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Research Article

A Comparative Analysis of Cosmetovigilance Frameworks in Key Regions: Europe, the United States, Japan, and India

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Abstract
Cosmetovigilance is defined as the surveillance or monitoring of cosmetics-related adverse events or effects. Monitoring and assessing the safety of cosmetic products after they are on the market is crucial. Manufacturers conduct this post-market surveillance to ensure the safe use of their products by consumers.
Due to the increasing demand for the use of cosmetics at the global level, the adherence to regulatory guidelines by the manufacturers from an international perspective is a must to provide the safe and effective use of cosmetics among cosmetic users and also to protect the environment. As the cosmetics industry expands, so does the need for robust regulatory frameworks that govern cosmetovigilance activities. This article reviews the cosmetovigilance frameworks across key regions-Europe, the United States, Japan, and the emerging market in India. It highlights the differences in regulations, enforcement, reporting mechanisms, recent updates and future trends toward improvisation in cosmetovigilance in India. This review aims to provide a comprehensive overview for regulators, manufacturers, and stakeholders interested in the safety and efficacy of cosmetics in India.

Keywords: Cosmetovigilance, Cosmetics, Regulations, Post-marketing.

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Introduction

The cosmetics industry is one of the fastest-growing global markets, driven by increasing consumer demand for personal care products. However, the safety of these products is paramount to protect consumers from potential adverse effects. Cosmetovigilance, akin to pharmacovigilance in pharmaceuticals, refers to the surveillance, collection, evaluation, and reporting of adverse events related to cosmetic products.[1,2] Regulatory frameworks for cosmetovigilance vary globally, depending on the market's size, the economic environment, and local health policies.[3] This review aims to outline the major global frameworks governing cosmetovigilance and compare their processes and challenges and provide best possible suggestions to regulators, manufacturers, and stakeholders to

harmonize and take it up to global standards to ensure the safety, efficacy, and user-friendly environment of cosmetics in India.

European Union (EU)

Regulatory Body and Framework

The European Union is a global leader in cosmetovigilance, with one of the most stringent regulatory frameworks. The key regulation is Regulation (EC) No 1223/2009, which governs the safety of cosmetic products across the EU. This regulation simplified the procedures and terminology to reduce administrative burdens and ambiguity. Additionally, it strengthened certain aspects of the cosmetic regulatory system, such as in-market control, to enhance consumer safety.[4]

- **Competent Authority:** European Commission and the Competent Authorities of EU member states

Requirements:

Pre-market notification via the Cosmetic Products Notification Portal (CPNP).

This includes five steps:

Step 1: Thorough Formula Review

Step 2: Creating a Cosmetic Product Safety Report (CPSR)

Step 3: Compiling the Product Information File (PIF) and CPNP Notification

Step 4: Ensuring Accurate Labels & Claims

Step 5: Legal Representation in the EU.[5]

A responsible person must ensure compliance with regulations and maintain product safety reports.

All cosmetic products sold in the EU must have a designated responsible person located within the EU, as per the Cosmetics Regulation. This person, who could be a natural person (i.e., an individual) or a legal entity (i.e., a firm), is accountable for making sure that any cosmetic product he puts on the EU market conforms with all Cosmetics Regulation standards.

One of the main tenets of the Cosmetics Directive was the idea of a single individual in charge of making sure cosmetic items complied with cosmetic laws. The primary function of the Responsible Person is still in place and is further defined by the Cosmetics Regulation.

By law the importer is responsible for the cosmetics he puts on the EU market, and the manufacturer based in the EU is responsible for the cosmetics he produces there. However, under a formal mandate, this duty may be delegated to another individual based in the EU. Each cosmetic product has a single Responsible Person. When multiple importers import a cosmetic product into the EU, each importer assumes responsibility for the unit products he imports (unless he appoints a mandated person), which results in varying CPNP numbers and names and addresses of the responsible parties, along with distinct PIFs. [6]

Mandatory reporting of Serious Undesirable Effects (SUE) by both industry professionals and consumers.

SUE Form A: Used by Responsible Persons or Distributors to report serious unexpected events (SUEs) to authorities.

