Available online on 15 Mar, 2023 at https://ijdra.com/index.php/journal

International Journal of Drug Regulatory Affairs

Published by Diva Enterprises Pvt. Ltd., New Delhi
Associated with RAPS & Delhi Pharmaceutical Sciences & Research University

Review Article

Open Access

Cosmetic Surveillance: An update and comprehensive Review

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Abstract

Surveillance has recently been expanded to include the safety of herbal and cosmetic products. A new phrase has emerged characterizing industry monitoring known as "Kosmetonadzor" to ensure the safety of cosmetic products. Wigan (1997) was the first in the literature to use the term to refer to the safety management of cosmetic products. It is now recognized as a public health concept worldwide.

As there is no systematic reporting system, side effects or side effects of cosmetics are relatively insignificant or overlooked. There is a follow-up management system for preparation. In India, market surveillance is usually focused on drug side effects. As a result, more emphasis has been placed on medical devices, blood products, biologics, natural products, and special diets, and less on related side effects. To sum up, Cosmetology refers to the monitoring of cosmetic products that have recently entered the market.

Conclusions

Cosmetic surveillance is a new approach to regulating the safety of cosmetic products. It is an important component of public health initiatives. As post-sale surveillance of cosmetics becomes more and more common worldwide, malfunctions in these items can be detected and corrected, so safety can be achieved. Physicians Family doctors and general practitioners play an important role in detecting ADRs caused by cosmetic items and, as a result, urge patients to report ADRs. Raising awareness of this new notion will be an important contribution to global public health.

In general, the Cosmetovigilance system can avoid both significant and minor adverse effects. Because the notification procedure is critical to the system, healthcare workers must be taught and supported as part of the Cosmetovigilance feedback system. Some regulation modifications are required to keep up with Turkey's developing cosmetics business.

In general, cosmetic monitoring systems can prevent both serious and minor side effects. As the reporting process is a key element of the system, medical professionals must be educated and supported in terms of cosmetic oversight within the feedback system. Some regulatory updates are needed to keep pace with the changing Turkish cosmetics market.

Keywords: Cosmetovigilance, Regulatory forms, ADR's, safety, Causality assessment,

Article Info: Received 03 Mar 2023; Review Completed 14 Mar 2023; Accepted 15 Mar 2023

Cite this article as:
Dhiman K, Kumar R. Cosmetic Surveillance: An update and comprehensive Review. Int J Drug Reg Affairs [Internet]. 2023 Mar 15 [cited 2023 Mar 15]; 11(1):71-75. Available from: http://ijdra.com/index.php/journal/article/view/587

DOI: 10.22270/ijdra.v11i1.587
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1. Introduction

Cosmetics are preparations that can be used for cleansing, beautifying, perfumery or protecting the skin, eyes, lips, hair or nails. (1) Unlike pharmaceuticals used to treat or prevent diseases of the body, cosmetics are not considered to alter or affect the structure or function of the body. (2) The distinction between pharmaceuticals and cosmetics is ambiguous. Sensitization to many allergenic components has increased as the use of cosmetics has risen. (3) Apart from the active ingredient, additional cosmetic product constituents have been linked to unpleasant responses after using cosmetics. (4) Sensitivity edema, burning, and blisters were the most frequent ADR having a persistent make up operation in the United States. The time spent in pain spanned from 5.5 months to three years in duration. (5) Despite the fact that many ADRs exist in the general population, very few are reported to regulatory authorities. In a study of contact erythema patients, the majority of them reported unpleasant responses to cosmetic goods. In their investigation, they discovered that many patients with contact dermatitis had positive patch test results for cosmetics, and they claimed that cosmetics are key pathogenetic factors for the occurrence of atopic dermatitis. (6)

Regulations on pharmaceuticals relate primarily to the safety of items for use by a large community of healthy consumers. (7) Cosmetics are the post-sales monitoring of commercially available cosmetics. (8) Post-marketing monitoring is a method to track possible adverse effects from the use of cosmetic products and, if necessary, to make allowances and follow-up corrections. Cosmetovigilance also allows for the regulation or exclusion of potentially hazardous substances found in cosmetic goods. (9) The Middle East's personal care and beauty industry is developing twice as rapidly as any other part of the globe (Eye of Riyadh, 2018). Economic and cultural developments in Saudi Arabia have an impact on cosmetic usage habits. Aromas, hair products, cosmetics, face creams, and men's grooming are the primary cosmetics categories driving the expansion of the Country's personal care and beauty sector. (10)

Cosmetovigilance is the observation of unpleasant reactions to cosmetic goods by firms when they are used by customers. Aside from being a legal obligation under Article 23 of both the UK and EU Cosmetics Controls (11),Cosmetovigilance might be a useful tool for screening the item while it is on display and identifying any security signals. Specialists also track the occurrence of unfavourable effects using the legally mandated detailed framework for actual unfavourable effects. (12) CTPA plans to conduct intelligent training on Cosmetovigilance and company commitments for firms who are not members of the association. This CTPA training should provide an overview of the company's recording and documenting commitments inside the UK and the EU when a customer meets a hostile event, with a particular emphasis on making a causation assessment. (13)

