International Journal of Medical Science and Education
pISSN- 2348 4438 | eISSN-2349- 3208
Published by Association for Scientific and Medical Education (ASME)
Int.J.Med.Sci.Educ. Oct-December. 2019; 6(4):67-71
Available Online at www.ijmse.com
Review Article

COSMETOVIGILANCE: A SYSTEM ENSURING SAFE USE OF COSMETICS

Dr. Heena Rathi[1*], Dr. Priyanka Rathi[2], Dr. Mohit Biyani[3]

1. Department of Pharmacology, 2. Associate Professor, Department of Pharmacology, RUHS College of Medical Science, 3. Department of Anaesthesia, S.M.S. Medical College and Attached group of hospitals, Jaipur (Rajasthan) India.

*Corresponding author – **Dr. Heena Rathi**

Email id – drheenarathi@gmail.com

Received:06/11/2019 ***Revised:12/12/2019*** ***Accepted:20/12/2019***

ABSTRACT

Cosmetics, now a days have become the need of an hour since each individual is using them almost every day. Various products which are being consumed as cosmetics include products for skin care, hair and scalp, nails and cuticle and for maintaining hygiene of oral cavity. These products may show adverse effects or reaction in some individuals they contain many chemicals which may be harmful to some population and may cause contact dermatitis, photo allergic reactions and long term use may also lead to carcinogenicity or some systemic disease. Cosmetovigilance is a recent concept wherein information on safety of cosmetic products and their ingredients is collected and analysed. Several countries like France, Netherlands, the United States of America, Japan, East Asian countries and European countries have already established their cosmetovigilance system. Although India is the 4th largest cosmetic market in Asia but the unwanted or adverse reaction due to cosmetic products go unnoticed due to lack of proper organised reporting system. So, a proper vigilance system is required to protect health of Indian population.

INTRODUCTION

Cosmetics, according to the Association of South East Asian Nations (ASEAN), are defined as any substance or preparation which are applied either on the external surfaces like: on the skin, scalp, eyes, lips and nails or in the oral cavity with an intent to clean or deodorize them , change their appearance, protect or keep them in good condition **(1)**. Every person in the present era is very conscious of his/her appearance. It is for the reason that the desire to enhance beauty and appearance and to become more attractive without affecting the body structure or function has led to an increased use of these cosmetics.

Gazette notification G.S.R 426 (E) divides cosmetics into 4 gross categories that are described in table 1.**(2)**

Table 1: Different categories of cosmetics

Division	Subdivision
Skin products	Products for skin care, cleansing, removal of body hair, body hair bleach, body odour corrective products, products for shaving, products for makeup, perfumes, products for sun and self-tanning and others (2).
Hair and scalp products	4 subcategories- 1. Cleansing and care products 2. Products for hair colouring, hair styling products 3. Products for hair 4. Other products for scalp care (2).
Nail and cuticle	Nail varnish and remover, product for nail glue removing and other

products	products for nail and cuticle care (2).
Oral hygiene products	Tooth care, tooth whiteners, mouth wash and breath spray and other products for oral hygiene (2).

On an average, 9 cosmetic products being used by an adult daily. Nearly 25% of women are consuming 15 or more products in a day **(3)**. Multiple ingredients are used in cosmetics, they are one of the commonest causes of toxicity. During the manufacturing of cosmetic products various chemicals like preservatives and fragrances are added which may be harmful to the human body as some of them are known to have carcinogenic/ mutagenic potential leading to reproductive toxicity and endocrine disruption. Presence of these chemicals in the cosmetic products can produce adverse effects or reactions in the body. These effects may be seen either immediately after use or after chronic use. The commonly seen adverse reactions are- dermatitis, tissue damage, infection, discoloration, bleeding, nervousness, respiratory system reactions, vomiting, diarrhoea, urogenital reactions, and flammability induced death. Due to the absence of any formal and reliable monitoring systems (i.e. Cosmetovigilance) such adverse reactions often remain unnoticed or unreported. In an attempt to overcome this problem, the FDA established a network system for the sake of gathering consumer complaints. Likewise, European countries have also designed a project intending to collect information on cosmetics utilisation pattern which can be used as an input for adverse reaction assessment **(4)**.

