

Cosmetovigilance: Current Status And Need In India

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Abstract: Background: Usage of cosmetic products has been increased significantly in last few decades. Their usage has increased beyond the purpose of beautification. The definition of cosmetic product varies widely amidst different countries. Increased concern of physical appearance in population throughout the globe has been taken as an advantage by the cosmetic industries. Increased usage of different personal care products for prolonged period of time leads to exposure of the human body to wide variety of chemicals which may lead to adverse effects. Heavy metals have been found in certain cosmetic products which not only lead to dermatological but systemic adverse effects too. Further to this, pharmacologically active agents have been found in anti aging products. These cosmeceutical agents may possess chemical agents which are toxic to human body. Western countries have laid certain regulatory guidelines for manufacturing, labelling and marketing of cosmetic products. Cosmetovigilance ensures appropriate and safe use of cosmetic products. In India, Drugs and Cosmetic Act governs the regulations for the cosmetic products. Need of formal adverse event reporting system as well as strict regulatory guidelines for cosmetic products are required to curtail the adverse health outcomes due to cosmetic products. [Trivedi S Natl J Integr Res Med, 2021; 12(6): 94-97]

Key Words: Cosmetovigilance, Cosmetic Product, Personal Care Product , Cosmeceutical

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Introduction: The word cosmetic is not limited to a gender, population or country anymore. The coverage of cosmetic products have increased their arena beyond skin glowing agents like lipsticks, powders, creams but also include tooth paste, shampoo, conditioners and many more items of facial make up. Personal care products (PCPs) are also widely consumed by people of all ages on almost daily basis.

There are cosmetics for professional use as well as bulk institutional products and handmade cosmetics sold at craft sales or home-based businesses. While finding the literature, authors found a surprising fact that not only the definition of cosmetics but laws and regulations related to them vary widely amidst different countries. Any articles which are used with the purpose of cleansing, improving beauty or alteration of physical look is considered as cosmetic product as per US- FDA¹. Whereas Saudi FDA defines the cosmetics as 'any product contains one or more substance intended to use on the outer parts of the human body (skin, hair, nails, lips and the outer parts of the genital), teeth, and the mucous lining of the oral cavity for cleaning purposes, perfuming, to protect or keep the good condition, to change or improve appearance, or to change or improve the smell of

the body²." Cosmetics, according to the Association of South East Asian Nations (ASEAN) is any product applied externally on the human body with a view exclusively or mainly for cleaning them, perfuming them, changing their appearance, and/or correcting body odors and/or protecting or keeping them in good condition³.

Whereas according to the Drugs and Cosmetic Act (India), cosmetic product is one which apply by different means such as rubbing, sprinkling, spraying etc. to the any part of the human body for the purpose of beautification, cleansing or alteration of physical appearance in a way to make it more attractive⁴.

The usage of so called personal care products (PCPs) has been increased in last few decades because of overall increase in the concern of physical appearance in the society globally. This increased demand of personal care products reflected in mushrooming of cosmetic industries with emergent of many more cosmetic products. Excessive exposure of the general population to a wide variety of chemicals may pose adverse health effects⁵. Concern of the physical appearance has so much increased that non-acceptance of the age related changes in the skin textures and appearance with dissatisfaction and

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apprehension increase markedly. There has been demand for anti-aging products. This is one of the core reason that cosmetic industries had utilized this fact and developed anti-aging products which have incorporated biologically active ingredients to improve the skin texture⁶.

Cosmetic products may contain various harmful or toxic chemicals capable of causing harmful effects to the skin. Heavy metals have been involved in cosmetics commonly used by women.

Harmful effects of heavy metals in various cosmetics products like facial make-up have been reviewed in literature^{7,8}. There are chances of passage of heavy metals in systemic circulation especially through unbroken skin⁹. Their prolonged use may lead to significant accumulation in the body and responsible for various adverse health consequences not only related to the skin like contact dermatitis, hair loss and brittle hairs but involve different body systems too.

Some of the health risks associated with heavy metals in cosmetics is cancer, reproductive and developmental disorders, neurological problems, cardiovascular, skeletal, blood, immune system, renal problems, gastrointestinal and respiratory problems.

Adverse effects due to cosmetics are not only limited to the consumers but it can also affect the environment and animals¹⁰. Another recent development is increased use of cosmeceuticals.

