RESEARCH ARTICLE

Cosmetovigilance in India: Industry Expert Perspective

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ABSTRACT

Many cosmetic and cosmeceutical products and brands are available in the Indian market. The number of new and innovative cosmetic product categories available in India are on the rise for last two decades. The cosmetic industry ranges from local small-scale businesses to multi-crore international branded ventures. Most of the local ones are often not under any rules or regulations. There is a dearth of research on cosmetovigilance despite the growing popularity and demand for cosmetic items among consumers of cosmetics. "The term "cosmetovigilance" refers to the processes involved in assessing and keeping track of unprompted reports of unfavorable outcomes during or following regular or reasonably anticipated use of a cosmetic product."

Objective: The purpose of the study is to understand the cosmetovigilance system from industry experts' perspectives with special reference to regulatory aspects in the Indian context.

Method: This is a cross-sectional qualitative and quantitative study; the data was collected through a structured questionnaire and through a questionnaire guide from selected industrial regulatory experts (targeted respondents). The purposive sampling and convincing methods were used for the study. Descriptive statistics were used to analyze the data.

Result: Around 73% of regulatory experts said that companies should follow the regulatory guidelines for ensuring the safety and labeling of cosmetics. Around 66.6% responded that they have not come across any ACE reporting form by CDSCO.

Conclusion: From the point of view of consumer safety, the establishment of cosmetovigilance practises and a reporting form is essential. Nevertheless, the companies try their best to control the safety aspects of cosmetic products.

Keywords: Cosmetics, Cosmeceuticals, Cosmetovigilance, India, Industry, Regulatory expert.

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INTRODUCTION

The use of cosmetics/cosmeceuticals is increasing due to increasing consumer interest in physical appearances. In addition to defining a "cosmetic product," the European Union Cosmetic Directive emphasizes the necessity for a cosmetic not to endanger human health when used under normal or reasonably anticipated situations.[1,2] The cosmetics industry, worth billions of dollars and still growing, offers a diverse range of products, including cosmetics, skincare, hair, and body care. Color is a key factor in attracting customers and creating an appealing aesthetic in this industry.[3] According to Dr. Albert Kligman, cosmeceuticals are a combination of cosmetics and pharmaceuticals. Cosmeceuticals are cosmetics that have no adverse effects on the structure and function of the skin.[4] Adverse reactions can sometimes occur because of cosmetic use. Numerous studies have documented severe cosmetic side effects like hair loss, blistering, breathing issues, unconsciousness, dizziness, skin burns, and nausea. Consumers often underestimate the incidence of adverse cosmetic reactions, but documentation might help authorities in regulating cosmetics.[5,6] The fundamental objective should be to regulate cosmetic product's safety. It is possible to reduce the negative results of cosmetic products by promoting cosmetovigilance and running awareness programs for cosmetic products.[7,8] "The term "cosmetovigilance" refers to the processes involved in gathering, assessing, and keeping track of unexpected reports of unfavorable incidents that occur during or after the regular or reasonably anticipated use of a cosmetic product."[9] The study conducted by Vigan and Castelain stated that the use of the cosmetovigilance system could help in controlling or eliminating the harmful ingredients present in cosmetics, thereby boosting our confidence that these products can be used safely.[10] The new policy or any new reporting system needs to be framed in consultation with various stakeholders. Dermatologists, industry experts and respective regulatory authorities in regulated markets are key members of the formation of the cosmetovigilance system. To date, there is no such formal ADR reporting system and

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research work done from an industry expert perspective in India. The present study attempted to analyze Indian industry experts' perspectives towards the cosmetovigilance system.

RESEARCH METHODOLOGY

This is mixed study includes both qualitative and quantitative methods, which involved primary research. Primary data were obtained with the help of a questionnaire using Google Forms (quantitative) and also through telephonic interviews using a questionnaire guide (qualitative). The questionnaire was sent through a Google form link for the quantitative study. All the participants were informed about the objectives of the study. The Institutional Ethics Committee (IEC) granted ethical approval. (IEC No: 585/ 2020). Sampling technique: Non-probability purposive sampling method and convince sampling method were used. A sample of 20 regulatory experts from various pharmaceutical and cosmetics companies who had one or more years of experience in the regulatory field were selected for deploying the questionnaire for quantitative study. When surveys were not returned within the present time frame, two staged reminders were sent, and after each survey was returned, a thank you message was sent. Questionnaire design: The questionnaire included open-ended, closed-ended, multiple-choice questions and a Likert scale. Content validation: The questionnaire was validated. The experts in the field of cosmetovigilance approved it.

