

RESEARCH ARTICLE

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The Importance of Cosmetovigilance: Enhancing Cosmetic Safety and the Role of Unani Cosmeceuticals in Global Health

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Received: 05 March 2025

Accepted: 31 March 2025

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Published by: OZZIE Publishers
Web: www.ozziepublishers.com



Abstract

Cosmetovigilance, introduced in 1997, is crucial for systematically monitoring cosmetic product safety, aiming to identify and address adverse effects on human health. Despite its global relevance, many countries, including India, lack structured reporting systems for cosmetic-related reactions. As the Indian cosmetic market expands, driven by evolving consumer preferences for functional and specialised products, establishing a formal cosmetovigilance framework becomes imperative to ensure consumer safety. Additionally, the Unani system of medicine offers rich historical insights and natural formulations that serve as effective alternatives to synthetic cosmetics. This study highlights the importance of promoting Unani cosmeceuticals globally, emphasising their benefits such as lower costs and minimal side effects. To achieve widespread acceptance of these formulations, collaboration among researchers, industry stakeholders, and regulatory bodies is essential, alongside implementing a standardised cosmetovigilance system. This dual approach aims to enhance public health and promote sustainable beauty practices.

KEYWORDS: Cosmetovigilance, cosmetic safety, cosmeceuticals, etc.

1. INTRODUCTION

The term “cosmetovigilance” first appeared in French literature in 1997, but it was not widely recognised on an international scale at that time. It can be translated as “surveillance” or “monitoring of cosmetic product safety.” Before delving into this relatively new concept, it is important to clarify what surveillance means and what constitutes cosmetics[1].

Cosmetovigilance refers to the continuous and systematic monitoring of cosmetic safety concerning human health. Its goal is to identify adverse effects of cosmetic products and implement preventive measures when necessary. Regulations for cosmetics focus mainly on ensuring the safety of products intended for large groups of healthy consumers. Currently, the industry primarily leads the identification and analysis of adverse effects. Manufacturers are responsible for ensuring the safety of their products and ingredients before they hit the market, as well as for collecting reports of any adverse reactions[1]. Cosmetovigilance is a form of health

surveillance (table 1), i.e. public surveillance which deals with public health objectives [2].

Cosmetics

The Federal Food, Drug, and Cosmetic Act (FD & C Act) defines cosmetics based on their intended use 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.” This definition encompasses a variety of products, including skin moisturisers, perfumes, lipsticks, nail polishes, eye and facial makeup, shampoos, hair dyes, toothpastes, deodorants, and any materials intended to be used as components of cosmetic products. FD & C Act is a law that governs the safety and quality of food, drugs, cosmetics, and medical devices in the United States. Enacted in 1938 in response to a tragic incident involving a toxic elixir that resulted in the deaths of many, including children, the FD & C Act aims to protect public health[1,2].



Figure no. 1: Definition of health surveillance

Health Hazards Associated with Chemicals Used in Cosmetic Formulation[3-5]

Heavy metals that accumulate in the body can lead to serious health issues. These metals pose risks such as cancer, reproductive and developmental disorders, neurological problems, cardiovascular and skeletal issues, and damage to

the blood, immune system, and kidneys. Symptoms of exposure include headaches, vomiting, nausea, diarrhea, and lung damage. They may also cause contact dermatitis, brittle hair, and hair loss[5].

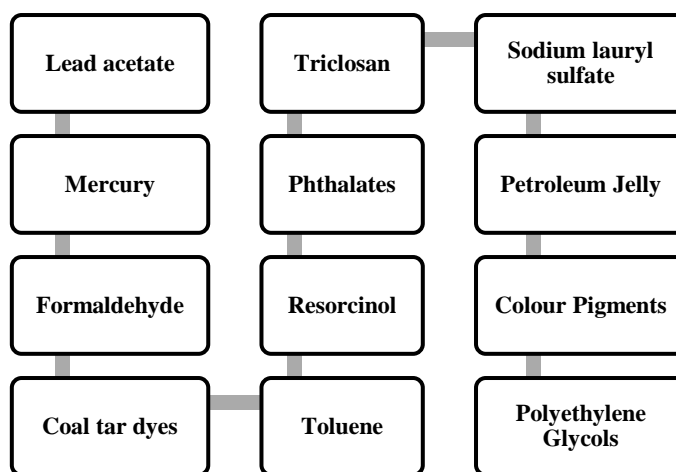


Figure no. 2: Heavy metals & chemical used in cosmetics[5]

