REVIEW ARTICLE

Cosmetovigilance: Global Practices, Indian Regulations, and Safety Challenges

Megha Patel[1], Aastha Patel[2], Asma Pathan[3], Himani Patel[3], Urmila Rajput[3], Himani Shah[3]

[1]Department of Pharmacy, Sumandeep Vidyapeeth Deemed to be University, Vadodara, Gujarat, India, [2]Department of Regulatory Affairs, Vidhyadeep Institute of Pharmacy, Surat, Gujarat, India, [3]Indubhai Patel College of Pharmacy and Research Centre, Anand, Gujarat, India

Abstract

The widespread use of cosmetic products has prompted global attention toward their safety, giving rise to the specialized field of cosmetovigilance. Initially emerging from pharmacovigilance, cosmetovigilance involves the systematic monitoring, reporting, and regulation of adverse effects associated with cosmetics. This review explores the historical context, evolving definitions, and increasing global need for cosmetovigilance systems. It presents a comparative overview of regulatory frameworks in various countries, including the USA, Canada, the European Union, Japan, and India. In addition, it discusses common cosmetic ingredients of concern such as hydroquinone, para-phenylenediamine, and benzophenones, and their associated toxicities. The article emphasizes the Indian regulatory setup, including detailed licensing procedures and import regulations. Noteworthy case studies of misleading claims, banned products, and spurious cosmetics illustrate real-world consequences of regulatory lapses. The review concludes with recommendations for strengthening cosmetic safety monitoring systems, improving consumer awareness, and enhancing regulatory transparency to protect public health.

Key words: Adverse drug reactions, cosmetic safety, cosmetovigilance, regulatory frameworks, toxic cosmetic ingredients

INTRODUCTION

Pharmacovigilance is the process of gathering, identifying, assessing, monitoring, and preventing hazardous medication reactions. The concept of vigilance has expanded to include the safety of cosmetics and herbal products. The term cosmetovigilance was first introduced by Vigan in 1997 to describe the surveillance of cosmetic product safety and is now regarded as a global public health concern.[1] According to section 201(i) of the Federal Food, Drug, and Cosmetic Act (FD&C Act), cosmetics are defined as "articles intended to be rubbed, poured, sprinkled, or sprayed on, introduced into, or otherwise applied to the human body… for cleansing, beautifying, promoting attractiveness, or altering the appearance."[2] This includes products such as perfumes, lipsticks, nail polish, makeup, shampoos, hair dyes, deodorants, and skin moisturizers. The term cosmeceuticals is sometimes used to describe cosmetic products with bioactive ingredients believed to have therapeutic effects. However, the FD&C Act does not legally recognize the category "cosmeceutical."[2] A product may be classified as a drug, a cosmetic, or both, depending on its intended use and ingredients. Examples of products falling into both categories include fluoride toothpaste, antiperspirant deodorants, moisturizers with sunscreen, and antidandruff shampoos; these must meet the regulatory requirements for both drugs and cosmetics.[3]

HISTORICAL EVOLUTION OF COSMETOVIGILANCE

The use of cosmetics dates back to ancient civilizations, with evidence from the Indus Valley Civilization between 2500 and 1550 B.C. indicating early application of natural substances

Address for correspondence:
Dr. Megha Patel, Department of Pharmacy, Sumandeep Vidyapeeth Deemed to be University,
Vadodara, Gujarat, India.
E-mail: patelmegha5456@gmail.com

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for personal grooming and esthetic enhancement.[4] In ancient Indian and Egyptian societies, cosmetology practices were deeply rooted in cultural, medicinal, and religious traditions. Historical Ayurvedic texts describe natural remedies, such as a mixture of woman's milk and powdered rind of *Aegle marmelos* for treating chapped lips, and depilatory pastes made from *Piper longum*, *Emblica officinalis*, and the latex of *Euphorbia nivulia* for removing unwanted hair.[5] The use of kajal in Hindu culture and kohl in Egypt symbolized both protection and beauty. Ancient Egyptians, Greeks, and Romans also employed various cosmetics often containing harmful substances such as mercury and white lead for skin whitening, body odor control, and ceremonial decoration.[6] Essential oils and natural pigments were widely used for skincare and spiritual practices, reflecting the longstanding human inclination toward cosmetic use.[7]

