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# Cosmetovigilance: Beautiful is Pain

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## Abstract

Cosmetics are defined as preparations used on the skin, mouth, nails, hair, and eyes to increase attractiveness, provide fragrance or protection against body odor, cleaning. The difference between drugs and cosmetics is sometimes not clear. Regulations covering cosmetic products that discuss the products used are safe and can be used by healthy people, product safety, and efficacious from cosmetic products approved by national authorities before being sold to consumers. Monitoring the safety of cosmetic products, and is a very important component of public health activities. After-sales supervision of cosmetic products must be widely spread in the community, and problems related to these products can be solved, and identified to achieve a safe product. In August 2022, a search for the term cosmetovigilance in the Google search database returned 38 articles Family physicians and expert care practitioners, have a very useful role in providing an understanding of Adverse Drug Reactions (ADRs) caused by cosmetic products, and with such occurrences, they can encourage patients to report Adverse Drug Reactions (ADRs) to the appropriate officials authorized. Raise awareness of the new concept and become a valuable commentary on public health at large.

## Introduction

Today's cosmetic products are needed by women and men. Even since birth, cosmetic products are used for the whole body every day. The definition of cosmetics is from the word 'kosmein', which is a word from Greek meaning decoration. Materials used to beautify in the past were mixed and obtained from materials that come from nature and are found in the surrounding environment. Currently, cosmetics are not only made from natural ingredients, they can also come from materials made synthetically with the aim of beautification. At first, cosmetics is a branch of medicine, therefore ancient cosmetologists included health experts as well, such as alchemists, traditional physicians or healers, and advisors of royal families. As the science of medicine developed, a separation of cosmetics and drugs occurred, including types of treatment effects, side effects, and so on.

The definition of cosmetics in BPOM Regulation (National Agency of Drug and Food Control) Number 30 of 2020 concerns technical requirements for marking cosmetics which defines preparations or ingredients used on the outside of the body, such as hair, epidermis, lips, nails, teeth, genitals, and oral mucous membranes which function to clean, add fragrance, increase attractiveness, maintain body odor, and keep the body in good condition (BPOM RI, 2020).

The FD&C Act defines drugs by their intended use, which were uses for diagnosis, mitigation, cure, disease prevention, treatment and other parts that have nothing to do with food which has the meaning of influencing the function of the human or animal body. Cosmetics are defined as their use, which is intended to be rubbed, sprinkled, poured, and sprayed or used on the human body for attraction, cleanliness, beauty, and changing one's appearance. The product in question, in the definition above, includes products such as perfume, skin moisturizer, eye make-up, face make-up, hair dye, nail polish, shampoo, nail paints, and deodorants, or other ingredients, used for the composition of cosmetic products (U.S. Food & Drug Administration, 2022). There are differences between the requirements for cosmetics in the United States and other countries regarding the legal definitions of drugs and cosmetics, restrictions on the use of color additives and other materials, and registration requirements. Some products such as sunscreen are regulated as cosmetics in Europe, while they are regulated as a drug in the United States. Meanwhile, in Indonesia, it is stated in the BPOM Regulation No. 30 of 2020 that sunscreen is a cosmetic product. The European Union Cosmetics Directive, cosmetic products are defined as products that have a function to be used on human skin, especially on the body, such as the hair, nails, lips, parts of the epidermis and external genital organs, mucous membranes in the oral cavity and teeth with functions of cleaning, changing appearance, eliminating body odor, protecting and maintaining a good condition of one's body (Eur-Lex, 2013).

Although the term cosmeceuticals are used occasionally for cosmetic products with ingredients of bioactive compounds said to have medical benefits, the FD&C Act does not recognize categories such as cosmeceuticals (U.S. Food & Drug Administration, 2022). Products can be cosmetics, drugs, or a combination of drugs and cosmetics, and the term cosmeceutical generally has no legal meaning. Based on the intended use and ingredients of the terms mentioned, some meet the definition of cosmetics and pharmaceuticals. For example, anti-dandruff shampoo, toothpaste with fluoride, antiperspirant deodorant, and moisturizer with sunscreen must meet the requirements for both cosmetics and drugs.