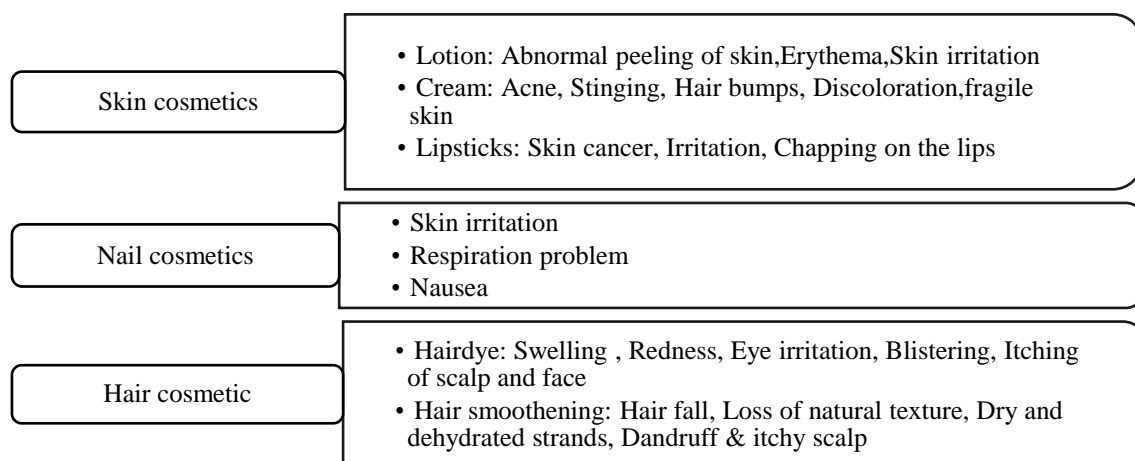


Figure no. 3: Adverse effect of cosmetics[6-8]

The concept of cosmetovigilance ensures the safe use of cosmetics across the country, preventing side effects and adverse reactions from going unreported. This is why many European countries, the United States, and some East Asian nations have begun implementing measures in this area. In India, regulatory guidelines for certain aspects of cosmetic

products can be found in the Drugs and Cosmetics Act of 1940.

Certain toxic chemicals are banned from use in cosmetic products due to their proven toxicity. For instance, the use and import of arsenic and lead compounds are prohibited.

under rules 135 and 145, while cosmetics containing mercury are banned according to rules 135A and 145D. Rule 134-A prohibits the import of hexachlorophene-containing cosmetics. Certain standards have also been defined for the color, dye or pigments that are used for the cosmetic products. There are various sections outlining rules for the regulation of cosmetics, covering aspects such as import and registration, manufacturing processes, labelling, packaging, and standards. According to Gazette notification G.S.R 426(E), cosmetic products are classified into four major categories: (i). Skin products (ii). hair and scalp products (iii). nail and cuticle products (iv). products for oral hygiene[12]. Misbranded and spurious cosmetics are not very uncommon. Misbranded cosmetics are defined as any cosmetic that contains any unprescribed color, inappropriate labelling or false/misleading product information[13]. Unfortunately, there is no established system of reporting adverse drug reactions from cosmetic products.

Cosmetovigilance worldwide

The U.S. FDA requires proper labelling and purity of cosmetics before marketing. In Europe, the Council advised member countries to implement systems for tracking adverse effects of cosmetics, resulting in cosmetovigilance systems in Belgium, Norway, Sweden, Denmark, Germany, and Italy. The Netherlands Food and Consumer Product Safety Authority and the Ministry of Health also committed to monitoring harmful effects and establishing a cosmetovigilance network[9,10].