With the expansion of the global cosmetic market and increased use of personal care products, adverse effects such as allergic reactions and dermatitis became more evident, leading to the emergence of cosmetovigilance. Originating from the broader concept of pharmacovigilance, cosmetovigilance was formally defined by Vigan in 1997 as the post-marketing surveillance of cosmetic product-related adverse events.[4] Unlike pharmaceuticals, cosmetics were initially not subjected to strict safety assessments, resulting in underreporting of adverse effects. The European Union pioneered regulatory efforts through the Cosmetics Directive (76/768/EEC), later reinforced by regulation (EC) No. 1223/2009, which mandated the reporting of serious undesirable effects within the European Union.[8] Other regions, including North America and Asia, followed suit with the implementation of their own monitoring frameworks.[9] Cosmetovigilance now plays a crucial role in public health, ensuring prompt identification, assessment, and prevention of harmful reactions, thereby safeguarding consumer safety worldwide.[10]

WHY COSMETOVIGILANCE MATTERS TODAY

The global use of cosmetics has grown substantially over the past few decades, driven by increasing self-awareness and the desire to enhance appearance without altering bodily structure or function.[11,12] Although definitions of cosmetics vary internationally, the industry has benefited from rising global concern for physical esthetics. However, prolonged use of personal care products can lead to chemical exposure and associated health risks, such as allergic reactions and dermatitis.[11]

India, the fourth-largest cosmetics market in the Asia-Pacific region after South Korea, China, and Japan, faces similar challenges.[13] Adverse reactions linked to both modern and traditional products, such as kumkum and kajal, are frequently reported. Section 135B of the Drugs and Cosmetics Act prohibits the import of animal-tested cosmetics. Given the public health implications and economic burden of cosmetic-related adverse events, implementing a robust cosmetovigilance system is essential. Such systems help detect harmful substances in cosmetics, thereby enhancing consumer trust.[14]

GLOBAL LANDSCAPE OF COSMETOVIGILANCE

In 2002, the first cosmetovigilance system study was carried out in France.[15] The first guideline on reporting adverse reactions, known as an unwanted event report, was then released by COLIPA in 2005 in accordance with the 76/768/EEC EU cosmetics directive.[16,17] The EU Public Health Committee established the ResAP as a cosmetovigilance system based on case reports in 2006, following a pilot study conducted by the Council of Europe's committee of experts on cosmetic products in 2004–2005. This system forms the foundation of the current framework.[18] Subsequently, cosmetovigilance systems were set up in Germany, Norway, Italy, Denmark, Sweden, and Belgium.[18]

USA and Canada

Under Canada's Natural Health Products (NHP) Regulations, which went into effect in January 2004, consumers and medical professionals are encouraged to report any undesirable adverse drug reactions (ADRs).[19] The NHP is responsible for ensuring that all cosmetic products are properly licensed, supported by adequate safety and efficacy data, appropriately labeled, manufactured according to good practices, and monitored for ADRs and clinical trials. The Cosmetic/Consumer Product Incident Report form is designed for both manufacturers and consumers, with incident reports required to be submitted within 15 days following the ADR.[19]

Similar regulations and agencies exist in the United States to ensure product safety. Cosmetics are overseen by multiple regulatory bodies and guidelines, including post-marketing adverse event reporting systems and the FD&C Act.[20] The U.S. Food and Drug Administration (FDA) regulates prescription and over-the-counter cosmetic-related products, overseeing labeling, manufacturing, safety, ADR surveillance, clinical trials, and product recalls. Although many cosmetic products are not FDA-approved, they are FDA-regulated under the FD&C Act to ensure consumer safety. The FDA encourages ADR reporting via MedWatch through hotlines or online forms, and supports this process through consumer complaint coordinators and individual case safety reports.[20]

Further advancing cosmetic regulation, the United States passed the Safe Cosmetics and Personal Care Products Act in 2013 and the Cosmetic Safety Amendment Act in 2012. These laws require ADRs to be reported directly to the Secretary of Health and Human Services within 15 days of occurrence.[21]

Europe

According to studies conducted by European consultations, several cosmetic ingredients such as preservatives, fragrances, and para derivatives are also found in detergents, industrial goods, and food products. This suggests that cosmetics alone may not always be responsible for elevated para-phenylenediamine (PPD) levels or positive PPD tests; exposure could stem from other sources, such as detergents or food. In response, the European Council recommended that member states establish systems to document and collect data on adverse cosmetic reactions. As a result, countries such as Germany, Italy, Denmark, Belgium, Norway, and Sweden have developed cosmetovigilance systems.[22]