Cosmeceutical is a cosmetic product claimed to have medicinal benefits. The term "cosmeceutical" was created in 1990s from cosm(etic) + (pharma)ceutic. Cosmeceutical products are marketed as cosmetics but majority of them contain biologically active ingredients.

Some of the antiaging products contain alpha lipoic acid and dimethylaminoethanol which are having biological actions. The term "Cosmeceutical" has not got recognition from US-FDA. While drugs are subject to review and approval process by FDA, cosmetics are not.

As the cosmetic products are not claiming to be having pharmacologically active agents, they bypass these reviewal and approval by regulatory bodies and hence put very big question mark on their safety issues¹¹.

Adverse health consequences can occur due to presence of toxic substances in their formulations. Even though the existence of various regulatory and quality control measures for the cosmetic products throughout the globe, there is definite need of strict measures for evaluating the toxic potential of the ingredients of cosmetic products.

Additionally, there is need for uniformity in the regulatory process of cosmetic products throughout the globe not only for manufacturing but for marketing as well as utilization by consumers. Cosmetovigilance ensures safety of cosmetic products and their ingredients, preventing the risks associated with the use of cosmetics become a serious public health problem¹².

On one hand US Food and Drug administration has made labelling and purity of cosmetics mandatory for marketing of cosmetics in the United States. Hence forth the responsibility lies on the manufacturer to provide quality cosmetic products. If a cosmetic has not been measured for safety by the manufacturer then they must put a warning label. In lieu of this, Consumer Commitment Code (CCC) was initiated by Personal Care Products Council (PCPC) in 2008 for the cosmetic industries on voluntary basis¹³.

On the other hand, European council advised its member countries to develop a system for record 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 Italy¹⁴. 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 network¹⁵.

Concept of cosmetovigilance ensures the safe use of cosmetics throughout the country as well as it makes sure that the side effects and reactions caused due to it do not go unreported. That is the reason most of the European countries, United States of America along with some East Asian countries have started taking steps in that direction. In India, regulatory guidelines on few aspects for the cosmetic products are available in the Drugs and Cosmetics Act, 1940. There are different section for rules for regulation of import

and registration of cosmetics, manufacturing process, labelling, packing and standards.

Certain prohibitions have been imposed for the toxic chemicals to be incorporated in cosmetic products as they have been proven to be toxic. i.e. The use and import of arsenic and lead containing compounds have been prohibited under rule 135 and 145 while cosmetics containing mercury are prohibited as per rules 135A and 145 D.

Rule 134-A prohibits import of hexachlorophene containing cosmetic. Certain standards have also been defined for the color, dye or pigments that are used for the cosmetic products. According to Gazette notification G.S.R 426(E), cosmetic products are classified in to four major categories: (i) Skin products (ii) hair and scalp products (iii) nail and cuticle products (iv) products for oral hygiene¹⁶. But unfortunately there is no established system of reporting of adverse drug reactions from cosmetic products.

While highlighting the pattern and extent of usage of cosmetic products and resultant adverse effects in India, it has been found that Indian beauty and personal care (BPC) industry is estimated to be worth USD 8 billion. India's per capita spend on beauty and personal care is it is growing in line with India's GDP growth¹⁷.

India is fourth largest cosmetic market in Asia Pacific region. As the most common site as well as the method of application, face and hand are the most common target areas for the adverse effects due to use of cosmetic products. In study conducted by Straetemans M et al. in 2007, tenderness, swelling, itching and bumps were the most common ADRs following the use of cosmetic products for makeup procedures and some of the ADRs were lasted upto 3 years¹⁸.

It is also logical that as the use of the cosmetic products is on increasing trend, the rate of sensitization to the products have proportionately increased. With the availability of many hair dye products without strict regulatory controls of quality and enormous use of these products, many cases of contact dermatitis are going to be reported with their usage. Similar to the spurious drugs, misbranded and spurious cosmetics are not very uncommon. Misbranded cosmetics are defined as if any cosmetic contains

any un prescribed color, inappropriate labelling or false/misleading product information¹⁹.

While spurious cosmetics are those which are having resemblance in name or appearance or manufacturing information is either misleading or fictitious²⁰. Some of the most common mild adverse reactions due to cosmetics are skin irritation, itching, burning but there has been cases of the long term use of some cosmetics.

Structured and organized reporting of adverse events due to cosmetic products is highly needed to generate awareness, reporting and subsequent preventing of adverse health consequences due to cosmetic products. Hence, an adequate system for Cosmetovigilance is required in India for the sake of the protection of health of the huge Indian population.

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