

Integrating Cosme to vigilance into Pharmacy Practice: A Clinical Pharmacist's Perspective

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Abstract

According to the Drugs and Cosmetics Act of 1940, cosmetics in India comprise items for oral hygiene, skin, hair, and nails. Despite rules, dermatitis and other Adverse Cosmetic Responses (ACRs) are nevertheless frequent. Underreporting of ACRs is a result of both low customer awareness and a lack of pre-market testing. It is recommended to solve this by putting in place a cosmetovigilance framework similar to the French ANSM system. Presentation of the Case:

After utilizing a recently released herbal cosmetic lotion, a 35-year-old woman experienced severe face dermatitis. She had no prior medical history of allergies or skin disorders. Patch testing and clinical analysis revealed hypersensitivity to an unidentified product component. The patient recovered fully in two weeks after the lotion was stopped and topical corticosteroids and antihistamines were administered. A healthcare provider submitted a structured adverse event report, and the manufacturer was notified of the incidence. Discussion and Conclusion: This case draws attention to regulatory shortcomings in India, specifically the lack of proper product labeling and required pre-market safety testing. A coordinated framework for cosmetovigilance can help stakeholders monitor ACRs together and enhance post-market surveillance. When it comes to reporting, informing consumers, and encouraging safer cosmetic procedures, clinical pharmacists are essential. Cosmetovigilance can greatly improve the regulatory environment and lower the incidence of adverse event reports (ACRs) in India by promoting adverse event reporting.

1.INTRODUCTION

The Drugs and Cosmetics Act, 1940, defines "cosmetics" as any article intended for application to the human body for purposes such as cleansing, beautifying, enhancing attractiveness, or altering appearance, including any component designed for use in cosmetic products. This broad general definition encompasses a whole range of products containing cosmetics such as skin care, hair care, nail and cuticles, and oral hygiene. Through the Gazette Notification G.S.R 426(E), the government of India has further categorized cosmetics into four categories; skin care products; hair and scalp products; nail and cuticle products; and oral hygiene products. These main categories consist of several subcategories. Therefore, the very exhaustive list of the cosmetic industry is covered.^[1] Although most cosmetics are safe, they can elicit adverse reactions, and contact dermatitis is one of the most common symptoms. A five-year investigation of 1609 participants was conducted and indicated that 12.2% of the individuals suffered from adverse reactions, majorly. The symptoms were described as itching, dryness, and burning sensations. The cutaneous reaction had its manifestations in slight scaling and redness to blistering. Other issues

such as irritation of the eyes, respiratory problems, and swelling of lymph nodes have also been linked to cosmetic use. Hair dye is one of the leading causes of dermatitis in India. Other parts of the world experience cases of dermatitis due to kumkum and bindi.^[1,2] Nevertheless, cosmetic regulations are given first priority while ensuring consumer safety because these products are intended to be used by healthy persons. Cosmetic products do not have pre-market testing for safety and efficacy by regulatory bodies like that with their pharmaceutical drug equivalents.^[3] At present, the reported number of adverse reactions to cosmetics is very low. This could be because of a variety of reasons; such as lack of medical consultation before the use of cosmetics, self-medication practices, and underdiagnosis by healthcare providers. Even when patients consult the doctor, ACRs in a large number of such cases are underestimated as contributing factors towards the development of skin conditions. Thus there is a substantial gap in understanding the types and prevalence of ACRs within the population. Because of an insufficient reporting, collection, and analysis system, we cannot even assess the impact of cosmetic products on the skin.^[4] Since 1999, the French Health Products Safety Agency (formerly Afssaps, now ANSM) has overseen the safety of

cosmetic products in France. They were in the process of developing a post-market surveillance system, called cosmetovigilance, to monitor the safety of cosmetics after they had been released to the market. The purpose of the Cosmetovigilance system is to monitor the safety of cosmetic products. Its mission includes the management of public health risks associated with certain components like animal ingredients, glycol ethers, aluminum, and camphor. Furthermore, its aim is incorporating adverse reactions standardized reporting forms to have a systematic evidence gathering of the given problem. Finally, the system carries out routine and emergency laboratory controls to ensure the quality and safety of cosmetic products.^[5]

2. COSMETOVIGILANCE IMPLEMENTATION

Cosmetovigilance system was established for the regulation of adverse cosmetic reactions that relies on a few major methodologies to enable the detection and handling of cases effectively. some methods of an effective cosmetovigilance system include-

1) Case Collection and Reporting by Health Professionals

The core of cosmetovigilance is the case collection, which focuses on adverse events related to cosmetics. However, health professionals are highly valued as they report adverse cosmetic reactions they come across. It also has the further benefit of not only improving the care of patients but also strengthening public health data to form a base for understanding the safety of the product and how to prevent harm.

