

Cosmetovigilance: the future of cosmetics safety

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Drugs or medicines are beneficial, but not always. Whenever a drug is taken, there is risk of unwanted reactions due to the drug. The unwanted, harmful effects of drugs are of different clinical expressions, different severity, from negligible dryness in mouth to even death, and also for different reasons. Adverse Drug Reaction (ADR) is a severe type of harmful effects of drugs that occurs when a drug is used in therapeutic dose range. ADR is now a reality in the modern therapeutics. After 'Thalidomide disaster in 1961', a number of incidences was noticed in the history of drug development. Understanding of harmful effects of drugs like, side effects & ADRs clear at that time. ADR is defined as 'any noxious change which is suspected to be due to a drug, occurs at doses normally used in men, requires treatment or decrease in dose or indicates caution in the future use of the drug'. This definition excludes trivial or expected side effects and poisoning or overdose.

Clinical trials are important ways in the discovery of new drugs. It is basically research of new drugs on humans. There are different advantages of clinical trial. It is considered as one of the most reliable methods for credible data generation for drug development. At the same time, it is never possible to know the whole story of a drug through clinical trials. A clinical trial can inform the minimum information determined by the legislation and by contemporary judgments about the acceptable balance between benefit and harm. Benefit-risk profile is more important for any drug/medicine to survive in the market. In fact, there is nothing that could tell about whole story of a drug/medicine.

As per present understanding 'safety' of any drug is more important than its 'efficacy'. Therefore, safety of any medicine/drug should be ensured first. With change in global concept of ethics, any type of harm to mankind is to be protected first. So, ensuring safety is the priority now. To overcome the shortcomings of pre-marketing trial, World Health Organization (WHO) has formulated a global 'Pharmacovigilance' program as an important post marketing tool in ensuring the safety of pharmaceutical and related health products. Concept of "Pharmacovigilance" was introduced in the science for ensuring safety. It is defined as the science and activities concerned with the detection, assessment, understanding and prevention of adverse effects of drugs (ADR) or any other drug related problem.

Cosmetics are products that are used to care for the face and body or to accentuate or change the appearance of the face or body. According to the Association of South East Asian Nations (ASEAN), "Cosmetics" 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.

Cosmetics have been in use for thousands of years. There are basic differences in cosmetics and drugs. Cosmetics are chemical substances or other products used for different purpose in the society. As drugs/medicines can cause harm to mankind anytime, the chance of human harm is more with cosmetics.

Common use of cosmetics may develop side effects or even adverse reaction in some cases. The Federal Food, Drug, and Cosmetic Act (FD&C Act), defines cosmetics, as “articles intended to be rubbed, poured, sprinkled, or sprayed on, introduced into, or otherwise applied to the human body for cleansing, beautifying, promoting attractiveness, or altering the appearance”. Examples of cosmetics are skin moisturizers, perfumes, lipsticks, fingernail polishes, eye and facial makeup preparations, shampoos, permanent waves, hair colors, toothpastes, and deodorants, as well as any material intended for use as a component of a cosmetic product. Study revealed that, 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. This indicates the effects of cosmetics on human body and mind.

Cosmetics are popular globally. Its industry turnover is around 299.12 billion in 2016, & is expected to reach US dollar (USD) 412.10 billion by 2024, globally. This indicates the popularity of cosmetics. India is the 4th largest market of cosmetics in Asia. The Indian cosmetics industry has an overall market standing of USD 15 billion in a global market of USD 299 billion.

As per Gazette notification G.S.R 426(E), Government of India, cosmetics are categorized into four gross types. These are –

- (1) **Skin products** {it is further subdivided into 10 subcategories: products for skin care, cleansing, removal of body hair, body hair bleach, body odor corrective products, products for shaving (pre or after shave), products for makeup, perfume, products for sun, and self-tanning and others},
- (2) **Hair and scalp products** {4 subcategories: cleansing and care products, products for hair coloring, hair styling products, and other products for hair and scalp care},
- (3) **Nail and cuticle products** {nail varnish and remover, products for nail care and nail hardening, product for nail glue removing and other products for nail and cuticle care}, and
- (4) **Products for oral hygiene** {tooth care, tooth whiteners, mouth wash and breath spray and other products for oral hygiene}.