Cosmetovigilance is the process of collection, analysis, and assessment of adverse reactions occurring in cosmetics consumers in order to identify any potential health risk, thus guaranteeing a further strengthened safety for consumers **(5)**.

Cosmetic ingredients and their hazards

One of the most common evil effects of cosmetics is allergic contact dermatitis (ACD). This may occur due to the presence of allergens in the cosmetic products. The most common of which are fragrances and preservatives **(6)**. Heavy metals are also commonly present as impurities in trace amount in cosmetics and personal care products. Since these are product impurities, their presence is not required to be mentioned on the label but these metals are known to be cumulative poison due to their long half-life **(7)**. These elements example- lead and cadmium are not only dangerous to humans but also to animals. Some of them may damage external or internal organ even at low concentration. According to the classification of cancer potential metals mercury is not having cancer causing agents, yet mercury chloride and methyl mercury are potential carcinogens in humans **(8)**. Other Heavy metals like nickel, cobalt, copper, and chromium are also allergens.

Skin cosmetics

Adverse effects include irritation-burning, stinging, itching, or other skin discomfort without visible, objective signs of inflammation. These discomforts are mainly observed on face in 1-10% of all cosmetic users **(9)**. The usual signs are mild erythema and scaling, but dermatitis may also occur. In humid climate, irritation occurs due to deodorants and anti-perspirants.

Photosensitivity due to sunscreens or lotions

Only a small proportion of cosmetics related side effects can occur due to Photosensitivity. Sunscreen preparation and skin care products contain UV filters. Exposure to sunlight in those persons who use UV filters extensively may lead to premature skin aging and cancer. These UV filters are important causes of photo contact allergic reactions.

Shaving products

Aftershave lotions and perfumes may cause allergy like contact dermatitis

Lipsticks

Lipstick generates reactive oxygen species which produce haemolysis and causes lipid peroxidation in human erythrocytes when exposed to sunlight. The lipstick and creams which were used for testing showed absorption in UV/Visible range. Daily application of lipstick (1-14 times a day) by women exposes them to the harmful effects of lead and other heavy metals and can potentially affect their health.

Hair Dyes

Adverse events of hair dye are mostly produced by an ingredient -PPD (Paraphenylenediamine). Due to presence of PPD in hair dyes some patients may experience photo allergic dermatitis or dye induced depigmentation.18-MEA (18-methyl eicosanoic acid) layer present in hair is responsible for hydrophobicity in hair. It protects hair by preventing too much water absorption from environment. Application of hair dye strips 18- MEA layer, making the hair texture coarse and dull. Apart from

making hair dull and coarse hair dyes play a significant role in hair fall. Most hair dyes contain PPD, which induces apoptosis (internally programmed and well-coordinated cell death) leading to hair fall **(10)**. . Other reactions include lymphomatoid reaction, erythema multiformae, and anaphylaxis after hair dye application. Few reports have linked an increase in incidence of follicular lymphoma in patients using permanent hair dyes **(11)**.

Others

Sticker bindi, kumkum, and kajal have also been found to be an important risk factor for the occurrence of contact dermatitis.

Adverse effects of cosmetics in pregnancy and children

The impact of use of cosmetics during pregnancy is another issue which needs to be dealt with great care. Couto et. Al have reported that the use of hair dye or hair strengthening products are associated with more adverse effects in first trimester of pregnancy. Hair cosmetics lead to development of acute lymphoblastic leukaemia and acute myeloid leukaemia in their children **(12)**.

Harmful ingredients present in baby products are:

- Skin irritation and allergies can be caused by 2-bromo, 2 nitropropane and 3 Dioclan.. These ingredients have carcinogenic potential **(13)**.

  Desitin diaper cream possess sodium borate which can accumulate in liver and brain causing health effects **(13)**.

Global status of Cosmetovigilance system

France- The safety of products is the responsibility of the member states of the European union. In 1999 the French government decided to replace the Medical Drug Agency by French Agency for the Safety of Health Products.

