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COSMETOVIGILANCE: REQUISITE OF THE HOUR

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ABSTRACT

Pharmacovigilance refers to the tasks of collecting, detecting, assessing, monitoring, and preventing medication-related adverse events. In India, the Drugs and Cosmetics Act and Rules control cosmetic, governed by CDSCO. The term "cosmetovigilance" refers to the process of gathering, analysing, and tracking spontaneous reports of unfavourable events that occur during or after normal or reasonably anticipated use of a cosmetic product. Cosmetics have now become a necessity of the hour, since practically everyone uses them on a daily basis in India and increase in its use has led to various side effects. The range of "vigilance" has been expanded to cover the safety of herbal and cosmetic items. However, due to a lack of standardized reporting formats and report validation, understanding and identifying these consequences is difficult. Another stumbling block is the lack of well-established cosmetovigilance system. It is evident that proper application of a cosmetics vigilance system can aid in the control or reduction of hazardous substances in cosmetics.

Keywords: Cosmetovigilance, Cosmetic, CDSCO, Cosmetic Regulation 2020

1. HISTORY OF COSMETICS

Cosmetics have been around for at least 7,000 years and are found in practically every civilisation on the planet. The term cosmetae was initially used to designate Roman slaves who were responsible for bathing men and women in scent. Men and women in Egypt, utilised scented oils and ointments to clean and soften their skin and hide body odour as early as 10,000 BC **[1]**. Cosmetics were also utilised by the Ancient Greeks. Around 840 BC, Jezebel is said to have painted her eyelids with cosmetics. Around 3000 BC, cosmetics were first discovered in China. Gum arabic, gelatin, beeswax, and egg were used to dye fingernails in China. Colours were used to indicate different socioeconomic classes **[2]**. Cosmetics have been used in Persia and the Middle East since ancient times. After Arab tribes converted to Islam and conquered certain places, cosmetics were only allowed in some locations if they were used to deceive or provoke uncontrollable desire **[3]**. Since the 4th or 5th centuries, henna has been utilised in India. It's used as a hair dye or in the mehndi art, which involves painting intricate designs on the hands and feet, especially before a Hindu wedding. Kohl, or kajal, has a long history in Hindu culture **[4]**.

2. INTRODUCTION

Cosmetics are items that are used to improve a person's look, scent, and texture **[5]**. In India, Drugs and Cosmetics Act 1940 and Rules 1945 control Cosmetics, Drugs and Cosmetics Act, Section 3(aaa) characterizes "cosmetic" as "any article expected to be scoured, poured, sprinkled or splashed on, or brought into, or generally applied to, the human body or any part thereof for purging, enhancing, advancing engaging quality, or changing the appearance, and incorporates any article planned for use as a part of corrective action **[6]**.

Gazette notification G.S.R 426(E) partitions beauty care products into 4 gross classifications:

- Skin items (items for healthy skin, purifying, evacuation of body hair, body hair blanch, stench remedial items, items for shaving (pre or facial cleanser), items for cosmetics, scent, items for sun, and self-tanning and others)
- Hair and scalp items (purifying and care items, items for hair shading, hair styling items and different items for hair and scalp care)
- Nail and fingernail skin items (nail stain and remover, items for nail care and nail solidifying, item for nail stick eliminating, different items for nail and fingernail skin care)

- Oral cleanliness (tooth care, tooth whiteners, mouth wash, breath splash and different items for oral cleanliness) **[7]**.

The Indian Cosmetics Market is divided into three categories: categories, distribution channels, and competition. The market is isolated into body care, hair care, variety beauty care products, men's prepping, aromas, and others in light of classification. Body care things, for example, hand cream and body moisturizer, finished off the market with a 45.01 percent share in FY2020. In FY2020, the India Cosmetics Market was esteemed at USD 13191.23 million, and it is normal to ascend at a twofold digit CAGR of 16.39 percent through FY2026, arriving at USD 28985.33 million **[8]**.