For the qualitative study, we conducted a telephonic interview with eight industry experts with appropriate verbal consent till saturation was obtained.

The study was performed for 6 months, from January – July of 2023.

Data Analysis

The obtained data was examined by suitable software like Microsoft Office Excel 2007. Analysis was purely descriptive data, which was assessed, interpreted, and symbolized graphically mainly on the responses of acquired through a questionnaire.

RESULT

The questionnaire was deployed to 20 regulatory experts we have received 15 responses. All 15 industry experts had more than two years of experience. Pharmaceutical companies employed most, some of the pharma companies were also manufacturing cosmetic/ cosmeceutical products and approximately 11 (73.5%) companies were located in Bangalore.

Figure 1 found that the study involves 67% female regulatory experts and 33% male regulatory experts.

From the Table 1, it was noted that the majority of the regulatory experts expressed their opinion that the company should follow the regulatory guidelines for ensuring the safety and labeling of the cosmeceuticals as follows for cosmetics. Around 66% of industry experts say that due to procedural difficulties, regulatory guidelines for cosmeceuticals has not been established in India.

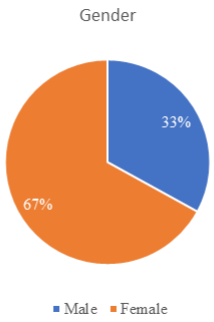

Figure 1: Demographic characteristics of respondents

Figure 2 found that, around 80% industry experts responded that the Pharmacist, Dermatologist, Pharmacologist, Regulatory specialist should be the members of cosmetovigilance committee from Indian system perspective.

From Figure 3, it was found that 66.6% of industry experts responded that they are aware of cosmetovigilance concept. Around 80% of regulatory experts said that the concept of cosmetovigilance is not popularized in India. The majority of the industry experts, 66.6% responded that they have not come across any ACE reporting form by CDSCO.

From Figure 4, it was noted that around 53.3% of respondents strongly agreed that cosmetovigilance should be taught in detail to industry experts, majority of respondents strongly agreed 60% that adverse cosmetic events form should be required in India and relevant authorities do not widely promote adverse cosmetic events (ACE) reporting in India. Finally, respondents say that the implementation of cosmetovigilance system in India can boost confidence in the safe use of products.

Proposed Manual and Adverse Events Reporting Form of Cosmetics Products for Indian Cosmetics Industry[11]

Definition of terminologies

- *Adverse events*

Any actual harm or unexpected incident that can be traced back to using a particular cosmetic product in a regular or predictable way.

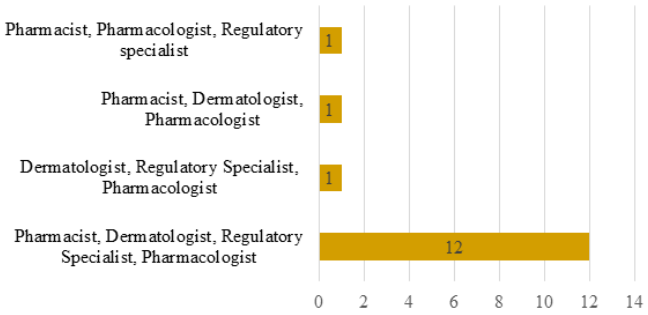

Figure 2: Members of cosmetovigilance committee from the Indian system perspective

Table 1: Concept on cosmeceutical

Variable	*Categories*	*Responses*	*Frequency*
Are you involved in the production or marketing of cosmeceutical items in India?	Yes	6	40
	No	9	60
Regulatory standards that companies should adhere to in order to ensure the safety of cosmeceuticals	As carried out for OTC product	0	0
	As carried out for drugs		
	As carried out for cosmetics	5	33.3
		10	66.6
Guidelines companies should follow for labeling of cosmeceutical products	As carried out for OTC product	1	6.6
	As carried out for drugs	3	20
	As carried out for cosmetics	11	73.3
Reasons for not establishing regulatory guidelines for cosmeceuticals in India	May not feel the need	1	6.6
	Financial incapability	0	0
	Procedural difficulties	10	66.6
	Inadequate manpower and infrastructure	4	26.6

