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COSMETVIGILANCE: ADVANCING SAFETY, AWARENESS, AND PUBLIC HEALTH

Esaram. Koteswara Rao*, Tirumalareddy Nagarjuna Reddy, Budagala.Gayathri, Dr.Chandu Babu Rao

Priyadarshini Institute of Pharmaceutical Education and Research, 5th mile, pulladigunta, Guntur-522017, Andhra Pradesh, India

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Abstract

Cosmetovigilance plays a vital role in ensuring the safety of cosmetic products by monitoring, detecting, and preventing adverse effects associated with their use. Despite its significance, awareness and implementation of cosmetovigilance remain limited. Studies indicate that while approximately 46.1% of healthcare professionals and consumers are aware of the concept, only a small percentage actively report adverse reactions. The lack of formal monitoring systems, self-diagnosis, and underreporting of mild to moderate adverse events contribute to the low number of documented cases. The cosmetic industry has evolved significantly, incorporating complex formulations to meet consumer demands. However, the absence of standardized scientific methods to evaluate long-term dermal exposure raises concerns about the safety of cosmetic ingredients. Furthermore, the rise of counterfeit beauty products in the market poses additional risks, making consumer education and regulatory vigilance crucial. National and international cosmetovigilance programs are necessary to monitor and regulate the safety of cosmetic products. These programs can help eliminate hazardous ingredients, enforce stringent safety measures, and enhance consumer confidence in the industry. Strengthening regulatory frameworks, increasing public awareness, and encouraging healthcare professionals to report adverse reactions are key steps toward improving cosmetovigilance practices.

Keywords: Cosmetovigilance, Cosmetic, Regulations, Allergic, Dermatology, Treatment.

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*Corresponding Author

Esaram.koteswara Rao

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Introduction

Cosmetic use is universal, and India is the 4th largest cosmetic market in Asia. The 'Drug and Cosmetics Act' defines cosmetics as any article intended to be poured, rubbed, sprinkled/sprayed on, or otherwise applied externally on the human body [1]. Roughly an adult uses nine cosmetics per day, and 25% of women use 15 or more cosmetics per day. Recently, another important aspect of cosmetics has been considered and their use can be associated with adverse effects (ADR). However, knowledge about these adverse effects is limited. Nearly 1-3% of the population is allergic to ingredients in cosmetics. The most common adverse reactions (AR) to cosmetics can be allergic or irritant in nature. Adverse effects of cosmetics can range from a small rash to toxicity in the long term. So far, the number of known adverse effects caused by cosmetics is very low due to a lack of information [1].

The concept of 'Cosmetovigilance' (CMV) is quite recent and evolving. The primary aim of CMV is to detect, monitor, assess, and report adverse cosmetic reactions (ACRs) associated with the use of cosmetics [2-4]. Cosmetovigilance was first introduced by Vigan (1997) to refer to postmarket surveillance carried out by the cosmetic industry [5-7]. It was initiated by the French health products safety agency as part of a pharmacovigilance system for cosmetics. Today, it is recognized globally as a concept of public health to address the safety of cosmetic products [2,8]. The Cosmetovigilance branch is emerging as a strong regulatory science to protect beauty and health [2].

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:

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].

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.

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 [4].

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 [5].

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 [6].

Classifications of cosmetics

Cosmetics are broadly categorized into four types:

- a) Skin Cosmetics
- b) Hair Cosmetics
- c) Nail Cosmetics
- d) Cosmetics for hygiene purpose

Skin cosmetics

A combination of therapy' and procedures is almost always necessary to obtain a satisfactory result. There are some intrinsic factors that can be aggravated or accelerated by extrinsic factors including improper or inadequate skin care, excessive sunlight exposure including artificial tanning and smoking among other factors. There are some of common conditions of skin problem that often occur in cosmetic dermatology field such as acne, rosacea, wrinkles, traumatic scars, age spots, melasma, textural problems including dry spots, sun damage, rough and dry skin, and facial redness [7].

Structure and Function of the Skin

The human skin is the outer covering of the body and is the largest organ of the integumentary system. The skin has up to seven layers of ectodermal tissue and guards the underlying muscles, bones, ligaments and internal organs. Human skin is similar to most of the other mammal's skin, and it is very similar to pig skin. Though nearly all human skin is covered with hair follicles, it can appear hairless. There are two general types of skin, hairy and glabrous skin (hairless). Because it interfaces with the environment, skin plays an important immunity role in protecting the body against pathogens and excessive water loss. Its other functions are insulation, temperature regulation, sensation, synthesis of vitamin D, and the protection of vitamin B folates. Severely damaged skin will try to heal by forming scar tissue(8)

Structure of Skin

Three layers of skin

- Epidermis
- Dermis
- Subcutaneous tissue(hypodermis)

Epidermis

The epidermis, the outermost layer of skin, provide a waterproof barrier and create our skin tone.