Pharmacovigilance refers to the tasks of collecting, detecting, assessing, monitoring, and preventing medication-related adverse events **[9]**. Cosmetics have a significant impact on the skin at the rate at which they are used, and can produce both effective and ineffective results. The widespread use of cosmetics by a large number of people has resulted in the discovery of a various adverse effects in consumers as well as occupational dangers. These adverse reactions can have a number of short- and long-term health effects for customers. Any unpleasant and unanticipated response to cosmetics and personal care products (CPCPs), including lack of efficacy, is considered an adverse reaction **[10]**.

COSMETOVIGILANCE

"Cosmetovigilance" refers to the tasks involved in gathering, evaluating, and tracking spontaneous reports of unfavourable outcomes observed during or after normal or reasonably anticipated usage of a cosmetic product **[11]**.

Vigan (1997) was the first to use the term in the literature to refer to industry's post market surveillance. The French health products safety agency laid out cosmetovigilance as a part of the pharmacovigilance framework for beauty care products. Beauty care products that have an unprescribed variety, inaccurate naming, or bogus/deceiving item data are alluded to be misbranded. When a cosmetic's name, product, or manufacturer information is deceptive or false (information that does not exist and is used to deceive buyers), it is classified as spurious **[12]**.

3. HAZARDS ASSOCIATED WITH COSMETIC ADDITIVES

Allergic contact dermatitis is one of the most prevalent side effects of cosmetics (ACD). This could be caused by the presence of allergies in the cosmetics. Fragrances and preservatives are the most common. Heavy metals are also regularly found as contaminants in cosmetics and

personal care products in trace amounts. Although their appearance on the label is not required since these metals are product impurities, they are cumulative poisons due to their long half-life.

Lead and cadmium, for example, are hazardous not just to people but also to animals. Even at low concentrations, several of them can harm external or internal organs. Although mercury chloride and methyl mercury are likely carcinogens in humans, mercury does not have cancer-causing agents according to the categorization of cancer-causing metals. Nickel, cobalt, copper, and chromium, among other heavy metals, are allergens **[13]**.

3.1 Skin Cosmetics

Irritation (burning, stinging, etc.) is one of the most common side effects. Itching or other forms of skin irritation that aren't obvious. Inflammation can be seen objectively. These annoyances occur in 1-10% of all cases, they are mostly seen on the face of the users of cosmetics. The typical symptoms are modest. Erythema and scaling are common symptoms, but dermatitis can also develop. Deodorants cause discomfort in humid climates as well as antiperspirants **[14]**.

3.2 Sunscreens or Lotions

Photosensitivity can cause a tiny percentage of cosmetics-related negative effects. UV filters are found in sunscreen preparations and skin care products. Individuals who habitually use UV channels might encounter untimely skin maturing and disease because of their openness to daylight. These UV filters are a leading cause of allergic responses to light contact **[15]**.

3.3 Shaving Products

Contact dermatitis can be triggered by aftershave lotions and perfumes.

3.4 Lipsticks

When presented to daylight, lipstick produces receptive oxygen species, which cause haemolysis and lipid peroxidation in human erythrocytes. The lipsticks and lotions that were employed in the tests demonstrated UV/Visible absorption. Women who use lipstick on a daily basis (1-14 times per day) are presented to the unsafe impacts of lead and other weighty metals, which may have an impact on their health **[16]**.

3.5 Hair Dyes

The most common cause of hair colouring side effects is a chemical called PPD (Paraphenylenediamine). Some people may develop photo allergic dermatitis or dye-induced depigmentation as a result of the presence of PPD in hair colours. Hair colour strips with an 18-MEA layer are used to make the hair texture coarse and drab. After hair dye application, other symptoms include lymphomatoid reaction, erythema multiformae, and anaphylaxis.

Few studies have connected the use of permanent hair dyes to an increased risk of follicular lymphoma.

3.6 More items

Sticker bindis, kumkum, & kajal have all been found to have major contact dermatitis risk factors **[16]**.