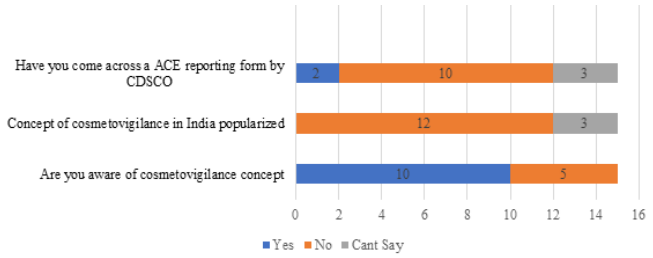

Figure 3: Concept on cosmetovigilance system

- *Serious adverse event*

Serious events are medical events resulting in death or life-threatening (life-threatening events are events where the individual is at risk of death at the time they occur), requiring hospitalization, or resulting in significant disabilities or incapacity for long periods of time.

What should be the industry's reporting structure?

The entity that is in charge of distributing the cosmetic product onto the market is required to notify the CDSCO of any unfavorable events, despite of the report's origin (consumer, healthcare provider, etc.).

Is there anything that needs to be reported?

All serious negative consequences need to be reported. Non serious adverse events are not necessary to be reported. Adverse events that pose a threat to life must be reported to the relevant regulatory bodies via phone, email, etc., within seven business days. Within the next eight calendar days, the adverse cosmetic event report form needs to be filled out and any more information that the regulatory body might require. All serious negative consequences that are not fatal need to be reported within 15 calendar days.

Proposed adverse events reporting form.

To:
Name & Address of the Regulatory Authority:
Department:
Telephone no:
Fax no.:
Email

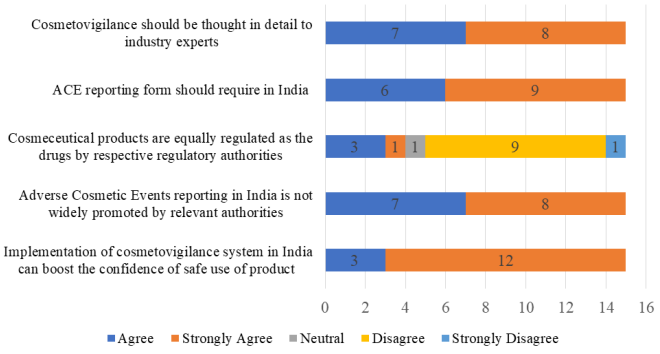

Figure 4: Concept on adverse reaction reporting form

Information of company

Name of the company:	Company Address:
Detail of reporting person (Name and designation:	Email:
Tel Number:	Fax:

Information of product

Name of the product	
Ingredients	
Type of product / intended use	
Name and country of manufacturer	
Date of expiry	
Batch number	

Detail of adverse effects

Name of the person	Gender
Age	Weight of the person
Nationality	
Date of adverse reaction occurred	
Description of adverse events	
Route of administration of products	
person hospitalized due to negative events	Yes No
Individual seek medical attention?	Yes No

Result	Recovered Not yet recovered. Death Unknown
Source of report	Health care profession Consumer Others (specify)

Signature of a reported person with date:

DISCUSSION

As with medicines, cosmetics are typically well accepted, but they can nevertheless have unfavorable side effects. Due to the absence of standardized reporting forms and report validation, it is difficult to understand and identify these consequences.[4,12,13] Even when consumers or patients seek medical advice, it has been noted that the negative consequences of cosmetics and toiletries are underestimated.[14,15] Regulatory professionals are the primary contacts for regulatory agencies when they approve drugs. In addition, regulatory professionals have a unique perspective on transparency in the approval process for drugs in different countries.[16]

Canada and USA

Canada

The natural health products (NHP) regulations healthcare professionals & consumers are encouraged to report adverse reactions, which started in January 2004. NHP is responsible for providing information regarding the product recall to all consumers, about the clinical trials related to the cosmetics, responsible for assuring cosmetic products licensing, safety and efficacy, labeling, etc.[17]