SUE Form B: Used by National Competent Authorities to share SUE information with other EU authorities and the responsible person.

SUE Form C: Used by Competent Authorities to share SUE information reported by healthcare professionals or consumers. Initial reports require:

- Reporter's identity
- Nature and onset date of the suspected SUE
- Name of the specific cosmetic product

If complete information is unavailable, the reporter should submit updates as soon as possible. The European Commission will maintain a list of Competent Authorities.[7]

Key Features

- **Post-Market Surveillance (PMS):** The framework ensures that products continue to be monitored for safety after they enter the market. [1]
- **Cosmetic Product Safety Reports (CPSR):** Mandatory for every product, covering toxicological profiles, product testing, and exposure assessments.[8]
- **Notification Requirements:** Serious undesirable effects (SUEs) must be reported to the national authorities, which are then collected and shared among EU member states.[9]

Challenges

- Cross-border Harmonization: Although the EU has a single market, variations in implementation and enforcement among member states can present challenges.

United States

Regulatory Body and Framework

In the U.S., the Food and Drug Administration (FDA) previously oversaw cosmetic products under the Federal Food, Drug, and Cosmetic Act (FD&C Act). Unlike EU regulations, this act did not require pre-market approval for cosmetics.

The FDA does not pre-approve a cosmetic product for marketing and distribution in terms of product and market management. The person in charge of the product's availability on the market, whether they be judicial or physical, is accountable for adhering to the rules and regulations. But the reality that no Pre-market approval does not imply that the FDA has no control over products; rather, it allows for testing and examination of products that are already on the market. Any product that poses a risk to human health was withdrawn, and administrative sanctions was imposed. When imported goods enter the United States, they are inspected and either approved for access or a Notice of Action or Warning Letter was sent.[10]

However, producers and goods that supported the Voluntary Cosmetic Registration Program (VCRP). But only cosmetics that were available for purchase was registered, and it served as a way for the maker or

distributor to notify the FDA of the cosmetics he has introduced to the market rather than conferring official clearance.[11]

On March 27, 2023, the U.S. Food and Drug Administration (FDA) stopped accepting and processing applications for the Voluntary Cosmetic Registration Program (VCRP). The FDA halted the VCRP to prepare for a new program mandated by the Modernization of Cosmetics Regulation Act of 2022 (MoCRA). This new program will streamline the process of registering facilities and listing products.

On August 7, 2023, the FDA released a draft guideline outlining the requirements for registering cosmetic product facilities and listing products, as mandated by MoCRA. The goal of this new law is to enhance the safety of cosmetic products.

Requirements:

MoCRA provides new authorities to FDA including:

Records Access: The FDA may view and copy certain information pertaining to a cosmetic product, including safety records, if specific requirements are satisfied.

Mandatory Recall Authority: If a cosmetic is found to be adulterated or misbranded and there is a reasonable chance that using or being exposed to it will result in major negative health effects or death, the FDA has the power to mandate a recall if the responsible party declines to do so willingly.

New requirements for industry from MoCRA:

Adverse Event Reporting: The individual responsible for a cosmetic product must inform the FDA within 15 business days of any serious adverse events related to its use in the US. The responsible party must also include a copy of the product label on or inside its retail packaging. Additionally, within a year of the initial notification, the responsible party must provide the FDA with any further medical or other information about the adverse event within 15 business days. During inspections, the FDA will have access to these adverse event reports.[12]

The FDA advises that industry-responsible persons report serious adverse events related to cosmetics using the existing Form 3500A. This form can be downloaded and filled out on the MedWatch website.

Competent Authority: FDA's Center for Food Safety and Applied Nutrition (CFSAN)

Key Features

- Introduction of responsible persons in the US whose names will appear on the label of the cosmetic product
- Recall of cosmetics from the market (implementation of traceability principles)
- Labelling of allergens and contact information for adverse event reporting
- Ensuring mandatory GMP compliance
- Registration of facilities (in the US or abroad), which must be updated every 2 years.
- Product listing, management of adverse events (implementation of cosmetic surveillance procedures): receiving, reviewing, responding, reporting. Record keeping and reporting of adverse events.
- Safety case (introduces the concept of safety assessment)[13,14]

Challenges

Comprehensive Safety Assessments: Conducting in-depth safety assessments of products and ingredients requires significant resources and access to scientific expertise and sophisticated testing protocols.