Need for Cosmetovigilance in India

The Indian cosmetic industry is mature and growing in the context of product development and marketing because consumers' preferences are changing from simply cosmetic to more functional, advanced and specialised products. India is the fourth largest cosmetic market in the Asia Pacific region after Japan, China and South Korea. The unwanted or adverse reactions due to cosmetic products are very low or go unnoticed due to a lack of a proper, organised reporting system. In India, as far as drugs are concerned, there is a post-marketing vigilance system that usually focuses on adverse reactions of drugs,

recently much consideration is given to medical devices, blood products, biologics, special nutritional and natural products, whereas less attention has been addressed to adverse reactions related to cosmetic products. In general, the surveillance of cosmetic products that are placed on the market is called cosmetovigilance. Post-marketing vigilance systems for cosmetics differ from country to country. In the United States, a consumer can report a cosmetic-related problem to the FDA. Consumers reported information that helps the FDA monitor the safety of cosmetics on the market. In Mercosur (Argentina, Brazil, Paraguay, Uruguay, and Venezuela), cosmetic companies/importers are requested to evaluate and keep a cosmetovigilance report. In Europe, the cosmetovigilance system is developing at a fast pace. Few countries have a formal post-marketing cosmetovigilance system, and some have an informal one. Germany and Sweden are the two countries that have a formal cosmetovigilance system. In formal cosmetovigilance systems, the regulatory authorities are responsible for the collection of adverse reactions to cosmetics (ACRs) by different professional categories like medical practitioners, general practitioners and public health services. Based on Germany and Sweden's cosmetovigilance systems, India can establish a formal cosmetovigilance system, which could enhance the safety of cosmetic use in the future and is crucial for protecting public health[1,6,11].

Cosmetovigilance centers

The WHO has established the world-based Cosmetovigilance centre in Sweden (Uppsala Monitoring Centre). In India, the headquarters of the Cosmetovigilance Central Drug Standard Control Organization (CDSCO) is in New Delhi. CDSCO regulates the approval of new drugs and clinical trials, banning drugs and cosmetics, regulating import registration and licensing, etc.

Reporting Process and Function of Cosmetovigilance in India

The country has established a cosmetovigilance system to safeguard the population from potential harm posed by certain new cosmetics. Recognising the scale of this responsibility, the Central Drug Standard Control Organization has launched a comprehensive and collaborative National Cosmetovigilance Program[2].

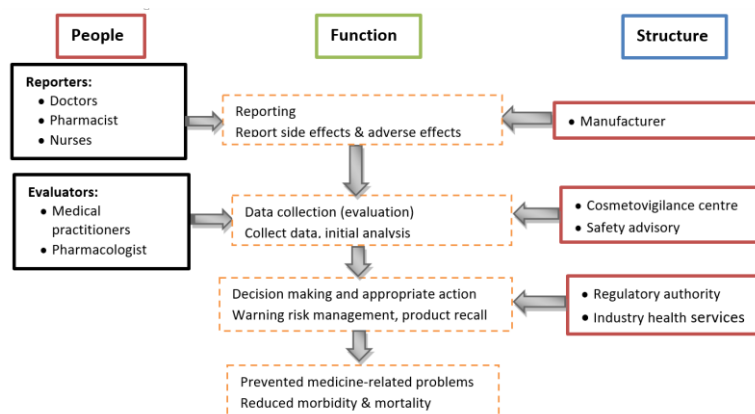


Figure no. 4: Reporting process and function of cosmetovigilance in India

Cosmetics and cosmeceuticals in the Unani system of medicine

Contrary to the common belief that cosmetics are a modern invention, historical evidence shows that Arab physicians established a foundational branch of medical science known as *Ilm-ul-Zeenah* (the science of beauty, or cosmetology) long before contemporary cosmetic products were developed. The teachings of Prophet Muhammad (pbuh) have significantly influenced this field, advocating for the use of beautifying substances, especially perfumes. This study aims to explore the concepts of cosmetics and perfumery within the Unani system of medicine, as well as the potential practical applications of Unani cosmeceutical formulations. Extensive descriptions of various forms of cosmetics and perfumeries can be found in the rich classical literature of Unani medicine[14].