Side effects due to cosmetic use are very common. Though there are few studies, still different study reported different adverse effects as a result of use of cosmetics. Data suggested that most common sites of side effects are face and hands with itching (70.9%), dryness of skin (63.3%), and burning sensation in skin (50%), with female predominance. Nausea, vomiting, watering of eyes, respiratory distress, local lymph node swelling, etc are few other side effects. There are very few reporting on adverse effects due to cosmetics use. A report suggests that even there is ‘loss of vision’ due to cosmetic use. Most frequently, fairness cream, and demelanizing agents are causing problems due to cosmetics. Majority of the patients had mild to moderate reactions and recovered completely after medical management. A cross-sectional study for the cosmetic utilization behaviors and adverse reactions explored that, out of 425 participants, 50.6% reported that they had at least one adverse reaction in the past two years. This indicates that adverse reactions due to use of cosmetics are now a reality. Cosmetics are used by all aged male and female. Even ‘pregnant women’ all over the world are using different types of cosmetics. The safety of these cosmetics is of doubt. This reminds the horrible incident of ‘Thalidomide disaster’. Detection of adverse effects of cosmetic products, and to prevent adverse effects by taking appropriate measures are more important for safe use of cosmetics.

Here lies the importance of vigilance about the ill effects of cosmetics, after its entrance in the market. Probably, it is the time to consider the risk-benefit ratio, even for cosmetic use. Till now, there is no organized system of evaluation of side effects or adverse effects of cosmetics after its marketing in India. The identification and analysis of harmful effects related to cosmetic products is basically industry driven, till date. It is the responsibility of manufacturers to determine that products and ingredients are safe before they are marketed, and then to collect reports of adverse reactions. Generally, companies used to collect safety status of cosmetic products and submit it to the regulatory agencies through ‘safety reports’.

As the sale & use of cosmetics is increasing very fast, there is a need to develop a system to monitor the safety status of cosmetics, post marketing, in an organized way. Presently, drug-drug interaction is a reality. Just like that, probability of drug-cosmetics, cosmetics-cosmetics, and cosmetics-food, interactions should be searched. Research may be initiated for ensuring the safety of cosmetics. So, the concept of “Cosmetovigilance” is emerging. Cosmetovigilance is the systematic monitoring of the safety of cosmetics in terms of human health. It was first used in literature by ‘Vigan’ (1997) to refer to the monitoring of cosmetic product safety. Detection of adverse effects of cosmetic products, and to prevent adverse effects by taking appropriate measures are more important for safe use of cosmetics. Concept of Cosmetovigilance is a quite recent one and is different from industry surveillance, the primary aim of which is use of safety information for commercial purpose. Cosmetovigilance is a public health surveillance on cosmetic products with a public health objective, mainly safety.

Industrialized countries like, United States of America, European union, France, Netherlands, etc started their Cosmetovigilance programme as a programme for public health. Asian countries like Japan, are also started their programme for early detection and safe use of cosmetics. It is true that development of scientific background of Cosmetovigilance is not easy. So many problems are related with safe use of cosmetics. Case detection, causality assessment, legal and regulatory effects and also its market impact are crucial issues. Causality assessment in Cosmetovigilance is defined as analysis of the relation between a cause (cosmetic product) and an effect (manifestation). Severity assessment and preventability assessments are also major issue in case of cosmetics. So, future research may clear the concept of Cosmetovigilance, its scientific and financial aspects. But, it is important to start the identification, establishment of ill effects of cosmetics along with its data banking. Public health system may be used for such work. Regulatory and legal issues should be considered to ensure the ‘safety of human health’.

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