In the year 2000, France constituted a cosmetology commission. Later on in the year 2002 the working group on the safety of use of cosmetic products (GTSPC) was established with a goal to formulate the basis of a national cosmetovigilance system and to provide the organisation with data on adverse effects related to cosmetic products. The results of French cosmetovigilance are available on the website - French National Agency of Medicine and Health Products (ANSM). Based on surveillance it was found that vitamin K which was used in various cosmetic products may act as allergens causing sensitization. Subsequent to this, the use of vitamin K was banned. Cosmetovigilance has also led to a greater awareness on the risk of paraphenylenediamine (PPD) sensitisation from temporary black tattoos; and contributed to the new regulation on hair dyes.

Europe- various researches conducted by the European consultations reported that some cosmetic ingredients like: preservatives, perfumes, and para derivatives are also found in detergents, industrial products, food and so on. It means if any individual having increase PPD or positive PPD test, it is not necessary that it is only due to cosmetic products. It may occur due to detergents or industrial products or food. Consequently, all the member states of European council were advised to develop a system for recording and collection of the undesirable effects of cosmetic products in order to protect human health. This lead to creation of cosmetovigilance system in Belgium, Norway, Sweden, Denmark, Germany, and Italy **(15)**.

Netherlands- The Netherlands Food and Consumer Product Safety Authority and Ministry of Health agreed to monitor harmful effects of cosmetics and express their willingness to work toward establishing a cosmetovigilance network **(16)**.

United States under the US Food Drug and Cosmetic Act 1938 an agency was established which is responsible for the safety of Personal Care Products (PCP)/Cosmetics. The US Food and Drug administration has made labelling and purity of cosmetics mandatory for marketing of cosmetics in the United States. Thus , it is the responsibility of the manufacturer in United States to provide good quality cosmetic products. If a cosmetic has not been measured for safety by the manufacturer. Then they must put a warning label. In 2008, the Personal Care Products Council (PCPC) initiated a programme called the Consumer Commitment Code (CCC) on a voluntary basis for all the companies in the industry. The 6 principles to the CCC are as follows-

1. A cosmetic product can be marketed only if the safety of each ingredient and finished product has been established by the company **(17)**.
2. The company will have to provide additional sufficient information regarding the safety of the ingredient which is present in a concentration that exceeds the permissible limits that are mentioned by the regulatory authorities,Food and Drug Administration **(17)**.

3. If the data on safety of an ingredient is found to be insufficient by the regulatory authority then the company should further provide substantial information on the safety **(17)**
4. A company must submit periodic safety update reports to the FDA in accordance with their cosmetic reporting program **(17)**.
5. In case of any known serious unexpected adverse events occurring due to use of any cosmetic product, the company should immediately inform the Food and Drug Administration **(17)**.

Japan and East Asia- Amongst all industrialised countries, Japan has the most stringent regulations for the safe use of cosmetics and cosmetic ingredients. Categorization of cosmetics is similar to US regulation but some additional categories are also added in Japanese regulations called- quasi-drugs . Japanese regulations mandates a registration process for cosmetic products which should include the evidence for efficacy and safety of them.

The website of the ministry of health, labour and Welfare provides all the detail of the registration process. Thus, those ingredients which are approved by it can be used in cosmetic articles. Following Japanese model other Asian countries like- China, South Korea, Taiwan, and others have introduced cosmetovigilance system **(17)**.

Need of cosmetovigilance in India

Cosmetic industry in India is mature and growing in terms of product developments and marketing because user's preferences are changing from only cosmetic, to more functional, advanced and specialised products. India is fourth largest cosmetic market in Asia pacific region. But the unwanted or adverse reaction due to cosmetic products goes unnoticed due to lack of proper organised reporting system. In India, the pharmacovigilance system monitors the adverse drug reactions and recently consideration is also being given to medical device, blood products, biologics, and special nutritional and natural products, however adverse reaction related to cosmetic products have still remained unmarked. It is time that India should also initiate to have a formal cosmetovigilance system. This could contribute to increase the safe use of cosmetics which is important for the safeguard of public health. In the year 2014,Vigan and Castelain recommended in their study that proper use of cosmetovigilance system can help to regulate or eliminate harmful ingredients present in cosmetics and subsequently boost our confidence on safe use of these products **(16)**.

