



Review Article

A comprehensive review of cosmetovigilance practices and trends

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Abstract

Cosmetovigilance is a critical and well maintained platform to focus on the monitoring, assessing and preventing adverse effects associated with cosmetic products. Now globally the cosmetic industry is expanding so in order to ensure the safety and efficacy of such cosmetic products there should be a surveillance system which is the cosmetovigilance. Key elements are adverse event reporting, signal detection, and post-market surveillance. The article is expanding to global regulatory approaches, compared with European Union regulatory affairs. The main challenges faced are underreporting, varying regulatory standards, and the rise of unregulated online markets. The usage of digital tools, artificial intelligence, and big data analytics are discussed as transformative solutions to enhance cosmetovigilance systems. When this has been established then everyone should follow the guidelines including manufacturers, healthcare professionals and consumers too. The review underscores the need for harmonized global standards and increased consumer awareness to bridge existing gaps. By promoting proactive safety measures and transparency, cosmetovigilance not only safeguards public health but also supports innovation and trust in the cosmetic industry.

Keyword: Cosmetovigilance, Adverse event reporting, Cosmetics, Regulatory affairs

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1. Introduction

Cosmetovigilance is a branch of science that deals with the study of Adverse Cosmetic Reaction (ACR) that include the process of collecting, evaluating, and monitoring of ACR and also reporting of undesirable adverse events that are occurred during the usage or after the usage of a cosmetic product.¹⁻²

The term “cosmetovigilance” was first used in Vigan (1997) as part of post marketing surveillance. Cosmetovigilance was first introduced by the French health products safety agency for the pharmacovigilance system of cosmetics.³⁻⁴

The below table will give an idea on the steps of monitoring and reporting.⁵

The main objective of cosmetovigilance is to allow the manufacturing industries and the consumers to know the adverse reactions and will get rid of those adverse reactions and to make the product safer.⁶

Adverse Effect reporting	Establish point of contacts
	Adverse effect report forms
Assessment of reports	Signal detection
	Evidence evaluation
	Causality/ frequency/ severity
	Validation
Risk management	Benefit -risk assessment
	Safety alerts/ recalls
	Changes to product information
	Monitoring

This is achieved by changing the formulation composition, changing the usage method if needed, and recalling the product.⁷

By these all methods we can make a regulation same all over the world and can improve the trust between the user and manufacturer and also to protect the public health. Frequent monitoring should be carried out on cosmetics to

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know the Adverse Cosmetic Reaction (ACR) to produce a safe and efficient product by following the regulatory requirements.⁸⁻⁹

Martine Vigan and Florence Castellani (2015): Here Cosmetovigilance is said to be a recent concept. The term Cosmetovigilance has already been listed. This was introduced as a part of a surveillance program for ensuring the safety of public health who use cosmetic products and also Cosmetovigilance is not like other surveillance carried out by industrialists, where their aim or objective is for ensuring the safety of commercial products. In 2006 European Regulation started a surveillance system that is cosmetovigilance on the basis of cases reported. Then in 2013 the New European Regulation decided that if any serious undesirable effects reported by any of the consumers then it should be informed to all the other regulatory authorities and the person who was affected by the side effect. It is said that there are two problems that aren't solved yet they are causality assessment and reporting categories. Cosmetovigilance systems are a good platform for recognizing the safety of cosmetic products and the API used in them. This can be used in Europe for ensuring the safety of cosmetic products. Cosmetovigilance helps to avoid the unwanted adverse effects caused by cosmetic products ingredients by regular monitoring.¹⁰

Joanne G. W. Saavedra et al (2013): In this study it is found that usage of cosmetic products is leading to Contact Dermatitis. Like Europe, the Netherlands also built a platform or an area to report the undesirable effects of cosmetic products. The main objective of this study was to provide information regarding the adverse effects that can be caused by cosmetic products and the ingredients that are used to formulate those cosmetic products. It also observed that the current EU legislation provides all the information and ensures the safety of public health. Here in this study general practitioners and Dermatologists and the consumers in the Netherlands have created a questionnaire based on the Adverse effects that have been reported in their country. Dermatologists carried out various patch tests and other quality checks for ingredients used in the preparation of those cosmetic products. A website and a public awareness program were introduced to let the consumer know about the adverse effect and reporting methods. The result of the study was observed in between July 2009 to May 2011 where there were more than 1600 cases with severe adverse effects ranging from 1-4%. In the study the adverse effect caused by cosmetic products was make-up and moisturizers. And the main ingredient was found to be isothiazolinones and fragrance ingredients and when three patients were subjected for testing found to be positive for co-polymers.¹¹