United States

The FDA manages prescription and non-prescription cosmetic products. Similar to the NHP in Canada, the FDA also follows products' manufacturing, safety & efficacy, ADRs, research, & recalls.[18]

Netherlands

The Ministry of Health and the Netherlands Food and Consumer Product Safety Authority agreed to monitor the negative effects of cosmetics and stated their willingness to work together to establish a cosmetovigilance network.[19]

India

Adverse events are underreported in India due to the lack of cosmetovigilance system. India should develop a proper monitoring system like other countries so the unwanted reactions due to cosmetics can be reduced. Healthcare professionals should be encouraged to report adverse events. The makers of cosmetic products are in charge of ensuring that their products comply with the cosmetic standards in the absence of a formal marketing authorization.[20,21]

Industry Expert Perspective Regarding Cosmetovigilance System

We have performed the qualitative study (through a telephonic interview by using a questionnaire guide containing open-ended questions) on eight industrial regulatory experts having more than three years of experience and who has knowledge regarding the regulations cosmetovigilance concept for a better understanding about the topic. Based on the interview with those industry experts, their responses/feedback are discussed below.

Industry experts say that use of the cosmeceutical products are increasing day by day. Cosmeceutical Company should follow the guidelines that are present for cosmetics to ensure the safety, efficacy, and labeling of the products. The regulations should be stringent/strict. Without following the regulation product should not be approved. This practice will help society to reduce the negative consequences form beauty products. These products are applied/used externally or topical and not used internally like medicines. This might be the reason for not establishing the regulatory guidelines for these products. Procedural difficulties might be another reason for not establishing the guidelines in India. Most of the small-scale companies follow their own procedure while manufacturing the products, even it is not necessary to get approval from the regulatory bodies as like medicines. Even though some cosmetics labels may read "natural cosmetics," allergic responses can still occur with those products. Sensitization tests, such as skin patch tests or recurred open application tests, are advised prior to utilizing certain cosmetics, such as chemical sunscreens and hair dyes.

According to industry experts, negative consequences are becoming more frequent every day as a result of greater consumption of beauty products. Due to the absence of proper vigilance or monitoring systems, adverse events are neglected. So it is better to develop a proper vigilance system in India and it is also better to develop the adverse events reporting form. Awareness programs, conferences, and workshops should be conducted to create knowledge on cosmetovigilance systems to healthcare providers, industry workers as well in academics. Industry experts says that one regulatory person from the industry, one physician, preferably a dermatologist, one pharmacologist, one government authority and one lawyer should be the members of the cosmetovigilance committee. In this research, we have developed an adverse events reporting form and taken the perception of industry regulatory experts on this form. They says that the company which is responsible for placing the cosmetic product in the market shall report the adverse events to the CDSCO, regardless of the source of the report (consumer, healthcare professional, etc). It would be better if the serious adverse events were reported to the regulatory authorities within one week by email. Non-serious adverse events are not necessary to report. Government authority should take proper action against the company and the products responsible for adverse events by sending a warning letter or by recalling the products. This practice will help to rule out the incidence of negative consequences.

Finally, in order to reduce the adverse events proper monitoring system should be developed. It is necessary to develop a cosmetovigilance system in India. Industry plays a major role in reducing side effects through proper

mechanisms. There should be strict regulations for the industry to manufacture the products, and for assessing their safety and efficacy, the industry should follow the regulations properly so the chances of adverse events can be minimized.

Limitations of the Study

This study used a small sample, and a bigger sample size could have been necessary to get a more accurate image of the cosmetovigilance system in Indian situations. We cannot rule out respondent bias in this case.

CONCLUSION

Cosmetovigilance is a novel idea for monitoring the safety of cosmetic products. It could be viewed as a crucial element of public health initiatives. A significant barrier is the absence of specific legislation, but it is also the shortage of specialists with knowledge of this kind of niche regulation for cosmetics. The requirement for cosmetovigilance is a public health concern that requires people to take responsibility for protecting consumers from cosmetics. The establishment of cosmetovigilance is an urgent issue, regardless of the agency in charge of cosmetics regulation. Customers require it. Nevertheless, companies try their best to control the safety aspects of cosmetic products.

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