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Review Article

Cosmetovigilance: a review and practice in India

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ABSTRACT

Cosmetovigilance is a rapidly expanding area of research under pharmacovigilance in India. This study analyses the cosmetic consumption practices and associated adverse drug reactions reported by particulars. According to the US Food and Drug Administration's (FDA), cosmetics are defined as 'article for beautification, cleansing or altering physical appearance' (U.S. Food and Drug Administration, 2018). The consumption of personal care products (PCP) has been rising for quite a while in passing decades which something has to do with physical appearance in the community globally which directly gave rise to emergent of cosmetic industries. Their continuous exposure could lead to significant accumulation in the body and for several adverse health outcomes which can appear as redness, scales and blisters, marking to no visible changes whereas major manifestation can range up to loss of hair, fragile nails and contact dermatitis. Data suggest hair dye is one of the leading causes for contact dermatitis in India. Counterfeit cosmetics is fraudulent or imitation beauty products that are designed to mimic genuine and reputable brands. These counterfeit products are often produced and distributed without the authorization or approval of either original brand or regulatory bodies. Impurities such as high level of heavy metals (lead, cobalt cadmium, mercury and aluminium) are reported in many cosmetics products (lipstick, lip glosses, eye shadow and hair dye) while they pose peculiar health threats like hand dermatitis, asthma and infertility, which is common among hair and saloon technicians.

Keywords: Cosmetovigilance, Contact dermatitis, Heavy metals, Pharmacovigilance

INTRODUCTION

Cosmetovigilance: a review and practice in India

Cosmetovigilance is a rapidly expanding area of research under pharmacovigilance in India. This study analyses the cosmetic consumption practices and associated adverse drug reactions reported by particulars. Cosmetics are the chief characteristics of the human routine life style in all age group and are spread among the individuals for variety of uses and purposes. According to the US Food and Drug Administration's (FDA), cosmetics are defined as 'article for beautification, cleansing or altering physical appearance' (U.S. Food and Drug Administration, 2018).¹ Whereas section 3 (AAA) of drug and cosmetic Act defines

'cosmetics' as 'any article intended to be rubbed, poured, sprinkled or sprayed on or introduced into or otherwise applied to, the human body or any part thereof for cleansing, beautifying, promoting attractiveness or altering the appearance and includes any article intended for use as component of cosmetic.' The simple basis behind particular rationale that the wish to magnify beauty and presence and to become more attractive without altering the body structure or function has led to growing use of these products.² The consumption of personal care products (PCP) has been rising for quite a while in passing decades which something has to do with physical appearance in the community globally which directly gave rise to emergent of cosmetic industries. Personal care products may contain numerous injurious or damaging chemical could cause harmful effects to skin. Detrimental

effects of heavy metal in variety of cosmetic products for examples like facial makeup have been mentioned in literature. Their continuous exposure could lead to significant accumulation in the body and for several adverse health outcomes which can appear as redness, scales and blisters, marking to no visible changes whereas major manifestation can range up to loss of hair, fragile nails and contact dermatitis. With increased use of cosmetics, the rate of sensitization to many allergic components has increased. Data suggest hair dye is one of the leading causes for contact dermatitis in India.^{3,4}

The term Pharmacovigilance defines the activities related to the collection, detection, assessment, monitoring and prevention of adverse reaction (ADRs) due to pharmaceuticals. An ADR is any response to a drug which is noxious and unintended, including lack of efficacy. Recently the spectrum of vigilance broadened to include safety of herbal products and cosmetic product as well Whereas Cosmetovigilance is the process of collection, analysis and assessment of adverse reactions occurring in cosmetics consumers to identify any potential health risk, thus guaranteeing a further strengthened safety for consumers.^{5,6} Gazette notification G.S.R. 426 (E) divides cosmetics into 4 gross categories that are described in table 1.⁷

Table 1: Different category of cosmetic products.