Trivedi et al (2021): The study reported that the usage of cosmetic products in the world has increased for a few previous years. Actually, cosmetic products should be used for the purpose of changing the appearance for good looking

but nowadays it is being used for other purposes more than beautifying. Cosmetic is defined in various ways in different countries. This chance is taken as an advantage by the cosmetic industries for their growth. The cosmetics are formulated by various chemicals and pharmaceutical agents the longer duration of usage can lead to many side effects that may be major or minor adverse events. Nowadays cosmetic products formulation also includes various heavy metals that can cause dermatological problems as well as slowly lead to systemic adverse events. In some anti-ageing preparation, some pharmacologically active agents are used that have certain chemical properties which may be toxic to the human body. Western countries have implemented some guidelines and regulations for the manufacturing of cosmetic products, their labelling and packaging also. By the application of Cosmetovigilance we can enhance safety of the cosmetic products being used by the consumers. In India according to The Drugs and Cosmetics Act there are regulations to be maintained for the formulation of a cosmetic product and also there should be a reporting system for the adverse event that occurred from cosmetic products for ensuring the safety of public health.¹²

Lidia Sautéing et al (2008): In this study he reported that cosmetics and toiletries are very common in public and their usage is increasing mainly because of all of the need to be physically attractive and, at the same time, these products are considered to be safe. Even though they are safe and well-tolerated, they learned in recent years that they can have serious side effects. The number of adverse effects reported is too low, this is mainly because of thus are underestimated as a result of self-diagnosis and self-treatment, which are common in mild-to-moderate conditions, as in the case of cosmetics. Moreover, such effects are underestimated because of the absence of proper monitoring systems like cosmetovigilance. Thus, requires the creation of a reporting form, as well as resolution concerning professional categories to report and the further validation of the collected forms. Thus, are all not only to investigate but also to prevent risks caused by cosmetic use. A pilot project was developed to test the effectiveness of a thus system by the validation of either a reporting form or the role of physicians and community pharmacists as reporting categories. Collection of reporting forms began in July 2006 and it is still in progress. In conclusion, their experience regarding the notification of adverse effects of cosmetics, however limited to restricted area, indicates that an effective monitoring system is essential for protecting public health. This system should provide education and training for all representative, including health professionals, consumers, and relevant authorities.¹³

Kisha M Lucca et al (2020): In this study it reported that cosmetovigilance is a public health surveillance based on cosmetic products and the main objective is public health safety in Saudi Arabia. There is a wide radical development in Saudi on beautifying products. To ensure the safety of cosmetic products the Saudi food and drug authority takes all

the responsibilities and they aim to assess self-reported adverse reactions on cosmetic products in the public health. To achieve this, they conduct a three-month cross-sectional study by preparing a questionnaire for data collection which is a modified form of previously conducted studies for cosmetic utilization and adverse reactions. In this study almost 425 participants and 50.6% reported that in the past 2 years at least one adverse reaction occurred. The commonly reported adverse reactions are redness of skin 19%, itching 13% and pimples 15%. The majority reported adverse reactions are in hair care and skin care products about 29% and 25%. The main importance and objective of cosmetovigilance is monitoring the safety of cosmetic products.¹⁴

Geetika Mehta et al (2024): In this article state that the main reason for the growth in the cosmetic industry is follow up of cosmetics to improve the attractiveness and also recognize that minimal use of cosmetics may also lead to harmful consequences for both the overall wellbeing and the board community. The main objective of these study was providing information about the usage pattern of skin care product to consumers and to determine the prevalence and cosmetic related adverse events. The main method for these studies was conducting a four-month cross sectional study in a satellite city of the national capital region (NCR) of India by preparing a questionnaire and get the data from 435 respondents then they analyzed using frequencies and percentage. In the 435 respondents 32.9% experienced at least one adverse effect on the use of skincare products the prevalence was higher in females about 36.6% and the mainly reported adverse reactions are hair loss, allergies and dry skin. The majority of reported adverse reactions due to the use with soap (21%) then shampoo (17%) The main aim of conducting the study was to improve the system efficiency, widely spread the information on cosmetovigilance and promote the reporting of any adverse effect.¹⁵