The term pharmacovigilance is defined as any activity related to the collection, assessment, detection, and prevention of adverse reactions (ADR) due to drugs, and monitoring of adverse drug reactions (ADR) is a response from unintentionally harmful drugs, including the lack of efficacy of a drug (World Health Organization, 2022). Recently, this awareness of the safety of herbal and cosmetic products is increased to maintain the quality of a product (Toklu, 2016; Vigan & Castelain, 2014).

Cosmetovigilance is defined as activities regarding acts of collecting, evaluating, and monitoring spontaneous reports of events that do not observe during or after normal use of cosmetic products or can be reasonably estimated (Vigan & Castelain, 2014). It was first used in literature by Vigan (2017) to refer to post-market surveillance conducted by the industry (Moretti & Velo, 2018; Sautebin, 2018). Cosmetovigilance initiate by the French Safety of health products agency as part of the pharmacovigilance system for cosmetics (Moretti & Velo, 2008). Today, it is recognized globally as a public health concept to address the safety of cosmetic products. Figure 1 illustrates the steps for monitoring reports of cosmetic side effects.

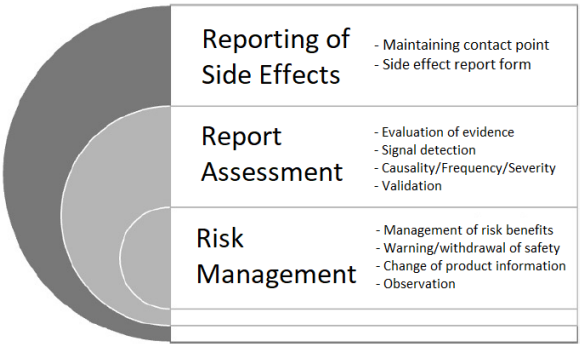


**Figure 1.** Monitoring reports of cosmetic side

## Research Methods

As of August 2022, the searches for the term cosmetovigilance on the Google search page generated 18 articles and identified 15 articles

related to the topic, 3 articles unrelated to the topic were excluded, and 5 more articles and the Food and Drug Administration (FDA) website were included because they were related to ADR reporting with cosmetics.

**Results and Discussion**

Although cosmetic products can be well-tolerated, as seen in drugs, unwanted effects can see with cosmetics and toiletries. (Moretti & Velo, 2018; Sautebin, 2018). However, the knowledge and identification of this effect are challenging due to a lack of standard reporting forms and report validation (Moretti & Velo, 2018; Sautebin, 2018). In addition, the absence of good cosmetology system is a problem on its own (Sportiello *et al*., 2019). It reported that the adverse effects of cosmetics and toiletries are underestimated, even as consumers or patients pursue medical consultations. (Lindberg *et al*., 2014; Lindberg & Tammela, 2014).

In Canada, consumers and healthcare professionals are encouraged to report ADRs that are unwanted or have side effects according to the Natural Health Products Regulations (NHP), which started in January 2004. NHP is responsible for ensuring that all cosmetic products undergo appropriate licensing, establish sufficient evidence of safety and efficacy, require appropriated labeling, provide good manufacturing practices, report ADRs, be aware of clinical trials related to cosmetic products, and be an information source for product recalls to all consumers. There is a report from Incident Report on Cosmetic Products per Consumer, specifically for consumers and manufacturers. Incident reports must report within 15 days of the ADR (Government of Canada, 2021).

In the United States, some similar regulations and departments ensure safe product use, and the department is the FDA. The FD&C Act, Guidance for Industry Post Marketing Adverse Event Reporting for Non-prescription Human Drug Products Marketed without an Approved Application, and the Dietary Supplement Non-prescription Drug Consumer Protection Act regulate prescription and non-prescription cosmetic products in the country. Same NHP in Canada, the FDA follows product labeling, manufacturing, safety and efficacy, ADR, research, and withdrawal. In some situations, cosmetic products may not be FDA approved, but FDA regulated by the FD&C Act to ensure that the product marketed is safe for use. Consumer cosmetic users, healthcare providers, and manufacturers were required to report cosmetics-related advertising to the FDA. ADRs can be reported to the FDA via MedWatch via an electronic form or by calling the hotline. (U.S Food & Drug Administration, 2022). There is a director of consumer complaints in the FDA that helps manage ADR reports. For over-the-counter products, separate reports can be solved, individual case safety reports. In addition to further addressing cosmetic safety measures, the United States issued two measurements: Cosmetics Safety Amendment Act of 2012 and the Safe Cosmetics and Personal Products Laws in 2013. These two actions drive more ADR reporting directly to the Secretary of Health and Human Services within 15 days after ADR (U.S Food & Drug Administration, 2022).