East Asia and Japan

Among developed nations, Japan enforces some of the strictest regulations concerning cosmetic safety and ingredients. While its classification system is similar to that of the United States, it also includes a unique category known as "quasi-drugs." According to Japanese legislation, cosmetic products must undergo a registration process supported by evidence of safety and efficacy. The Ministry of Health, Labor, and Welfare provides full procedural information through its official website. Inspired by Japan's model, other Asian countries such as China, South Korea, and Taiwan have also implemented cosmetovigilance systems.[23]

India

In India, the regulation of cosmetics falls under the Drugs and Cosmetics Act, 1940, and Rules, 1945. Part XIII governs the import and registration of cosmetics, Part XIV covers manufacturing for sale or distribution, and Part XV outlines labeling, packaging, and standard requirements. Rule 145 and Rule 135 prohibit the use and import of compounds containing arsenic or lead. Rules 135A and 145D ban mercury-containing cosmetics, whereas Rule 134A prohibits the import of products with hexachlorophene. In addition, Rule 134 mandates that cosmetic colorants must conform to specifications listed in Schedule Q and by the Bureau of Indian Standards.[24]

TOXIC INGREDIENTS IN POPULAR COSMETICS

Women's skincare choices are often influenced by peer pressure, advertising, and social norms. Research suggests that women who use cosmetics may experience anxiety and lower self-confidence.[25] Many cosmetic products contain harmful chemicals that can negatively affect the skin. While synthetic ingredients are widely used for their cost-effectiveness, natural alternatives such as Shea butter and rose extract are gaining popularity for being safer and more sustainable.[26] Prolonged use of makeup, nail polish, and perfumes can cause allergic reactions, and excessive use of moisturizers may lead to irritation or exfoliation.[27] Table 1 highlights frequently used cosmetic products along with their concerning ingredients and associated adverse health effects, emphasizing the need for rigorous safety assessment and consumer awareness.

Skin lightening agents

Hydroquinone (HQ) and other skin-lightening agents are considered among the most hazardous substances. They have been associated with ochronosis and potential mutagenicity.[28] Ochronosis, a rare adverse effect, appears as

Table 1: Common cosmetic products, harmful ingredients, and their potential health effects

Cosmetic product	Ingredients of concern	Possible health effects
Lipstick	Lead, Cadmium, Parabens	May affect the nervous system; linked to hormone imbalance
Foundation	Talc (possible asbestos contamination), formaldehyde-releasing agents	Can cause skin irritation; may affect respiratory health
Sunscreen	Oxybenzone, Octinoxate	Associated with hormonal disruption and skin sensitivity
Nail Polish	Toluene, Dibutyl phthalate, Formaldehyde	May impair fertility and cause breathing difficulties
Hair Dye	Para-phenylenediamine, Ammonia	May cause allergic skin reactions and potential carcinogenic effects
Perfume/Fragrance	Phthalates, Synthetic musk compounds	Could disrupt hormonal balance and trigger allergies
Skin Whitening Creams	Mercury, Hydroquinone	Risk of kidney damage, skin darkening (ochronosis), and nerve issues
Shampoo/ Conditioner	Sodium lauryl sulfate, Parabens	May cause scalp dryness or hormone-related effects
Mascara/Eyeliner	Carbon black, Preservatives like parabens	Possible eye irritation and long-term toxicity concerns
Moisturizer	Mineral oils, Synthetic fragrances	May clog pores and interfere with natural hormone function

progressive darkening of the skin in areas where HQ creams are applied for several years. HQ functions by inhibiting the tyrosinase enzyme, thereby halting melanin synthesis. It may also prevent the formation or breakdown of melanosomes and inhibit DNA and RNA synthesis in melanocytes. Although widely used, HQ has been proven cytotoxic to melanocytes and potentially mutagenic to mammalian cells.[29] It can lead to irritation, redness, and burning, in addition to exogenous ochronosis. Due to these safety concerns, it is banned from over-the-counter sales in the U.S. and many countries.

Black henna

Black henna, a combination of natural red henna and PPD, is used for temporary tattoos. PPD enhances the color, pattern, and longevity of the tattoos but is linked to several adverse effects, such as blisters, skin seeping, and erythematous rashes.[30,31] Non-dermal symptoms such as sneezing and shortness of breath have also been documented. Some users reported localized hypertrichosis without other symptoms.[32] In the 1980s, fatal poisoning cases in Sudan highlighted the life-threatening risks of PPD, including facial swelling, respiratory obstruction, renal failure, and renal tubular necrosis.[33]

Sunscreen products

Modern sunscreens can cause allergic, phototoxic, or photoallergic reactions. Benzophenones are common sensitizers, while dibenzoyl methanes, para-aminobenzoic acid, and cinnamates may cause photoallergic dermatitis.[34] Fragrance-related products can provoke symptoms such as dizziness, headaches, and airway irritation. Fragrance chemicals such as phthalates, coumarins, and phthalyl compounds are suspected hormone disruptors and carcinogens.[35]