Supply Chain Transparency: Ensuring full traceability of all ingredients used in your products requires reviewing existing supply chain processes and implementing new tracking systems as well as maintaining comprehensive documentation.

Good Manufacturing Practices (GMP) Compliance: Compliance with GMP standards may require upgrading factories or changing production methods, resulting in increased complexity and operational costs.

Adverse Event Reporting: Establishing a system to monitor, track, and report negative consumer reactions would increase the administrative burden and require rapid response to avoid regulatory penalties.

Stricter Labeling and Marketing Regulations: Ensuring all product claims are substantiated and ingredients are clearly disclosed requires careful attention to detail, which may require changes to existing product labels and marketing materials.[15]

Japan

Regulatory Body and Framework

The cosmetics industry in Japan, one of the wealthiest countries in Asia, has grown significantly. It is the world's third-largest market for cosmetics. Japanese customers are intelligent and knowledgeable about cosmetics formulations and products. The market's enormous desire for natural and organic components pushes producers to introduce goods with labels that read "natural" or "clean." However, before introducing any cosmetic product in Japan, firms need to understand the regulatory routes.

Under the Pharmaceutical and Medical Devices (PMD) Act, the Ministry of Health, Labour, and Welfare (MHLW) is in charge of regulating cosmetic items. In Japan, the MHLW, the public health authority (HA), approves applications for quasi-drugs, receives notifications about cosmetics, keeps track of adverse impact reports, and inspects business locations.

The two primary categories into which cosmetics are divided in Japan are

- **General Cosmetics** include Perfumes and Eau de Colognes, Makeup Products, Skincare products, Haircare Products) and
- **Quasi-drugs** include Acne Treatment Products, Skin-whitening Products, Anti-dandruff Products, Sunscreens

Depending on the product category, importers and manufacturers must apply for marketing clearance after completing the relevant regulatory procedures for their cosmetic products.

Although it may not be immediately evident how general cosmetics and quasi-drugs differ from one another, the main distinction lies in their makeup, as the former contain active components while the latter do not. Cosmetics and quasi-drugs should be made using substances that meet the MHLW's requirements. Although the rules governing each category may vary slightly, quasi-drugs must meet strict standards.
To guarantee the safety and effectiveness of cosmetics and quasi-drugs, ingredient analysis is necessary before registration. The regulatory procedure for quasi-drugs and cosmetics is different.

After obtaining the Marketing Authorization Holder (MAH) license, makers and importers of cosmetics are required to file a notification before they can access the market and sell the product. A local representation or entity must be established by the MAH. It is in charge of Japan's imports of cosmetics. The PMD Act and other pertinent laws and guidelines are followed while labeling. Additionally, labels must be written in the local language, which is Japanese.[16,17]
Competent Authority: PMDA and MHLW

Requirements:
- Companies must submit a safety dossier for approval before placing cosmetics on the market.
- Strict labeling regulations, particularly for "quasi-drugs" (products between drugs and cosmetics).
- Reporting of adverse effects is mandatory for serious incidents.[18]

Key Features
- Quasi-Drugs: Products such as sunscreens, hair growth treatments, and skin whiteners fall into this category, requiring more stringent approval than ordinary cosmetics.
- Mandatory Adverse Event Reporting: Companies must report serious adverse events, creating a structured post-market surveillance mechanism.[19,20]

Challenges
- Compliance Burden: High regulatory burdens on companies to get product approval, particularly for quasi-drugs.[21]
- Cultural Factors: Japanese consumers are highly safety-conscious, creating additional pressure on companies to maintain stringent safety practices.[22,23]