4. COSMETICS NEGATIVE IMPACT ON PREGNANT WOMEN AND CHILDREN

Another issue that needs to be addressed with caution is the usage of cosmetics during pregnancy. Hair colour or hair strengthening products are linked to higher negative consequences in the first trimester of pregnancy. Intense lymphoblastic leukaemia and intense myeloid leukaemia create in their youngsters because of hair beauty care products **[17]**.

4.1. NEGATIVE EFFECTS OF COSMETICS

4.1.1 Heavy metal toxicity

Pollutants like exorbitant degrees of weighty metals (lead, zinc, and cadmium) in beauty care products (lipsticks, lip sparkles, eye shadows, and henna hair color) cause weighty metal poisonousness. Mercury compounds are easily absorbed through the skin, causing allergic reactions and neurotoxicity when they accumulate in the body. Cosmetic components such as heavy metals and toluene leak into the environment, posing a harm to the ecology **[18]**.

4.1.2 Face affected by topical steroid use

Abuse of topical corticosteroids as a "fairness cream" can cause a variety of side effects, including skin atrophy, hirsutism, acne, perioral dermatitis, and telangiectasia. Long haul, unpredictable use can bring about the advancement of Topical Steroid-Dependent Face (TSDF), which is described by serious bounce back erythema, consuming, and scaling of the face when effective corticosteroids are halted. Long-term usage of strong topical corticosteroids can produce systemic consequences such adrenal suppression and the emergence of cushingoid disease **[19]**.

4.1.3 The reproductive fitness and child birth defects of the toxic trio

The toxic trio of formaldehyde, phthalates, and toluene (the toxic trio) play a role in the risk of reproductive health impacts for cosmetologists in the workplace. According to studies, there is a Premature birth is on the rise, as is the chance of complications. Hairstylist in comparison to a control group, pregnancy abnormalities were found. a group of teachers and salespeople whose only vocation is teaching. Openness to the dangerous threesome had an effect. Conceptive illnesses with connection to low birth weight were explored, and three of the examinations showed a huge expansion in the likelihood of having a low-birth-weight newborn child. Pregnant ladies who breathed in formaldehyde,

phthalates, or toluene were connected to negative regenerative results such intrauterine development impediment and early birth **[20]**.

5. BEGINNING OF COSMETO-VIGILANCE IN THE WORLD

Cosmetovigilance was initially implemented in France in 1999. The discovery of new hazardous chemicals was made possible by active observation. Vitamin K3 (used as a cosmetic ingredient) was discovered to cause sensitization and was therefore banned in cosmetics. The danger of PPD (p-phenylenediamine) hypersensitivity from temporary black tattoos has become more well-known as a result of active observation. Active observation was possible to influence new hair dye regulations. Photosensitization from a ketoprofen gel resulted in octocrylene sensitization **[21]**.

The foundation for a cosmetovigilance system based on case notifications was laid by a European decision in 2006. In order to protect human health, the European Council suggested that each member state create a mechanism to track unfavourable impacts of cosmetics. Belgium, Norway, Sweden, Denmark, Germany, and Italy established cosmetovigilance systems as a result of the resolution. During a pilot project, ten Dutch health agencies compiled a list of unfavourable effects of cosmetics and identified the suspect ingredients. Geriatricians, dermatologists, and consumers all reported cases. To draw attention and increase community participation, public campaigns in the media were used.

A client can report a cosmetic related objection to the FDA in the United States. Purchasers give data to the FDA for the office to monitor the wellbeing of beauty care products available. Restorative organizations/merchants in Mercosur nations (Argentina, Brazil, Paraguay, Uruguay, and Venezuela) are expected to break down and keep up with cosmetovigilance reports. Germany and Sweden have a formal cosmetovigilance system, while other European countries have an informal one **[21]**.