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
Hair and scalp products	4 subcategories: cleansing and care products, products for fair colouring, hair styling products, products for hair, other products for scalp care
Nail and cuticle products	Nail varnish and remover, product for nail glue removing and other products for nail and cuticle care
Oral hygiene products	Tooth care, tooth whiteners, mouth wash and breath spray and other products for oral hygiene

COSMETIC COMPONENTS WITH POSSIBLE RISK AMONG CONSUMERS

Allergic contact dermatitis (ACD) is the most common adverse effects reported following use of cosmetic products, which could be due to exposure of allergens like fragrance and preservatives used in cosmetic products. Heavy metals are well known adulterants happened to be in trace amount in personal care products. While they are impurities in cosmetics, they are not demanded to be

mentioned on the label but these heavy metals are tended to be cumulative poison due to their long half-life. Few examples like lead, cadmium, nickel, cobalt and copper are both hazards in animal and humans. As mentioned in classification of cancer potential metals mercury is not having cancer causing agents per se, yet mercury chloride and methyl mercury are potential carcinogens in humans.^{8,9}

Skin cosmetics and their manifestation

Deleterious outcomes can be presented as irritation-burning, itching or other sort of skin discomfort with or without visible sign of inflammation. These manifestations are mainly observed on face in 1-10% of all cosmetics users. Sunscreen compounds and skin lotions contain ultraviolet (UV) filters. Exposure to sunlight in those persons who use UV filters extensively may lead to premature skin aging, photosensitive allergic reaction and precancerous lesions.¹⁰

Hair dyes, lipsticks and shaving products

Adverse events of hair dye are mostly produced by an ingredient PPD (Paraphenylenediamine) which can manifest as photo allergic dermatitis or dye induced depigmentation. Furthermore, lipstick generates reactive oxygen species which produced hemolysis which leads to lipid peroxidation in human erythrocytes when exposed to sunlight. Such lipstick and creams were shown to absorb UV/Visible range in testing so daily application of lipstick (1-12 times/ day) by women exposes them to the harmful effects of lead and other heavy metals whereas aftershave lotions and perfumes may cause allergy like contact dermatitis.¹¹

Counterfeit and spurious cosmetics

Counterfeit cosmetics are fraudulent or imitation beauty products that are designed to mimic genuine and reputable brands. These counterfeit products are often produced and distributed without the authorization or approval of either original brand or regulatory bodies. They are sold in intent to deceive consumers into believing they are purchasing legitimate and originally safe cosmetics. Misbranded and spurious cosmetics are defined as per provision of Drugs and Cosmetics Act 1940 and Drug and Cosmetics rule 1945. Cosmetics are called misbranded if it contains an unprescribed color, unsuitable labelling or contain false/misleading product information. Cosmetics are labelled as spurious when its name resembles another cosmetic; the product resembles another cosmetic or if manufacturer information is misleading/ fictitious or does not exist, which can dupe customers. Spurious cosmetics are commonly reported in Indian market. Spurious cosmetics in branded bottles are found to be sold to parlours and salons. Impurities such as high level of heavy metals (lead, cobalt cadmium, mercury and aluminium) are reported in many cosmetics products (lipstick, lip glosses, eye shadow and hair dye) while they pose peculiar health threats like hand dermatitis, asthma and infertility, which

is common among hair and saloon technicians. Spurious cosmetics erode the market share of authentic products, leading to reduced revenues and profitability of genuine manufactures and cause financial losses.^{2,12,13}

INTERNATIONAL SCENARIO OF COSMETOVIGILANCE

United States under the US food drug and cosmetic Act 1938 an organization was put in place which is responsible for the safety of Personal Care Products (PCP). The US food and drug administration has made labeling and purity of cosmetics mandatory for marketing of cosmetics in united states. In 2008, the personal care products Council (PCPC) commence a plan of action called the Consumer Commitment Code (CCC) on a voluntary basis for all the companies in the industry.

