

Review of the Cosmetovigilance System in Ayurveda in order to Monitor Cosmetic Product Safety.

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Abstract— Due to ongoing surveillance system which is basically meant for the safety of cosmetic products, Cosmetovigilance is gaining worldwide recognition. This review will thus help in providing crucial public health initiative, in order to explore about the current state of cosmetovigilance, by helping in the field of detection, assessment and prevention of most of the adverse reactions which are associated with cosmetic product usage. Thus, an increasing consumption of cosmetic products for personnel use will further necessitate the importance of public health initiatives in order to keenly monitor all types of adverse reactions which can threaten the life, ranging directly from localised impact like minor skin allergic responses to long-term generalised systemic effects. This paper will also help us in examination of not only the existing framework, but also help us to discuss the need for harmonized global standards methods which are used to create increased awareness among consumers in order to know about the side effects of cosmetic products and ensure their safety. Hence the focus should be will totally on the proactive approach in order to analyse the existing frameworks and highlight the harmonized global standards & consumer awareness in order to ensure consumer safety and support innovation in the cosmetic sector, thus fostering cosmetic industry in india.

Index Terms— Cosmetovigilance, causality assessment, adverse effects, assumption, consumer safety.

I. INTRODUCTION

Cosmetovigilance is basically made up of two words i.e “Cosmeto” (meaning cosmetic products) and “Vigilance” (meaning awareness). Thus, Cosmetovigilance system is that system which deals with the genuine ways of obtaining information on the safety of these products and their ingredients, which in turn leads to high level of safety among public domain. The 2006 European resolution has laid the ground work for a Cosmetovigilance system based on case

notifications. As of 2013, the new European regulation requires that serious undesirable effects reported to the competent authority should be transmitted to the competent authorities of the other Member States and to the person responsible for the cosmetic product. Although in india, Cosmetovigilance specially in the field of Ayurveda is a new term, but once it occupies the whole market, it will become the best way to set our minds at ease about the products and their potential hazards being placed on the market. Although the history of cosmetic use with an assumption that “natural is safe”, dates back millennia, leading to the underreporting of adverse reactions of these products, has now gained traction through the formal system of Cosmetovigilance recently in the late 20th and early 21st centuries. Post-marketing surveillance of these cosmetic products, is very- very essential in order to ensure consumer safety. Despite its importance, there is yet no structured cosmetovigilance system specifically tailored for Ayurvedic formulations, which takes important factors like causality assessment and reporting categories into their consideration. The global cosmetics market is today experiencing a major shift towards Ayurvedic cosmetics, used for beauty enhancement. Although traditionally perceived as safe, but if proper way of administration or preparation is lacking, even the herbal cosmetic products are not free from risk. Most of the Cases of skin irritation, contact dermatitis etc go undocumented due to the absence of a structured monitoring system. In our Ayurveda classics, the concept of drug safety and efficacy although is rooted in classical texts under different terms like Shodhana, Anupana, Matra or Desha-Kala, but still if we talk from modern surveillance structure, there is a lacuna of proper reporting system.

II. METHODS

In this Review article, data is collected from secondary sources like Scientific publications (PubMed, Scopus, and Google Scholar), WHO, CDSCO, Ministry of AYUSH documents & reports, EU and FDA regulations on cosmetovigilance, Ayurvedic pharmacopoeias and textbooks and in last but not least from Case reports from Ayurvedic clinical practice. Out of so many important publications, we can take the example of publication entitled Comparative analysis done between global cosmetovigilance standards (e.g., EC Regulation 1223/2009) and the Indian AYUSH regulatory framework¹, including the Drugs and Cosmetics Act, 1940, and Drugs and Magic Remedies Act, 1954. Due to Variability in the quality of raw materials, processing techniques and storage conditions, even the safe cosmetic products lead to inconsistent product safety concern due to various adverse effects, which we need to check and report timely, before it's too late.

III. RESULTS

Cosmetovigilance system is that system which deals with the genuine ways of obtaining information on the safety of these products and their ingredients, which in turn leads to high level of safety among public domain. But from the above literature, it's well cleared that there are so many current challenges⁵ in the path of cosmetovigilance which we need to consider now, before it's too late. These are as: -

1. Lack of Specific Cosmetovigilance cell in Ayurveda: We all know that Ayurveda drugs are regulated under the Ministry of AYUSH, but still till date there is no specific cosmetovigilance reporting system for Ayurvedic cosmetic products. Hence, we should focus more and more on developing such cells, so that proper documentation⁴ of safety of these products can be done with the establishment of a structured monitoring system.
2. Underreporting of Adverse Reactions: Thinking Ayurvedic products are safe, most of the consultants and consumers do not report adverse reactions. Hence most of the reported cases come through dermatological books or journals⁶ or published case reports in reputed journals, but not from any official surveillance channels.

3. Lack of Drug Standardization: Inconsistent composition, Lack of batch-to-batch uniformity, Poor labelling, Misbranded or spurious products, Variability in the quality of raw materials, processing techniques, and storage conditions are some of the factors which leads to the question of drug standardization which in turn further leads to inconsistent product safety.
4. Global Comparison: Due to the exponential growth of the cosmetic industry, the need for robust cosmetovigilance systems has become increasingly vital across the globe. Hence global comparison has become an important part in order to maintain the standards of cosmetovigilance. For example, in Europe², robust cosmetovigilance mechanism includes mandatory reporting of serious undesirable effects. Similarly in USA³, FDA's MoCRA 2022 mandates reporting of serious cosmetic adverse events. But as far as India is considered Cosmetovigilance is although part of pharmacovigilance under CDSCO, but Ayurvedic cosmetics are not included.
5. Need of the hour: -If we go through the current Market Trends, we will be surprised to see that The Indian Ayurvedic cosmetics market is almost to reach INR 500 billion by 2026, which in itself is red flag for the urgency of establishing safety protocols of cosmetic products.

IV. DISCUSSION

Ayurvedic cosmetic products do fall into a regulatory grey area in many countries, especially if we talk about India where although Ayurveda is officially recognized with global market to reach INR 500 million by 2026, still lacks regulatory clarity or in other words, we can say, it is still evolving. The "Nidana Parivarjana" concept of Ayurveda emphasizes prevention, but modern applications require systematic safety evaluations of cosmetic products, which often straddle the line between three different heading like Drugs (therapeutic intent), Cosmetics (external use without therapeutic claims)& Traditional Remedies (cultural/ritualistic use), which in turn blurs regulatory classification as many cosmetics contain medicinal herbs (e.g., Kumari, Haridra, Chandan), claiming therapeutic actions like "cures acne" etc, which under drug laws, would require drug approval. Keeping above difficulties in

mind, there is an important need to Establish a Cosmetovigilance Wing in AYUSH followed by well-developed ADR Reporting Forms tailored to Ayurveda-based products and integrated into clinics and Panchakarma centre's & mass awareness.

V. CONCLUSION

The assumption that Ayurvedic cosmetic products are inherently safe has led to a there is an important need to establish a Cosmetovigilance Wing in AYUSH followed by well-developed ADR Reporting Forms tailored to Ayurveda-based products and integrated into clinics and Panchakarma centers & mass awareness in order to enhance the safety, credibility, and global acceptance of Ayurvedic cosmetic products.

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