One of the first published large-scale studies based on a 4-year report (2003-2006) of the company's four hair coloring products collected from 45 countries. Analysis of undesired events performed to determine the time, affect state, and product type. The incidence of allergic contact dermatitis to direct hair dye products is lower than oxidative hair dyes. Interestingly, the history of black henna tattoos appeared as the major risk factor for a serious allergic contact reaction. This study is the first to identify risk factors due to cosmetic hair dye products. They concluded that it is important to recognize security issues so that warning against product labels can be revised accordingly (Krasteva *et al*., 2014).

Another large-scale study from Europe was published the same year. The data were based on a report from an industrial company in France (Kornfeld-Lecanu *et al*., 2014). They have set up their alert system to control cosmetics and household cleaning products. Between 2005 and 2007, a total of 102,689 consumers contacted the consumer department, including 842 (0.82%) who reported a skin reaction. After the data collected had been analyzed, 0.144 cases of skin reactions per million units sold were found to be caused by cosmetic or household products. This study shows the importance of quality reporting and the implementation of a structured alert system to retrieve reliable data. In 2005, The European Cosmetic Toiletry and Perfumery Association (COLIPA or Cosmetics Europe) issued guidelines for adverse event report management as a tool to align the industry regarding the collection and evaluation of adverse incident reports (Figure 2). The Post Launch Guidelines and Colipa aim to assess the causality of unwanted effects from cosmetic products on human health (Bons *et al*., 2014; Zweers *et al*., 2013).