REFERENCES

1. ASEAN Cosmetic directive (ACD), 2008 , ASEAN definition of cosmetics and illustrative list by category of cosmetic products.
2. Guidelines on Registration of import of cosmectics. Available from: http://www.cdsco.nic.in/writeraddatta/Guidelines%20on%20Registration%20%of%20Import%20of%20cosmetics.pdf.
3. Linda B, Sedlewicz B, Cosmetic preservatives: Friend or foe? Skinmed 2005;4:8-100.
4. California cosmetics bill becomes law, William Reed Business Media SAS. Available at: http://www.cosmeticsdesign.com/Market-trends/California-cosmetics-Bill-becomes-law accessed March 5,2009.
5. Lidia Sautebin. A Cosmetovigilance survey in Europe. Pharmacological Rasea 2007; 55(5):455-60.
6. Hamilton T, de Gannes G.C. 2011. Allergic contact dermatitis to preservatives and fragrances in cosmetics. Skin therapy letter.com, http://www.skintherapyletter.com/2011/16.4/1.html
7. Ayenimo J .G, Yusuf A.M, Adekunle A.S, Makinde O.W. Heavy metal exposure from personal care products. Bull Envirion Contam Toxicol 2010;84:8-14
8. Peregrino C.P., Moreno, M.V., Miranda, S.V, Rubio A.D, Leal, L.O. Mercury levels in locally manufactured Maxican skin lightening creams, Int. J. Environ. Res. Public Health 2011;8:2515-23.
9. Varsha Jadhav, Swati Dhande, Vilasrao Kadam. Cosmetic side effects. World journal of Pharmacy and Pharmaceutical Sciences 2017;6(1):327-43.
10. Chyle SM, Tiong YL, Yip WK, Koh RY Len YW, Seow HF, et al. Apoptosis induced by para-phenylenediamine involves formation of ROS and activation of p38 and JNK in change liver cells. Environ Toxicol 2012;29(9):981-90.
11. Sagrajrang S, Renard H, Kuhaprema T, Pornsopone P, Arpornwirat W, Brennan P. Personal use of hair dyes- increased risk of non

Hodgkin's lymphoma in Thailand. Asian Pac J Cancer Prev 2011;12:2393-96.

12. Couto AC, Ferreira JD, Rosa AC, Pombo-de-Oliveria MS, Koifman S; Brazillian. Collaborative study group of infant Acute leukemia. Pregnancy, maternal exposure to hair dyes and hair straightening cosmetics, and early age leukemia. Chem Biol Interact 2013;205:45-52.
13. Naveed N, The perils of cosmetics. Journal of Pharmaceutical Science and Research, 2014;6:338-41.
14. Decision du 08/03/2006/http://ansm.sante.fr/S-informer/decisions-de-l-agence- Decisions-de-police-sanitaire/decision-relative-a-l-interdiction-de-fabrication-de-conditionment-d-titre-gratuit-ou-onereux-et-d-utilisation-de-produits-cosmetiques-de-la-vitamine-K1-bom-INCI-phytonadione/(language)/fre-FR.
15. Cosmetovigilance. http://www.health.belgium.be/eportal/searchResaults/index.htm
16. Vigan M, Castelain F. Cosmetovigilance: Definition, regulation, and use "in practice". Eur J Dermatol 2014;24(6):643-49.
17. Gerhard J, Nohynek, Eric Antignac, Thomas Re , Herve Toutain. Safety assessment of personal care products/ cosmetics and their ingredients. Toxicology and Applied Pharmacology 2010;243(2):239-59.

How to cite this article: Rathi H., Rathi P., Biyani M., Cosmetovigilance: a system ensuring safe use of cosmetics. Int.J.Med.Sci. Educ 2019;6(4):67-71