India
India recently updated its cosmetic regulations with the 2020 Cosmetic Rules under the 1940 Drugs and Cosmetics Act.
A cosmetic, as defined by the 1940 Act, is any substance used on the human body for cleaning, beautifying, or altering appearance.
The 1940 Act and its rules regulate cosmetic manufacturing through state-issued licenses and inspections. Cosmetic imports, however, are regulated by a central registration system overseen by the Drug Controller General of India.[24,25]

On August 9, 2024, the Central Drugs Standard Control Organization (CDSCO) revised its regulations for cosmetic registration and import. The new policy allows companies to submit up to 50 products per application through the online portal SUGAM, with multiple applications permitted. The aim is to streamline the process and ensure timely approvals, aligning with the Cosmetic Regulations of 2020.
All cosmetics imported into India must be registered, providing details such as packaging size, variants, and manufacturing locations. To be eligible for import, cosmetics must adhere to the standards outlined in the Ninth Schedule or comply with both Indian regulations and the standards of their country of origin.
Furthermore, cosmetic products must not make false or misleading claims to consumers. By adhering to these regulations, companies can ensure the safe and compliant importation of cosmetics into India.[26]
- **Competent Authority:** Central Drugs Standard Control Organization (CDSCO)
- **Requirements:**
- Mandatory registration of imported cosmetics.
- Post-market surveillance through adverse effect reporting, although reporting is often less structured compared to the EU or Japan.

Key Features
- India has established a cosmetovigilance system that mandates reporting of adverse reactions or safety concerns associated with cosmetic products.
- Manufacturers, importers, and marketers are required to report any adverse events to the authorities.
- Cosmetics cannot be manufactured or imported unless they meet the specifications in the Ninth Schedule or other applicable safety standards.
- Local manufacturing facilities must be licensed, and imported products must meet the regulatory requirements specified for both safety and quality. [27]

Challenges
- **Limited Knowledge:** Operations in the cosmetic industry sometimes suffer from lack of awareness. The players, mainly the small ones, are unaware of some cosmetovigilance requirements, for example, the obligation to report the adverse events and meet post-market surveillance.
- **Cosmetovigilance Systems:** Very few companies in India have systems for monitoring and reporting adverse reactions. It is, as if India, a country which is still in its teenage of development, when compared to the highly developed regions, as Europe and the U.S.[28]
- **Strict Labeling Requirements:** Cosmetic labeling which meets language requisites, product information and safety warnings can be a task for international firms not used to Indian demands.
- **Prohibition on Animal Testing:** Choosing to ban India from using animals for testing cosmetic products is a noble act of ethics but it comes with negative implications for the already traditional tested methods of big companies, especially) if the modern techniques of alternative testing are not available as well as are expensive for them.

- **Access to Alternatives:** A few of the manufacturers may find it hard to get alternative testing methods (e.g., in vitro or computational methods) which are not only environmentally friendly but also easy on the pocket. [3]
- **Misleading Claims:** The killing of false or misleading statements (Rule 36) requires the proper planning of the production labels and brand marketing. The sunless ones. The company should avoid exaggerating entertainment. Moreover, the theme of the people demand perfect appearance and so on. Besides the very fast diet that shall keep you in a good figure.[26]

Suggestions for establishing safety and efficacy of cosmetics in India.

As consumer demand for transparency, safety, and accountability grows, the future of cosmetovigilance is likely to see several developments:

- **Technology-Driven Surveillance:** AI, big data, and digital platforms may streamline global cosmetovigilance reporting and enhance cross-border information sharing.
- **Global Harmonization:** Organizations such as the International Cooperation on Cosmetics Regulation (ICCR) continue to push for harmonized guidelines that can be adopted across jurisdictions.
- **Increased Consumer Participation:** More proactive consumer reporting via mobile apps and online portals will likely play a bigger role in future safety monitoring.

Conclusion

Cosmetovigilance is an evolving field that requires coordinated efforts from regulatory bodies, manufacturers, and consumers to ensure the safety of cosmetic products. While regions like the EU and Japan have well-established frameworks, others, including the U.S., India are still developing their regulatory landscapes. Moving forward, increased cooperation and the use of advanced technologies will be key to creating a more harmonized and effective cosmetovigilance system in India.

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