The history of cosmetics and beautifying agents dates back to the dawn of civilisation. In ancient times, people used animal fat as a moisturiser to keep their skin supple. Archaeological evidence reveals that cosmetics were utilised in both ancient Egypt and Greece[15].

In ancient Egypt, skincare relied on natural ingredients such as castor oil, beeswax, olive oil, milk, and rose water. The ancient Greeks also embraced cosmetics, using olive oil (*roghan-e-zaitoon*) as a moisturiser and applying a paste of bread soaked in milk to their faces overnight as an anti-aging treatment. During the *Misri tib* or Egyptian medicinal era, the use of kohl and henna was well-documented in North Africa. To treat scars and burns, a special ointment was created using red ochre, kohl, and sycamore juice. Remedies for wrinkles included ingredients like frankincense gum and fresh Moringa. An alternative treatment involved a poultice made from carob grounds and honey or an ointment containing honey.

Additionally, Africans chewed licorice root sticks, a practice that continues today for freshening breath. These ancient practices laid the groundwork for many modern skincare rituals[14]. Arab physicians elevated cosmetics to new heights, coining the term "*adviya e muzayyana wa moattara*," which translates to cosmeceuticals and perfumery. The use of natural substances for beauty has existed since humans began utilising cosmetic products.

Unani Cosmeceutical Preparations Based on Site of Use[16]

In the Unani system of medicine, there is a wide variety of preparations derived from natural sources specifically for skincare. Traditional literature on Unani medicine includes numerous formulations, which are categorised as follows:

- **Ghaza:** A fine, aromatic powder that is applied to the face and body to improve complexion.
- **Ghamra:** Moisturizing agents
- **Ghaliya:** Talcum powder
- **Ghusool:** Cleansing products

- **Ubtan:** Exfoliating pastes, emollient
- **Kuhāl:** Eye cosmetics
- **Khizab:** Hair dyes
- **Nura:** hair remover
- **Surma:** Traditional eye kohl
- **Roghan:** Oils for skin and hair
- **Marham:** Ointments
- **Tila:** Herbal oily preparation
- **Zimad:** Therapeutic pastes

These formulations reflect the rich heritage of Unani medicine in promoting skin health and beauty.

Need for cosmetovigilance in the Unani system of medicine:

Unani cosmeceuticals offer a natural alternative to synthetic products. Numerous formulations can be found in classical texts, highlighting their historical significance. The advantages of Unani cosmetics include lower costs, minimal side effects, ease of preparation, and safety for users. Given these benefits, Unani cosmeceuticals have a promising future compared to synthetic cosmetics. Now, it is essential to promote Unani cosmeceutical formulations globally as a natural approach to beauty. This can be achieved through systematic research and development efforts, which necessitate active collaboration among scientists, technologists, the cosmetic industry, and government organisations. To achieve global acceptance of Unani formulations, a standardised cosmetovigilance system is essential[17].

Conclusion

Cosmetovigilance plays a vital role in ensuring the safety and efficacy of cosmetic products, protecting public health in an increasingly diverse and evolving cosmetic landscape. As the Indian cosmetic market continues to grow and consumer preferences shift toward functional and specialised products, establishing a structured and organised cosmetovigilance system is necessary. This system would enable better monitoring of adverse reactions and enhance consumer confidence in cosmetic safety. Moreover, promoting Unani cosmeceuticals as a natural alternative to synthetic products can further benefit public health and offer a sustainable approach to beauty. Collaboration among stakeholders, including scientists, industry professionals, and regulatory authorities, will be crucial in implementing effective cosmetovigilance measures and advancing the global acceptance of Unani formulations.

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