2) Community and Clinical Pharmacist Involvement and Consumer Participation

Questionnaires may be offered by community pharmacists and clinical pharmacists to consumers to gain live, off-the-street feedback on consumer reactions to cosmetic products. Surveys may be administered by pharmacists at busy times to maximize the number of responses generated. A similar study conducted by Di Giovanni C et al. resulted in Ten pharmacies canvassing over 4,000 consumers in a matter of 15 days in one survey; although some refusals were involved, such data can be invaluable.

3) Consumer-Initiated Reporting

Direct reporting from the consumer is also a very important area. Consumers are allowed to immediately report any adverse drug experience they may experience. To ensure that these would be devoid of inaccuracies, however, they should be consulted, first and foremost, with healthcare providers. The further step will, thus, help solidify the total quality of the data.

4) Manufacturers' role in cosmetovigilance

They have a strategic role in cosmetovigilance as they maintain active post-market safety surveillance of their products. They will create easy-to-use reporting mechanisms for consumers, collect and analyze adverse cosmetic reactions, or ACRs, and monitor risks related to an ingredient or batch of products. Manufacturers will collaborate with health authorities, report serious ACRs, and make the regulatory system more open to the public and safe for them.^[6]

5) Survey Method:

As a study conducted by Sautebin L, The standardized questionnaire was sent via e-mail to cosmetovigilance authorities in 28 countries. In direct responses, 10 countries returned information regarding their cosmetovigilance activities. Eight countries forwarded the questionnaire to more appropriate contacts; replies from such contacts were returned from 4 other countries. Useful responses towards the collection of data have been received from 50% of the countries that were surveyed.^[7]

6) Internet for cosmetovigilance

Study by Polimeni G created a website(farmacovigilanza.org) that supports cosmetovigilance by offering reliable, timely drug and cosmetic safety information in Italian, tailored to the needs of healthcare professionals. Dedicated sections on cosmetics and herbal products

provide focused resources, enhancing users' awareness of adverse reactions. Surveys reveal that the majority of users find the site informative and objective, with over 85% noting improved safety practices, including increased vigilance regarding drug interactions and cosmetic safety. This approach meets regional demand for accessible safety information and serves as a potential model for similar initiatives in other countries.^[8]

3. CHALLENGES IN COSMETOVIGILANCE

Regulations vary globally, with the EU enforcing strict guidelines compared to limited FDA oversight in the U.S., leading to uneven safety standards.^[9] Consumer underreporting is common, often due to low awareness and the perception of cosmetics as low-risk, which limits adverse event data.^[10] The increasing complexity of ingredients, particularly with new and "natural" compounds, adds to the difficulty of identifying harmful agents, while the long-term effects of these ingredients are often unknown. Limited centralized reporting systems, especially in areas without strong regulations, and conflicts of interest within the industry further complicate data collection and analysis, potentially delaying safety signal detection. Improving public awareness, standardizing reporting systems, and ensuring independent oversight could strengthen cosmetovigilance and enhance consumer safety.^[10]

4. ROLE OF CLINICAL PHARMACIST

Due to the extremely low doctor-to-patient ratio, patients are more likely to be duped by false information and quackery. The clinical pharmacist can be quite helpful in circumstances where the busy clinician lacks the time to discuss the negative effects of extended unsupervised usage.

With a PharmD or MPharm in Pharmacy Practice, a clinical pharmacist is qualified to monitor and explain the long-term effects of medications, which is essential in reducing abuse and misuse. They can offer prompt advice on adverse occurrences from their position at the patient interface, assisting in the safer direction of healthcare. Given that clinical pharmacists have been found to improve healthcare outcomes, involving them in patient care will free up dermatologists to concentrate more on their clinical duties. Dermatologists must acknowledge their importance and successfully incorporate them into the treatment team.

Disseminating instructional information, planning awareness campaigns through the media, and educating patients and healthcare professionals about the negative effects of drugs are important ways to prevent unsupervised drug use. In order to prevent abuse and lower medical expenses, clinical pharmacists can play a key role in treatment, rehabilitation, and the creation of adverse event notification systems. Notably, the IADVL taskforce has influenced government policies such as the prohibition on Steroid-Containing Fixed Drug Combinations, which has helped combat topical steroid abuse in India. Addressing drug abuse and enhancing healthcare delivery, especially in poor nations, requires a multidisciplinary approach that actively involves clinical pharmacists.^[12]

5. CONCLUSION

The safety of cosmetics and their potential side effects especially due to the pre-marketing limit of testing makes cosmetovigilance an important aspect of public health. This is in spite of regulation; for example, that found in the Drugs and Cosmetics Act of India, existing loopholes continue to expose consumers. Due to variation in national speeds in ethical health care practice, reporting adverse events especially related to cosmetics is very low. Assessing the impact of any safety monitoring mechanism such as cosmetovigilance requires teamwork among healthcare providers and consumers/manufacturers but most importantly, clinical pharmacists who are at the forefront in terms of informing and assisting the consumers. Therefore, there is need to raise the public awareness improve the mode of reporting, and bring about the third eye to other relieve the burden of health risks caused by beauty products.

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