1993;4(3):150–3.
29. Fiume MM, Heldreth B, Bergfeld WF, Belsito DV, Hill RA, Klaassen CD. Safety assessment of Diethanolamine and its salts as used in cosmetics. *Int J Toxicol*. 2017;36(5):89–110.
30. Saraogi P, Kaushik V, Chogale R, Chavan S, Gode V, Mhaskar S, et al. Virgin coconut oil as prophylactic therapy against alcohol damage on skin in COVID times. *J Cosmetic Dermatol*. 2021;20(8):2396–408.
31. Siddique S, Parveen Z, Ali Z, Zaheer M. Qualitative and quantitative estimation of hydroquinone in skin whitening cosmetics. *J Cos Dermatol Sci Appl*. 2012;2(3):224–8.
32. Matsumoto M, Todo H, Akiyama T, Koizumi MH, Sugibayashi K, Ikarashi Y, et al. Risk assessment of skin lightening cosmetics containing hydroquinone. *Regul Toxicol Pharmacol*. 2016;81:128–35.
33. Sainio E, Jolanki R, Hakala E, Kanerva L. Metals and arsenic in eye shadows. *Contact Dermatitis*. 2000;42(1):5–10.

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