2. Cosmetovigilance and it's importance

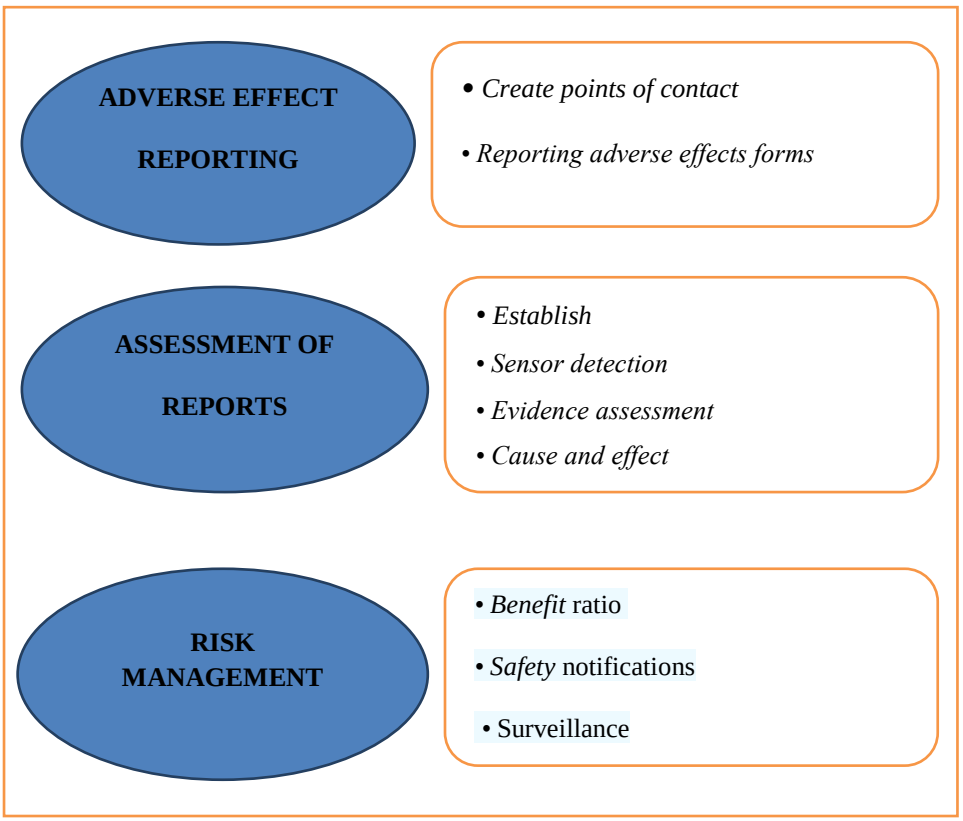

Figure 1. Safety monitoring / vigilance activities

3. Forms for all types of Cosmetics under Cosmetics Rules 2020: (14, 15)

Form Cos-1: Registration certificate for the request to import of cosmetics from other countries to India

Form Cos-1

Form Cos-2: Import Registration certificate to import cosmetics to India

Form Cos-2

Form Cos-3: Application for seeking permission to import or manufacture new cosmetics in India

Form Cos-3

Form Cos-4: Application for Import of Already Registered Cosmetics

Form Cos-4

Form Cos-4A: Application For import of previously registered cosmetics into India with their registration number

Form Cos-4A

Form Cos-5: License for manufacture of cosmetics for sale or distribution.

Form Cos-5

Form Cos-6: Loan license application for sale or distribution of manufactured cosmetics.

Form Cos-6

Form Cos-7: GMP Self-certification for cosmetics manufacturing (which is given by the applicant along with Form COS- 5 or Form COS- 6)

Form Cos-7

Form Cos-8: License for Cosmetics Manufacturing for Sale or Distribution

Form Cos-8

Form Cos-9: licence for loan for the sale or distribution of cosmetics

Form Cos-9

Form Cos-10: Notice for the person by whom from sample is taken

Form Cos-10

Form Cos-11: Application for inspection book

Form Cos-11

Form Cos-12: Import registration certificate for new cosmetics permission to obtain manufacturing license

Form Cos-12

Form Cos-13: For the test and analysis application from the cosmetic purchaser under Section 2 6 of the D & C Act of 1940.

Form Cos-13

Form Cos-14: Application for test and analysis of Government Analyst pursuant to Section 26 of the Drugs and Cosmetics Act of 1940

Form Cos-14

Form Cos-15: Application for receipt of cosmetics stock for record, register, document, or material object seized under section 22 (1) (c) or (cc) of the Drugs and Cosmetics Act, 1940.

Form Cos-15

Form Cos-16: Application for cosmetic samples taken when a fair price offered under subsection (1) of Section 23 of the Drugs and Cosmetics Act, 1940 is refused.