Shampoos

Although shampoos and conditioners have brief skin contact, issues can arise, especially if they enter the eyes. Hair matting during shampooing is a known problem.[36] Alkaline shampoos can damage hair shafts, whereas neutral pH products are better for chemically treated hair.[37] The risk of contact allergy is low due to dilution and rinse-off properties.[38,39] Hair bleaching agents such as ammonium persulfate and hydrogen peroxide have been associated with allergic responses.[40]

REGULATORY FRAMEWORK IN INDIA

In India, the regulation of cosmetics falls under the purview of the Drugs and Cosmetics Act, 1940, and the Drugs and Cosmetics Rules, 1945. These provide a robust legal framework to ensure the safety, quality, and efficacy of cosmetic and pharmaceutical products. The act aims to prevent adulteration, mandate licensing for manufacture and sale, and establish advisory bodies such as the Drugs Technical Advisory Board and the Drugs Consultative Committee.[41,42] The associated rules, including Rule 67 and Rule 97, detail requirements for product classification, labeling, storage, and display.[41] Regulatory oversight is a shared responsibility between the CDSCO and the state drug regulatory authorities (SDRAs). The CDSCO oversees national-level functions such as import registration, right to information responses, and consumer grievance redressal,[42,43] whereas SDRAs manage licensing, inspections, and enforcement at the state level.[44,45]

Manufacturing cosmetic products in India requires adherence to stringent infrastructure and hygiene standards, along with regulatory approval. A manufacturer must obtain a license through Form 32, applying via Form 31, and submit accompanying documentation such as layout plans, machinery lists, and quality control protocols.[46-50] Various licensing options exist, including Form 32A for loan licenses and Form 37 for renewals. To ensure the safety of raw materials, heavy metal testing must be performed in accordance with Indian Standard IS 6608:2004, and specific regulations exist for colors, dyes, and pigments used in cosmetics.[51-55]

Cosmetic imports into India are regulated under Rule 129D, which prohibits the import of misbranded or harmful products, especially those containing mercury, arsenic, or lead.[41,56] Imported products must display the importer's name, product details, manufacturing date, and maximum retail price clearly on their packaging.[57,58] The import registration dossier must include Form 42, a free sale certificate, a manufacturing license, and detailed product specifications. Only authorized Indian agents or companies with a registered presence in the country are allowed to import cosmetics.[59-61] In addition, the CDSCO also plays a critical role in drug approvals, especially in cases involving serious or rare health conditions, where local clinical trial data may be waived to expedite access.[62,63]

MISBRANDED AND SPURIOUS COSMETICS

Counterfeit and mislabeled cosmetics are banned under the Drugs and Cosmetics Act, 1940, as they may contain unauthorized ingredients or deceptive labeling. Products imitating other cosmetics or lacking authentic manufacturer details are classified as spurious and pose significant consumer safety risks.[64] Table 2 shows a summary of notable safety concerns and regulatory actions highlighting the role of cosmetovigilance in consumer protection.[65-75]

Table 2: Cosmetic safety and regulatory incidents

Company/Product	Year	Issue	Regulatory action/Ban
Johnson and Johnson-Baby Powder	2019–2023	Alleged asbestos contamination in talc-based baby powder linked to cancer.	Recalled in 2019; Discontinued in the U.S. and Canada in 2020; Global phase-out by 2023.
Claire's – Makeup kits	2017–2019	The FDA found asbestos in talc-based cosmetics such as eye shadows and glitter products.	Voluntary recalls; FDA issued safety alerts; Claire's removed talc-based items.
L'Oréal – Cosmetics with PFAS	2021–2022	PFAS ("forever chemicals") are linked to health risks such as cancer and hormone disruption.	Faced lawsuits; Pressure from legislators; Ongoing review, but no full ban yet.
SKKN by Kim – Skincare line	2022	Accused of violating trademark (not health-related, but regulatory/legal dispute).	No ban, but faced legal challenge over brand name; Settled trademark dispute.
Revlon – Hair straightening products	2022–2023	Certain hair relaxers are linked to uterine cancer in studies.	Lawsuits filed in 2022–23; the FDA proposed a ban on formaldehyde in these products.
Tresemmé (Unilever)	2020–2022	Formaldehyde-releasing preservatives allegedly caused scalp burns and hair loss.	Class-action lawsuits filed; No recall yet, but significant consumer backlash.
Herbal essences and Pantene (P&G)	2021	Certain dry shampoos and conditioners contained benzene.	Voluntary recall of aerosol products; FDA and media scrutiny increased.
Batiste dry shampoo (Church and Dwight)	2022	Independent laboratory tests found high levels of benzene in spray products.	Voluntary recall in 2022; Class-action lawsuits filed.
Johnson's baby shampoo (India)	2019	Found to contain formaldehyde in Indian government testing.	Temporarily banned in Rajasthan; J&J denied results; regulatory tension followed.
Forever living – Aloe Vera products	2017 (EU)	Misleading marketing and toxic additives in cosmetics and beverages flagged by regulators.	Sales restrictions and labeling enforcement in several EU countries.
Lush cosmetics – Preservative-free	Multiple years	Lack of preservatives led to spoilage or bacterial growth in some products.	No recalls, but faced increased public and media scrutiny.
Shiseido – Sunscreen products	2021 (Asia)	Some products failed to meet advertised SPF levels in independent testing.	Products were pulled from shelves in Asia; the company issued an apology and began reformulations.