6. COSMETIC REGULATIONS IN INDIA

Cosmetics in India are governed by the D&C Act 1940 and Rules 1945. Part XIII deals with cosmetics purporting and enrolling rules. The manufacture of cosmetics for sale or distribution is covered in Part XIV. Part XV governs cosmetics labelling, packaging, and standards.

After Japan, China, and South Korea, India is Asia Pacific's 4th large cosmetics market. Section 135 B of the D&C Act prohibits importation of cosmetics that have been examined on animals.

In the past, unfavourable responses to cosmetic goods have received very little

attention in India. Unwanted or unpleasant reactions to cosmetic products are either extremely infrequent or go unnoticed owing to a lack of a well-organized reporting system. As a result, the need for a well-organized reporting agency is critical **[6]**.

6.1. NEW RULES AND REGULATIONS OF COSMETICS 2020:

The Cosmetics Rules were recently issued in an official gazette notification dated December 15, 2020, and are in effect throughout the country as of that date. To facilitate a smooth transition, all licences issued under the old Drugs and Cosmetics Rules 1945 will be considered valid until they expire or for 18 months after the new regulations take effect, whichever comes first. Any cosmetic product created outside of India can be sold in India if the product formulation, label text, and claims on the label and website comply with the Cosmetic Rules of 2020. In addition, all cosmetics entering India must be registered via the e-Government system (SUGAM) using Form COS-1. In India, either the manufacturer or the authorised agent must submit the application. CDSCO issues the registration certificate via Form COS-2 after a comprehensive evaluation of the application form **[22]**.

For the first time, the Cosmetics Rules, 2020, define a "new cosmetic" as a "cosmetic containing a new substance that has never been used elsewhere in the world or is not recognised for use in cosmetics in any national or international literature." These new rules make registering cosmetics for importation much easier.

The Cosmetics Rules 2020 structure is partitioned into a few sections. The arrangements for Licensing Authorities, Delegation of Licensing Authority Powers, Government Analyst and its Functions, Powers, Duties, and Functions of Inspectors Specially Authorized to Inspect the Manufacturing and Sale of Cosmetics, etc are totally spread out in this part. Also, the Chapter sets out the necessities for applying for a permit or credit permit to make beauty care products available to be purchased or dissemination, fabricating at various areas, states of permit or advance permit for beauty care products assembling, award or dismissal of permit, etc. **[22]**.

6.1.1 New system for getting new cosmetic permit according to Cosmetic Rules 2020 [23]

Process is provided in Rule 23 as follows:

- Firm must apply for a new cosmetic production licence online using form Cos-5.

– The needed fee is listed in the Cosmetics Rules 2020 third schedule.

– Cosmetics Rules 2020, 2nd schedule part-2, list of papers to be submitted.

– Form Cos-8 will be used by SLA to issue the licence. SLA may reject the file if it is

not complete, and the applicant will be notified within 45 days.
-Within 30 days of receiving the licence, the company must upload it to the CDSCO website.
– SLA will inspect the premises and verify the information provided by the company in the self-certification form Cos-7 within 30 days of the licence being granted.

6.1.2 Cosmetic Rules 2020 revised licencing fee [23]

Fee provided under third Schedule of the New Cosmetic Rules 2020:
– The licencing fee is Rs. 10,000/-. (Free: ten items of each category)
– Retention fee of Rs. 10,000/-
- Monthly Late Price of 2% of the licencing fee
– Additional category fee: Rs. 10,000/-
– Duplicate licence fee: Rs. 500/-
– Rs. 1,000/- for testing laboratory permission

6.1.3 Forms under Cosmetics Act 2020:

Table 1 [22]

S. No	Purpose	Form
1	Manufacturing licence application	Cos-5
2	GMP conformity self-certification	Cos-7
3	Manufacturing Permit for Cosmetics	Cos-8
4	Form for collecting samples	Cos-10
5	Form of Seizure	Cos-15
6	Reasonable price Form	Cos-16
7	Government analyst memo	Cos-17
8	Non-Disposal Form	Cos-18
9	Government Analyst examination Report	Cos-19
10	Cosmetics testing permission application	Cos-22
11	License for testing laboratory for cosmetics	Cos-23