Layers of Epidermis

- Stratum basale aka stratum germinativum – deepest layer, separated from dermis by basement membrane (basal lamina) and attached by hemidesmosomes.
- Stratum lucidum - if present, thin clear layer consisting of eleidin (transformation product of keratohyalin); usually seen in thick skin only [9].

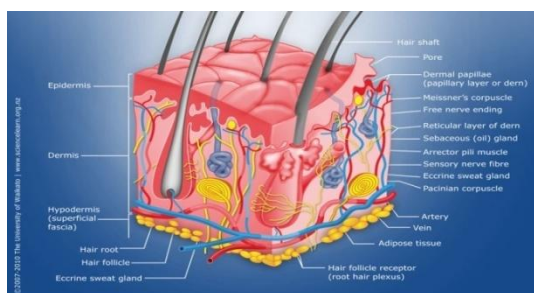


Fig 1 : structure of skin

Dermis

It consists of two layers of connective tissue which merge together, no clear demarcation

Papillary layer - Outer layer, thinner, composed of loose connective tissue and contacts epidermis

Reticular layer - Deeper layer, thicker, less cellular, and consists of dense connective tissue/ bundles of collagen fibers. The dermis houses the skin appendages (sweat glands and hairs), many sensory neurons, and blood vessels

Hypodermis

Deepest layer of skin and Contains adipose lobules along with some skin appendages (hair follicles),

sensory neurons, and blood vessels

Function of Skin

The skin has multiple functions including

- **Barrier:** water, bacterial, mechanical, UV light.
- Immunological.
- **Homeostasis:** temperature regulation and water loss
- **Sensory:** touch
- Endocrine
- **Exocrine:** secretion of sweat, sebum, etc

Skin Disease

Scabies

Scabies is a common ectoparasitic infestation caused by the human-specific mite *Sarcoptes scabiei*, transmitted through direct contact. It's prevalent in developing countries, particularly among young children, infants, and their mothers, due to close contact and overcrowding. In industrial societies, it's often seen in sexually active adults and the elderly in residential homes [10]. The parasite load can vary, with some individuals, like the elderly or those with weakened immune systems, having high parasite loads, while others may have low loads but still experience intense itching. Secondary bacterial infections, typically caused by Group A streptococci, are a significant complication of scabies [11].



Fig: 2 scabies

Bacterial Infections or Pyoderma

Bacterial skin infections or pyoderma are common in most developing countries. The usual bacterial causes are Group A streptococci or *Staphylococcus aureus*. Bacterial infections are common in communities. In many cases, no bacteriological confirmation is available from cultures, but surveys show that Group A streptococci account for a substantial number of cases which is not often the case in similar infections in temperate climates, where *S. aureus* dominates. Bacterial infection causes irritation and some discomfort. In some cases, the infection penetrates deep down through the epidermis, causing a necrotic ulcer—a condition known as ecthyma. However, some evidence suggests that streptococcal infection may cause additional long-term damage through the development of prolonged proteinuria, as described earlier in relation to scabies [12]

Fungal Infections

Fungal infections affecting the skin and adjacent structures are common worldwide, including ringworm, superficial candidosis, and infections caused by lipophilic yeasts and *Malassezia* species. The impact of these infections varies depending on local conditions, ranging from a nuisance to serious complications. For example, tinea pedis can lead to significant issues in diabetics, providing a portal of entry for aureus and increasing the risk of serious foot complications. Oropharyngeal candidosis is a common complication of HIV/AIDS, potentially leading to dysphagia and loss of appetite, and can be an early marker of the disease [13].

Acne

Acne is a common skin condition that occurs when hair follicles become clogged with oil and dead skin cells, leading to whiteheads, blackheads, and pimples. It can affect people of all ages and skin types, but is most prevalent among teenagers. Acne can range from mild to severe, causing emotional distress and potentially scarring the skin. Effective treatments are available, but the condition can be persistent, with new pimples and bumps emerging as others heal. Early treatment can help reduce the risk of long-term problems [14].