FDA: Food and Drug Administration

REAL-WORLD CASE HIGHLIGHTS

Several recent cases illustrate the need for stringent cosmetovigilance and accurate labeling in cosmetic and personal care products. In 2019, the Maharashtra FDA seized Sensodyne and Colgate toothpaste products for allegedly making misleading claims such as "clinically proven relief" and "daily protection for sensitive teeth," raising concerns about unsubstantiated product promises.[76] Similarly, Procter & Gamble Head & Shoulders Anti-Dandruff 2-in-1 Shampoo + Conditioner claimed to straighten hair, although it only smoothened it.[77] Hindustan Unilever Ltd. also faced scrutiny for its Sunsilk conditioner advertisements, which claimed the product kept hair set all day, claims that authorities found to be unsubstantiated.[78] Another significant example involves Hindustan Unilever's hand sanitizer marketed under the Lifebuoy brand. The company claimed the product could prevent COVID-19 and boost immunity, even though it was licensed as a cosmetic and not a therapeutic product. The Drugs Controller General of India issued a show-cause notice as the claims violated the Drugs and Cosmetics Act.[78]

In addition, widespread use of counterfeit cosmetics in India continues to be a serious concern. Raids on beauty parlors in Pune revealed numerous unlicensed products, some with dangerously high lead content.[79,80] These incidents highlight the urgent need for strong regulatory enforcement and consumer awareness to ensure safety and integrity in cosmetic products.

STRATEGIES TO CONTROL COSMETIC ADRS

To effectively control ADRs associated with cosmetic products, a multifaceted strategy must be employed involving

regulatory, clinical, industrial, and consumer-level actions. First, strengthening post-marketing surveillance through mandatory adverse event reporting by manufacturers, dermatologists, and consumers is vital. Establishing centralized cosmetovigilance databases and encouraging reporting via user-friendly digital platforms or mobile apps can enhance real-time monitoring. Regulatory bodies should enforce stricter labeling norms, safety testing, and ingredient disclosure to prevent the use of harmful substances such as HQ and PPD. Standardization of safety assessment protocols and pre-clinical toxicity testing, especially for emerging ingredients such as nanoparticles and botanical extracts, is also essential. At the healthcare level, dermatologists and pharmacists must be trained to recognize and report cosmetic ADRs. Public education campaigns about product authenticity, ingredient safety, and patch testing can reduce risk at the consumer end. Collaboration between regulatory agencies and industry stakeholders to create a harmonized global framework would further reduce the incidence of ADRs and protect public health.[11,23]

FUTURE DIRECTIONS AND CONCLUSION

As the global cosmetics industry grows, the need for a robust and harmonized cosmetovigilance system becomes increasingly vital. Future advancements lie in integrating digital technologies such as Artificial Intelligence-based reporting systems, mobile apps, and blockchain to improve adverse event tracking, transparency, and consumer safety. Harmonization of international regulations is essential, particularly in emerging markets, to ensure uniform safety standards. Collaboration among regulatory authorities, healthcare professionals, manufacturers, and consumers will strengthen risk assessment and post-marketing surveillance. Public education and long-term safety studies, especially on nanomaterials and bioactive ingredients, are also crucial. While developed nations lead in regulatory oversight, countries such as India are progressively enhancing their frameworks. Addressing challenges such as counterfeit products, misleading claims, and underreporting will require coordinated global efforts to ensure safer cosmetic practices and protect public health.

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