7. Necessity for Cosmetovigilance in India

India's cosmetic area is experienced and filling with regards to item advancement and showcasing. In the Asia-Pacific region, India is the fourth biggest corrective market. In any case, because of an absence of an efficient announcing framework, unwanted or troublesome responses to restorative merchandise go unnoticed. In India, the pharmacovigilance framework screens unfriendly drug responses, and clinical gadgets, blood items, biologics, and explicit wholesome and normal products have as of late been given thought, while unfavourable reactions to restorative things have stayed inconspicuous. It is previous time for India to lay out a precise cosmetovigilance component also. This could assist with expanding the protected utilization of beauty care products, which is urgent for general wellbeing assurance. In a review distributed in 2014, Vigan and Castelain recommended that right utilization of the cosmetovigilance situation can help to control or take out hazardous

substances present in beauty care products, henceforth expanding our trust in the protected utilization of these items **[11]**.

Cosmetics have now become a necessity of the hour, since practically everyone uses them on a daily basis in India and increase in its use has led to various side effects. The range of "vigilance" has been expanded to cover the safety of herbal and cosmetic items. However, due to a lack of standardized reporting formats and report validation, understanding and identifying these consequences is difficult. Another stumbling block is the lack of well-established cosmetovigilance system **[24]**.

8.CONCLUSION

Cosmetic product-related unwanted or unpleasant responses are either very rare or pass unrecognized because of absence of a well-efficient reporting system. It is evident that proper application of a cosmetics vigilance system can aid in the control or reduction of hazardous substances in cosmetics. Hence, it can be concluded that, a proper cosmetics vigilance system should be developed, which will help to achieve greater cosmetics safety in the future, which is critical for public health protection.

9. REFERENCES

[1] Cosmetics in ancient Rome - Wikipedia. (n.d.). Retrieved May 16, 2022, from https://en.wikipedia.org/wiki/Cosmetics_in_ancient_Rome

[2] A History of Cosmetics from Ancient Times - Cosmetics Info. (n.d.). Retrieved May 16, 2022, from https://www.cosmeticsinfo.org/get-the-facts/a-history-of-cosmetics-from-ancient-times/

[3] History_of_cosmetics. (n.d.). Retrieved May 16, 2022, from https://www.chemeurope.com/en/encyclopedia/History_of_cosmetics.html

[4] (PDF) Medical Effects of Cosmetics. (n.d.). Retrieved May 16, 2022, from https://www.researchgate.net/publication/296485304_MEDICAL_EFFECTS_OF_COSMETICS

[5] The Rising Demand for Esters and Sustainable Ingredients. (n.d.). Retrieved May 16, 2022, from https://www.acme-hardesty.com/esters-personal-care-market/

[6] Government Of India Ministry Of Health And Family Welfare (Department of Health) The Drugs And Cosmetics Act And Rules The Drugs And Cosmetics Act, 1940 (23 OF 1940) The Drugs And Cosmetics Rules, 1945 List Of Abbreviations Used. (n.d.).

[7] View of Cosmetovigilance in Public Health: A Review. (n.d.). Retrieved May 16, 2022, from

https://medicopublication.com/index.php/ijphrd/article/view/10191/9536

[8] India Cosmetics Market Report 2021: Analysis & Forecasts. (n.d.). Retrieved May 16, 2022, from https://www.globenewswire.com/news-release/2021/01/25/2163224/28124/en/India-Cosmetics-Market-Report-2021-Analysis-Forecasts-2014-2026-by-Body-Care-Hair-Care-Color-Cosmetics-Men-s-Grooming-Fragrances-Others.html

[9] Suke, S. G., Kosta, P., & Negi, H. (2015). Role of Pharmacovigilance in India: An overview. Online Journal of Public Health Informatics, 7(2), 223. https://doi.org/10.5210/OJPHI.V7I2.5595