Form Cos-16

Form Cos-17: Application for Memorandum to Government Analyst.

Form Cos-17

Form Cos-18: Application form required by a person not to dispose of stock in his possession

Under section 22 (1) (c) of the Drugs and Cosmetics Act, 1940.

Form Cos-18

Form Cos-19: Application Report of Cosmetics Testing or Analysis by the Government Analyst

Form Cos-19

Form Cos-20: Application form for Memorandum to the Director, Central Cosmetic Laboratory of India

Form Cos-20

Form Cos-21: Application for the Central Cosmetic Laboratory Test or Analysis Report for cosmetics.

Form Cos-21

Form Cos-22: Application to conduct tests on cosmetics for their approval of licensees for cosmetics manufacturing for sale.

Form Cos-22

Form Cos-23: Application for Approval for raw materials used in their manufacture.

Form Cos-23

Form Cos-24: Application of Test or analysis report by an approved institution

Form Cos-24

4. Rules covered worldwide

The Cosmetic rules cover the following areas:

"Article 10: Safety assessment: The responsible party must confirm that a cosmetic product has undergone a safety assessment in order to confirm that it complies with Article 3 before putting it on the market (generic safety standards).The evaluation is carried out based on the relevant information and an Annex I cosmetic safety report is prepared." (16)

a). In accordance with Annex I, Part A(9) of the Regulations, the safety report shall contain the following information: Correspondingly, other cosmetics. This includes statistical information. (17)

b). This is further explained as follows in the supporting guidelines to Annex I of the Regulation (18):"The cosmetic product safety report shall contain all available data, including statistical data, on unpleasant effects and major undesirable effects of the cosmetic product optionally other cosmetic goods. (19) In particular, the safety report contains information on unfavorable consequences that, according to the causality assessment, are very likely, probably, equivocal, or implausible to be attributed to the cosmetic product in issue. (20, 21)

c). With regard to SUEs, the following is stated in Article 23 of the Regulation (22, 23):"In the event of serious adverse reactions, the responsible person and distributors shall promptly notify the competent authority of the Member State where the serious adverse reaction transpired:

- Any serious adverse effects that you are aware of or can reasonably be expected to be aware of; (24)
- The name of the cosmetic product in question, allowing for its precise identification;
- The name of the cosmetic product in question, allowing for its precise identification;

d). Lastly, Article 21 of the Regulation grants the public the right to ask the controller for information about the EU and SUE. "Without prejudice to the protection of

trade secrets and intellectual property rights in particular, (25) the controller should ensure that existing data on uncomfortable effects and significant undesirable effects resulting from the use of the cosmetic product are made freely and in an appropriate manner available to the public. (26) It should ensure that existing data on unpleasant effects and significant undesirable effects resulting from the use of the cosmetic product are made freely accessible to the public in an appropriate manner." (27)

5. Adverse reactions related to cosmetic ingredients:

The prevalence of cosmetic adverse effects has been investigated through a number of research investigations. One study found that 24% of cosmetic users had any negative effects. (28) Systemic adverse effects make up 4.1% of all side effects, whereas cutaneous side effects make up 95.9% of the total. According to this study, rash (34.8%), itching (31.5%), eczema (22.8%), and other cutaneous side effects were the most prevalent. Headache (1.7%), nausea (1%), dizziness (0.6%), dyspnea (0.3%), and other disorders were noted as systemic adverse effects), dyspnea (0.3%), and other conditions were reported. (29)

In one of the most recent research completed in 2019, the occurrence of negative effects in 341 patients with contact dermatitis brought on by cosmetics was recorded utilising forms. (30) The occurrence of cosmetics-related adverse effects was connected with the combining of multiple types of cosmetic products (31.4%), with the mixing of two different brands accounting for 65.4%.

According to a pilot study conducted at a dermatology clinic in 2019, 1.58 percent of people experienced cutaneous adverse responses to cosmetics. The most frequent reactions were rashes and pruritus, which accounted for 30.9% of all cases, and itching (23.8%). Effects accounted for 95.9% of all side effects. According to this study, rash (34.8%), itching (31.5%) and eczema (22.8%) were the most common. Headache (1.7%), nausea (1%), dizziness (0.6%), shortness of breath. (31)

6. Conclusion:

Cosmetic surveillance is a new approach to regulating the safety of cosmetic products. It is an important component of public health initiatives. As post-sale surveillance of cosmetics becomes more and more common worldwide, malfunctions in these items can be detected and corrected, so safety can be achieved. Physician's Family doctors and general practitioners play an important role in detecting ADRs caused by cosmetic items and, as a result, urge patients to report ADRs. Raising awareness of this new notion will be an important contribution to global public health.

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Acknowledgements

We would like to express our sincere gratitude to IJDRA Journal for publishing our work.

Financial Disclosure statement: The author received no specific funding for this work.

Conflict of Interest

The authors declare that there is no conflict of interest regarding the publication of this article.

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