The 6 principals to the CCC are as a cosmetic product can be marketed only if the safety ingredients and finished products have been established by the company. 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.

If the data on safety of an ingredient is found to be insufficient by the regulatory authority, then company should further provide substantial information on the safety. A company must submit periodic safety update reports to the FDA in accordance with their cosmetic reporting program. In case of any known serious unexpected adverse events occurring due to the use of any cosmetic products, the company should immediately inform USFDA.¹⁴

The welfare of the 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, the year 2002 the working group on the safety of use of cosmetic products (GTSPC) was established with goal to formulate the basis of a national cosmetovigilance system and provide organization with data on adverse effects related to cosmetic products.

Such agency being at work with continuous surveillance it was found that vitamin K which was used in various cosmetic products may act as allergens causing sensitization, following to this data, the use of vitamin K was banned. It also led to more awareness on the risk of paraphenylenediamine (PPD) sensitization from temporary black tattoos and contributed on the making of regulation for hair dyes. European council were later advised to develop a system for recording and collection of the undesired effects of cosmetic products to protect human health in such countries like Belgium, Norway, Sweden, Denmark, Germany and Italy.¹⁵

ADVERSE EFFECTS OF COSMETICS IN PREGNANCY AND CHILDREN

The aftermath of use of cosmetics during pregnancy is another concerning matter to be dealt with urgently, Couto et al, has stated that the use of hair dye or hair strengthening products is affiliated with more harmful effects in first trimester of pregnancy. Hair cosmetics could lead to development of certain type of leukaemia in their children, moreover use of botulinum toxin and Sclerotherapy is another controversial area that needs to practice with caution and better to be avoided during the pregnancy. There are reported harmful ingredients present in baby products for example skin irritation and allergies can be caused by 2-bromo, 2-nitropropane and 3-Dioclan and Desitin diaper cream possess sodium borate which can accumulate in liver and brain causing health effects.^{16,17}

COSMETOVIGILANCE PRACTICES IN INDIA

Cosmetic manufacturing and consumption in India is already huge in terms of product growth and retail because users predilection are changing from only cosmetic, to more practical, advanced and specific products. Adverse effects due to consumption of cosmetic products overlooked due to lack of orderly reporting system while being India as fourth largest cosmetic market in Asia pacific region. Import of cosmetics tested in animals is prohibited in India as per section 135 B of drugs and cosmetics act. Like other diseases, disorders affiliated to cosmetics can potentially lead to pharmacoeconomic loss.

Going with words of Vigan and Castelain, 2014, proper use of cosmetovigilance can help to control or rule out hazardous ingredients in cosmetics and thus improve our confidence on use of these agents. Recently pharmacovigilance system has given consideration is to medical device, blood products, biologics and special nutritional and natural products, however adverse effects due to cosmetic products have still remained unmarked. It is time that our country should also initiate to have a formal cosmetovigilance system which will contribute to increase the safe use of cosmetics thus safeguard of public health.^{6,18}

CONCLUSION

Cosmetovigilance has been around us for decade yet cosmetic product safety monitoring is still evolving. This article has highlighted the negative impact of chemicals commonly found in cosmetics such as sulfates, parabens, phthalates, synthetic colors, fragrances, toluene and others associated health issues with them like skin irritation, hormonal disruption and even malignancy. Furthermore the article shed light on the alarming prevalence of counterfeit beauty products in the market. Counterfeit products contain high level of toxic substances such as lead, arsenic, mercury and microbial contamination. Such indications also demand rigorous post marketing surveillance data at global level, problem relating to a

product can be identified and solved and thus safety can be achieved product.

Overall, the importance of Cosmetovigilance cannot be overstated, Regulatory bodies, industry stakeholders, primary care practitioners and consumers must work together to ensure the safety and integrity of cosmetic products. Continued research, stringent regulations and public awareness are essential in safeguarding individual well-being and promoting a healthy cosmetics industry.

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