Carmen di Giovanni et al (2005): cosmetics are the products which are applied topically in order to wash, to perfume or to improve the look. However, the adverse reaction is very low due to underreporting. Adverse reaction mainly occurs due to self-diagnosis and self-medication. Generally adverse drug reactions due to cosmetics are not serious and are often considered as alterations of skin. Aim of the study was to access the prevalence and characteristics of adverse cosmetic events which acquired through the questionnaires provided by the pharmacist to the customers. 4373 subjects were interviewed and 845 of them refused to fill the questionnaire. Total adverse cosmetic event reported were 1507 out of which 18.2% of them reported more than one event. 98.5% of them reported to use cosmetic products. Females responding to questionnaires were 2716 and 812 males and so on. The study was concluded on suggesting that there should be a proper system for report, collect and evaluate the adverse reaction as higher number of consumers are present for the cosmetic product.¹⁶

Hale Z Tolu et al (2019): According to this study Pharmacovigilance is defined as the collection, detection, monitoring and prevention of adverse drug reactions (ADR) that occur from medications. Now the surveillance system to monitor the drugs has been enhanced for herbal and cosmetic products. So cosmetovigilance is the surveillance system that is used for the monitoring of adverse reactions that occur due to cosmetic products. In literature Vigan was the first to use this term in 1997 to monitor and ensure the safety of products. Now it is considered to be globally accepted for ensuring the safety of cosmetic products and to enhance public health.¹⁷

Sachdev Yadav et al(2024): In this study it is reported that to provide proper examination of four critical surveillance systems such as pharmacovigilance, cosmetovigilance, hemovigilance and materiovigilance. In order to ensure the safety of medicines, cosmetics, medical products and blood products their surveillance systems are being examined and evaluated. They mainly focus on problems and regulatory framework in their appropriated sectors. Exclusive significance is to guarantee public safety and health. Thereby it helps to improve overall health across the different product. Pharmacovigilance is an important part of healthcare that helps to monitor and assess safety of the products which is performed by a unified work of regulatory agencies, healthcare professionals and pharmaceutical industries and thereby enhancing the effectiveness of product in the patients. Hemovigilance mainly focus on monitoring and ensuring the safety of blood and blood product transfusions. cosmetovigilance involves the monitoring of adverse effect of the product and thereby ensuring the safety of the product. Materiovigilance is the monitoring and management of incidents on medical devices and accessing safety and their performance. combination of information from these four sectors provides a multidisciplinary approach to provide drug safety and thereby improving the product even though underreporting, data integration and need of strong regulatory framework are notable problems.¹⁸⁻¹⁹

Ugo Moretti et al (2008): In this study, it is reported that, a cosmetic product is mainly used on skin, eyes, mouth, hair, nails for the cleansing, better of skin, produce pleasant smell and protection from external environment. Regulations regarding the cosmetic product mainly focus on safety, efficacy aspects of the product because that product is used in a higher population. The national authorities do not approve and review the cosmetic product's safety, efficacy before they are marketed to the public. The determination of adverse reactions caused by the cosmetic product is an important one in all countries, and that occurs right now. This determination is widely extended, because cosmetic products are used in all countries. This process is done by the manufacturing company of cosmetic products. If the test fails, the complete batch will be removed. The manufacturer has a greater responsibility during the production of a cosmetic product. That person will confirm the product and

ingredients are safe for the people and that will not produce any adverse reaction. All the tests are done before the marketed product and the test reports are collected and reported. The manufacturer has knowledge about the preparation product, and he will do their maximum effort for the monitoring of efficacy and safety of their product.(2021)

2. Conclusion

According to the usage of cosmetic products in this generation there should be well maintained and a systematic surveillance system for monitoring and accessing the Adverse Cosmetic Reaction (ACR) to ensure the safety of cosmetic products and enhance public health. So globally it will be accepted and can follow a single regulatory guidelines.

3. Source of Funding

None.

4. Conflict of Interest

None.

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