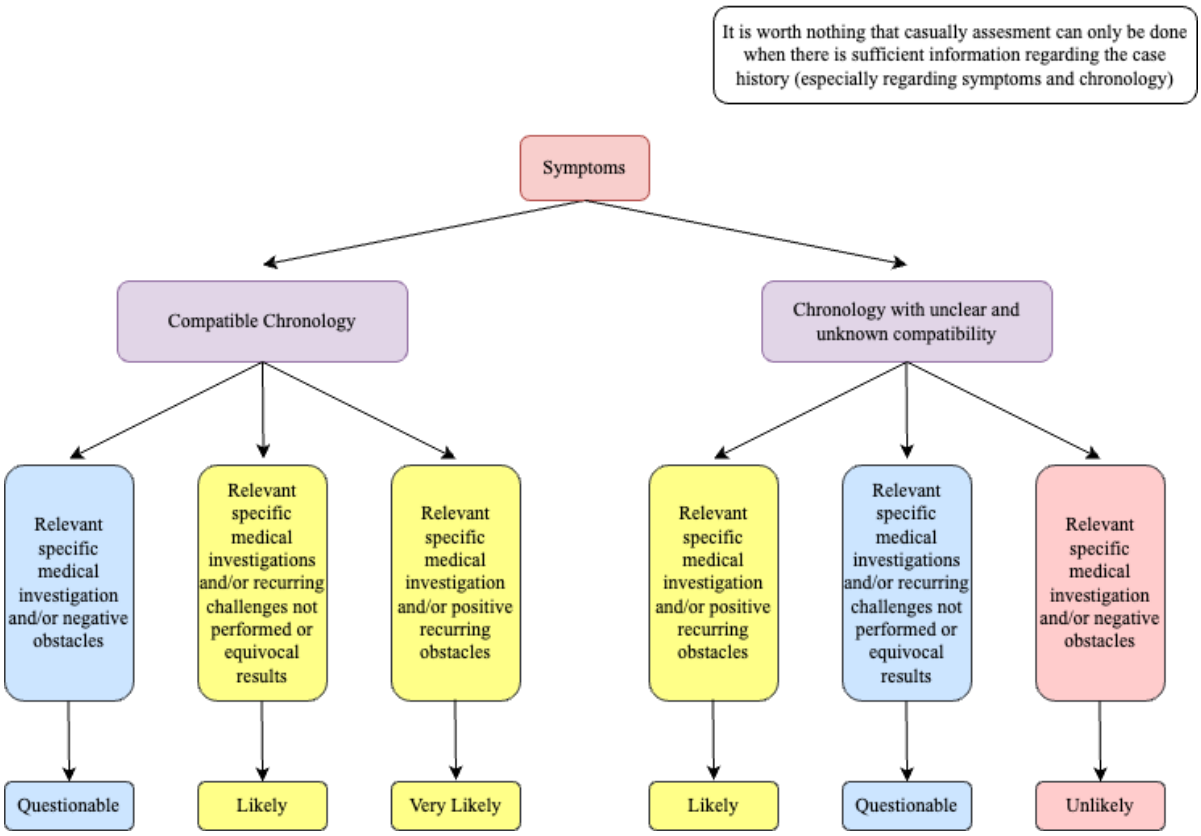


**Figure 2.** Adverse event reporting management

As previously mentioned, the difference between pharmaceuticals and cosmetics can be confusing due to the lack of a standard definition. Differences in the definitions and restrictions on the use of substances lead to several different regulations in the United States and Europe. A survey study in 14 countries showed that cosmetology was handled differently in European countries and suggested the need for a formal cosmetology system (Sautebin, 2017).

Another European study was conducted in Italy, and the results from their research project demonstrated skin reactions representing 96% of reported side effects of using cosmetic products. Most reports are filled out by dermatologists and pharmacists. In many countries, the pharmacist is one of the main points of contact in the system of pharmacovigilance (Toklu & Mensah, 2016). For this reason, they can also work as a good source for cosmetology. In a study conducted in Turkey, pharmacists stated that safety and efficacy were their primary concerns for cosmetics that are sold in pharmacies, and they hope that manufacturers respond and become responsible in case of adverse drug reactions (Sencan *et al*., 2018). in Naples, community pharmacists interviewed 4,373 consumers regarding cosmetic side effects (di Giovanni *et al*., 2016). About 96% of side effects are related to skin complaints such as burning and itching. Systemic side effects account for only 4% of all side effects. Interestingly, 60% of consumer report cosmetic-related injuries regardless of any consultation type. In addition, 2.5% of cases seeking medical consultation continue to use the product, while taking medication to treat the side effects.

A study conducted by Salverda *et al*. (2013) evaluated the overview of unwanted effects associated with cosmetic products in the Netherlands. Besides the survey performed by general practitioners, dermatologists, and consumers, dermatologists also perform patch tests (with certain batches and ingredients of related cosmetic products). Campaigns about public awareness were launched to promote the reporting of unwanted effects. Over 1,600 reports were received in 2 years. Severe unwanted effects are claimed in 1% - 4% of cases, with make-up and moisturizer being the most frequently reported products.

In another survey study in Brazil, 38% of participants stated that harmful drug reactions came from cosmetic products used in the last 2 years (Huf *et al*., 2013). Soaps, shampoos, and deodorants are said to cause mostly mild to moderate side effects. Less than 10% of adverse drug reactions are very severe. In a recent survey study conducted in Ethiopia with 600 participants, 61% of them reported that they experienced side effects (i.e. allergic reactions, acne, hirsutism) with the use of cosmetics (Bilal *et al*., 2017). The number of products and frequency of use were found to be associated with adverse drug reactions, despite the results representing only a small community, this study is very important to show the prevalence and factors for cosmetic-related side effects. Another article from India points out that misbranded or counterfeit