[10] Kaličanin, B., & Velimirović, D. (2016). A Study of the Possible Harmful Effects of Cosmetic Beauty Products on Human Health. Biological Trace Element Research, 170(2), 476–484. https://doi.org/10.1007/S12011-015-0477-2

[11] Vigan, M., & Castelain, F. (2014). Cosmetovigilance: definition, regulation and use "in practice." European Journal of Dermatology, 24(6), 643–649. https://doi.org/10.1684/EJD.2014.2493

[12] Tissier, M. H., & Lepagnol, F. (2002). [Cosmetovigilance: a French pharmacovigilance system for cosmetics developed by the French health products safety agency. A proposal for the future]. Therapie, 57(3), 273–282. https://europepmc.org/article/med/12422542

[13] Siti Zulaikha, R., Sharifah Norkhadijah, S. I., & Praveena, S. M. (2015). Hazardous Ingredients in Cosmetics and Personal Care Products and Health Concern: A Review. Public Health Research, 5(1), 7–15. https://doi.org/10.5923/J.PHR.20150501.02

[14] Irritant & Allergic Contact Dermatitis: Symptoms, Diagnosis & Causes. (n.d.). Retrieved May 16, 2022, from https://my.clevelandclinic.org/health/diseases/6173-contact-dermatitis

[15] Sunscreens And Photoprotection - StatPearls - NCBI Bookshelf. (n.d.). Retrieved May 16, 2022, from https://www.ncbi.nlm.nih.gov/books/NBK537164/

[16] Rathi, H., Rathi, P., & Biyani, M. (n.d.). International Journal of Medical Science and Education Cosmetovigilance: A System Ensuring Safe Use Of Cosmetics. Int.J.Med.Sci.Educ, 6(4), 67–71.

Retrieved May 16, 2022, from www.ijmse.com

[17] Sarma, P., Kumar, H., & Medhi, B. (2017). Cosmetovigilance in India: Need of the day. Indian Journal of Pharmacology, 49(5), 341. https://doi.org/10.4103/IJP.IJP_45_18

[18] Kader Mohiuddin, A. (2019). Heavy Metals in Cosmetics: The Notorious Daredevils and Burning Health Issues. American Journal of Biomedical Science & Research, 4(5), 332–337. https://doi.org/10.34297/AJBSR.2019.04.000829

[19] Coondoo, A., & Lahiri, K. (2017). Topical steroid damaged/ dependent face (TSDF). A Treatise on Topical Corticosteroids in Dermatology: Use, Misuse and Abuse, 137–150. https://doi.org/10.1007/978-981-10-4609-4_13

[20] Duong, A., Steinmaus, C., McHale, C. M., Vaughan, C. P., & Zhang, L. (2011). Reproductive and Developmental Toxicity of Formaldehyde: A Systematic Review. Mutation Research, 728(3), 118. https://doi.org/10.1016/J.MRREV.2011.07.003

[21] Cosmetovigilance: A Paradigm Shift in Terminology and Concept. (n.d.). Retrieved May 16, 2022, from https://www.researchgate.net/publication/334591733_Cosmetovigilance_A_Paradigm_Shift_in_Terminology_and_Concept

[22] Drugs and Cosmetics Act Amendment 2020. Retrieved May 16, 2022, from https://pdffile.co.in/drugs-and-cosmetics-act-amendment-2020/

[23] A Review of New Indian Cosmetics Rules 2020 | PharmaTutor. (n.d.). Retrieved May 18, 2022, from https://www.pharmatutor.org/articles/a-review-of-new-indian-cosmetics-rules-2020

[24] Toklu, H. Z., Antigua, A., Lewis, V., Reynolds, M., & Jones, J. (2019). Cosmetovigilance: A review of the current literature. Journal of Family Medicine and Primary Care, 8(5), 1540. https://doi.org/10.4103/JFMPC.JFMPC_447_18