Skin Cancer

The abnormal growth of skin cells most often develops on skin exposed to the sun. But this common form of cancer can also occur on areas of your skin not ordinarily exposed to sunlight. PAHs, in association with exposure to the sun can cause various cancers of the skin among bricklayers and tilers: these include malignant epithelioma, carcinomas and even the much-feared malignant melanoma ('Carcinogenic or mutagenic agents'). According to the latest statistics, in 2006 in the United Kingdom 21 % of all reported skin diseases were cancers. It is estimated, that approximately 11 % of deaths caused by skin cancers melanoma and non-melanoma [15].

If additional treatment is needed, options may include:

Freezing. Your doctor may destroy actinic keratoses and some small, early skin cancers by freezing them with liquid nitrogen (cryosurgery). The dead tissue sloughs off when it thaws. Excisional surgery. This type of treatment may be appropriate for any type of skin cancer. Your doctor cuts out (excises) the cancerous tissue and a surrounding margin of healthy skin. A wide excision-removing extra normal skin around the tumor-may be recommended in some cases. Radiation therapy. Radiation therapy uses high-powered energy beams, such as X-rays, to kill cancer cells. Radiation therapy may be an option when cancer can't be completely removed during surgery [16,17].

Rosacea: Rosacea is a chronic skin disease that affects more than 16 million Americans. The cause of rosacea is still unknown, and there is no cure. However, research has allowed doctors to find ways to treat the condition by minimizing its symptoms. There are four subtypes of rosacea. Each subtype has its own set of symptoms. It is possible to have more than one subtype of rosacea at a time. Rosacea's trademark symptom is small, red, pus-filled bumps on the skin that are present during flareups. Typically, rosacea affects only skin on your nose, cheeks, and forehead. Flare-ups often occur in cycles. This means that you will experience symptoms for weeks or months at a time, the symptoms will go away, and then return [18]

Adverse effects for using hair cosmetics

Hair Cosmetics

Hair cosmetics are also an important tool for increasing patient's adherence to scalp treatments, according to the diversity of hair types and ethnicity. True described them as "preparations intended for placing in contact with the hair and scalp, with the purpose of cleansing, promoting attractiveness, altering appearance, and/or protecting them in order to maintain them in good condition" Nowadays, hair care and style play a very important role in people's lives, both for men and women, so knowledge of hair products, mode of action, efficacy, ingredients and hair procedures has become more relevant in dermatologists' medical practice [19].

Example of Skin Cosmetics: Shampoo, Conditioners, Hair straighteners, permanent waves and hair sprays.

Nail Cosmetics

The nail as an anatomic structure protects the terminal phalanx of the digit from injury. Historically, it has served as a tool for protection and for survival. As civilizations developed, it attained the additional function of adornment. Nail beautification is a big industry today, with various nail cosmetics available, ranging from nail hardeners, polishes, extensions, artificial/sculpted nails, and nail decorations. Adverse events may occur either during the nail-grooming procedure or as a reaction to the individual components of the nail cosmetics. This holds true for both the client and the nail technician. Typically, any of the procedures involves several steps and a series

of products. Separate "nail-bars" have been set up dedicated to serve women and men interested in nail beautification [20]. This article attempts to comprehensively inform and educate the dermatologist on the services offered, the products used, and the possible/potential adverse effects related to nail-grooming and nail cosmetics.

Example of Hygiene

Washing Hands, Controlling Body Odor, deodorants and antiperspirants, perfumes, colognes, and scented soap, Puberty and Acne, Sun Protection, eczema.

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 [21].

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.

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 [22].

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.

Key takeaways from european cosmetic regulations

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 [21].

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 [22].

Conclusions

Cosmetovigilance is an essential public health initiative that ensures the safety and efficacy of cosmetic products by monitoring and addressing adverse reactions. Despite its significance, there is still a lack of awareness and reporting among consumers and healthcare professionals. Strengthening regulatory frameworks, increasing public awareness, and encouraging active participation from stakeholders can enhance the effectiveness of cosmetovigilance programs.

The cosmetic industry continues to evolve with innovative formulations and emerging trends, making ongoing surveillance even more critical. The rise of counterfeit products, the presence of harmful ingredients, and inconsistencies in global regulations further highlight the need for stringent safety measures and consumer education. Regulatory bodies worldwide must collaborate to establish uniform safety standards, enforce compliance, and promote transparency within the industry.

By fostering cooperation between regulatory agencies, the cosmetics industry, and consumers, a safer and more responsible cosmetic market can be achieved. Implementing robust cosmetovigilance programs will not only improve consumer trust but also reduce the risks associated with cosmetic use, ensuring long-term public health benefits

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All authors are contributed equally

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