cosmetics are commonly reported in India (Sauver *et al*., 2013). Additionally, dermatitis and other adverse drug reactions have been reported with the use of cosmetics with non-standardized traditional ingredients that can cause various symptoms, like seizures and so on. Doctors who often see patients with skin complaints and a recent observational study found that 42.7% of visits to primary care doctors are for skin-related problems (Drake *et al*., 2015). Although this includes many dermatological diseases, contact dermatitis is a possibility that contributed to a substantial percentage of these visits. The American Academy of Dermatology published guidelines regarding contact dermatitis, which notes that contact dermatitis is responsible for approximately 5.7 million physician visits per year (Krob *et al*., 2014). Contact dermatitis is defined as inflammation of the skin, caused by a substance that comes into contact with the skin. This can be categorized as allergic or irritant dermatitis, which means the product or substance cause allergic skin reactions, and cause skin irritation (Berne *et al*., 2018). Secondly, irritant dermatitis is much more common accounting for 80% of contact dermatitis (Usatine & Riojas, 2014; Zug *et al*., 2018). Common allergens that can produce skin reactions include mixtures of fragrance, Peruvian balsam, neomycin, thiomersal, formaldehyde, and other preservatives (Lazzarini *et al*., 2018). These ingredients are often found in nail polish, perfumes, shampoos, lotions, and cosmetics including foundation, mascara, and lipstick. A recently published study from Brazil noted that some common allergens and irritants are found in children's skin care products and are also labeled as hypoallergenic (U.S. Food & Drug Administration, 2022).

In the USA, The FD&C Act currently has no rules on the use of the term hypoallergenic. According to the FDA's website about hypoallergenic, as a cosmetics manufacturer, for products labeled as hypoallergenic, they are not required to submit proof of hypoallergenicity to the FDA. It can be used to carry out marketing without a hitch using terms such as hypo-allergenic, sensitive skin, or fragrance-free without any consequences (Hamann *et al*., 2015). The majority of consumers and doctors are not aware of this and sadly do not have a way of knowing if a particular product has been known to cause a skin reaction that can be detrimental especially contact dermatitis. Another study in the United States shows that 89% of children's products that are labeled hypoallergenic actually have known allergens or irritants in their formulations (U.S Food & Drug Administration, 2022).

Cosmetovigilance is the responsibility of consumers and their doctors. Special care should be advised for those with a history of atopy, asthma, or atopic dermatitis as these predispose them to contact dermatitis and adverse skin reactions. There are several organizations, such as the National Eczema Foundation, that conduct testing on common skincare products and provide product recommendations, which have passed their testing. Unfortunately, until more consumer-friendly databases are easily available and easy to interpret, adverse skin reactions will continue to be common. Skin reactions (contact dermatitis) will cause stress to the sufferer and cause a financial burden due to overwork, the cost of doctor visits, and the cost of medical treatment. Although for the majority of medical visits, ADRs are successfully treated and the causal agent identified, ADR notifications are not reported to the FDA or the manufacturer responsible for the product. The Safe Cosmetics and Personal Care Act of 2013 has encouraged adverse event reporting of cosmetic products by providers and consumers and requires reporting by product brand owners of serious ADRs. Currently, reports can be made through the FDA's MedWatch online system or through a hotline. The data is then collected under the Center for Food Safety and Applied Nutrition Adverse Event Reporting System (CAERS). As of December 2016, this data is publicly available on the FDA website, with reports dated as early as January 2004. CAERS received 3576 reports in 2016, which is up from 445 in 2014. These numbers are disappointing relative to the number of medical visits made to address contact dermatitis. Using cosmetology in practice can be greatly improved by raising awareness of the FDA reporting system among healthcare professionals. Professionals should take responsibility along with cosmetics manufacturers to educate patients about the consumer reporting options available. Not only will increased reporting bring awareness of possible safety issues with certain products but it will also encourage the FDA to launch investigations and review the literature on certain products and their ingredients. Awareness of the public CAERS database will now also increase interest in medical research, improving the overall medical literature and implementation of effective treatment of ADRs due to cosmetic products available in the market.

## CONCLUSION

Cosmetovigilance is a new concept of cosmetic product safety monitoring. This can be considered an important component of public health activities. When post-marketing surveillance of cosmetics has become widespread globally, problems relating to a product can be identified and solved, and thus safety can be achieved. Family medicine doctors and primary care practitioners have an important role to play in recognizing ADR induced by cosmetic products, and thereby encourage patients for ADR reporting. Raising awareness about this new concept will be a valuable comment on global public health.

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