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Review On Cosmetovigilance And Their Regulations

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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 aluminums) 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, Adverse drug reaction, high risk products.

I.INTRODUCTION:

The Federal Food, Drug, and Cosmetic (FD&C) Act defines drugs, in part, by their intended use, as “articles intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease” and “articles (other than food) intended to affect the structure or any function of the body of man or other animals. In another section, cosmetics are defined by their intended use, 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” [FD&C Act, sec. 201]. The products covered under this definition are skin moisturizers, perfumes, lipsticks, fingernail polishes, eye and facial makeup preparations, cleansing shampoos, permanent waves, hair colors, and deodorants, or any other substance intended for use as a component of a cosmetic product.1

There are differences between requirements for cosmetics in the United States and other countries with regard to legal definitions of drugs and cosmetics, restrictions on the use of color additives and other ingredients, and registration requirements. Some products like sunscreens are regulated as cosmetics in Europe, while they are regulated as drugs in the United States.[1,2] According to Cosmetics Directive of European Union, "a 'cosmetic product' by definition is any substance or preparation intended to be placed in contact with the various external parts of the human body (epidermis, hair system, nails, lips and external genital organs) or with the teeth and the mucous membranes of the oral cavity with a view exclusively or mainly to cleaning them, perfuming them, changing their appearance and/or correcting body odors and/or protecting them or keeping them in good condition.2

Even though the term "cosmeceuticals" is used occasionally for cosmetic products with bioactive ingredients purported to have medical benefits, the Federal Food, Drug, and Cosmetic (FD&C) Act does not recognize any such category as "cosmeceuticals."[3] A product can be a drug, a cosmetic, or a combination of both, but the term "cosmeceutical" has no meaning under the law. Based on the intended use and ingredients, some may meet both definitions of cosmetic and drug. Antidandruff shampoos, toothpastes with fluoride, antiperspirant deodorants, and moisturizers with sunscreen are examples. Such products must comply with the requirements for both cosmetics and drugs.

The term "pharmacovigilance" defines the activities related to the collection, detection, assessment, monitoring, and prevention of adverse reactions (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 products as well.

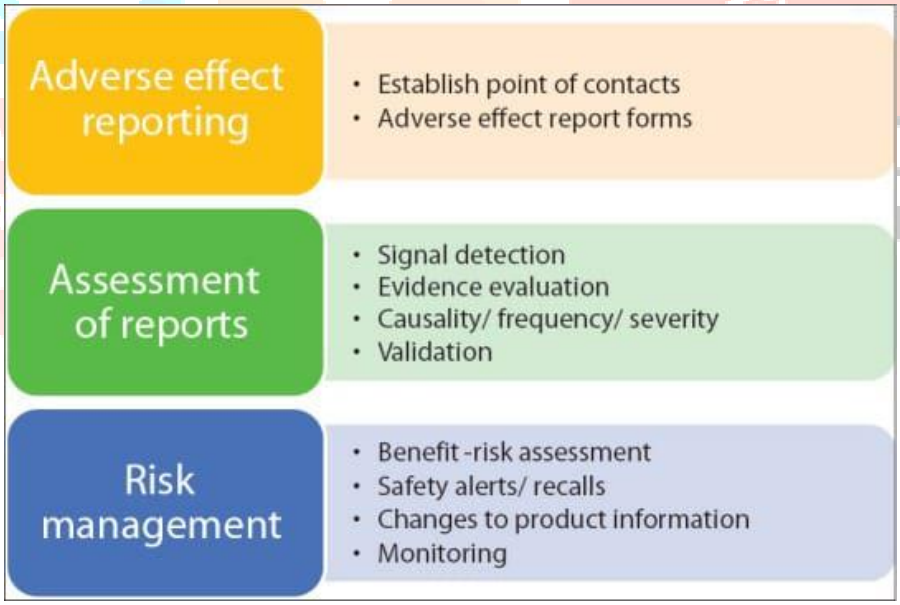

Fig1: Safety Monitoring and Vigilance Activities

II.WHAT IS COSMETOVIGILANCE?

Cosmetovigilance is the scientific and systematic process of monitoring, identifying, collecting, evaluating, and preventing undesirable or harmful effects associated with the use of cosmetic products. It is an important part of consumer safety because cosmetics are used frequently and directly on the skin, hair, nails, lips, teeth, and other external parts of the body.Cosmetic products include face creams, lotions, shampoos, conditioners, soaps, perfumes, deodorants, makeup products, hair dyes, sunscreens, lipsticks, skin-lightening products, and other personal-care products. Although cosmetics are generally intended to be safe when used normally, some products may cause unwanted effects in certain

individuals because of their ingredients, contamination, incorrect use, individual sensitivity, or prolonged exposure.

Cosmetovigilance plays an important role in maintaining the safety of cosmetic products throughout their use in the population. The safety evaluation of a cosmetic does not end when the product is introduced into the market. Once a product is widely used, information can be obtained from a much larger and more diverse group of consumers. This real-world information can help identify uncommon, delayed, or unexpected reactions that may not have been detected during the initial safety assessment.The scope of cosmetovigilance includes the surveillance of cosmetic products throughout their life cycle. It involves receiving reports of undesirable effects, documenting relevant information about the affected person and the product, evaluating the suspected relationship between the product and the reaction, and identifying possible safety concerns. The information obtained can be used to determine whether additional investigation or preventive action is necessary.

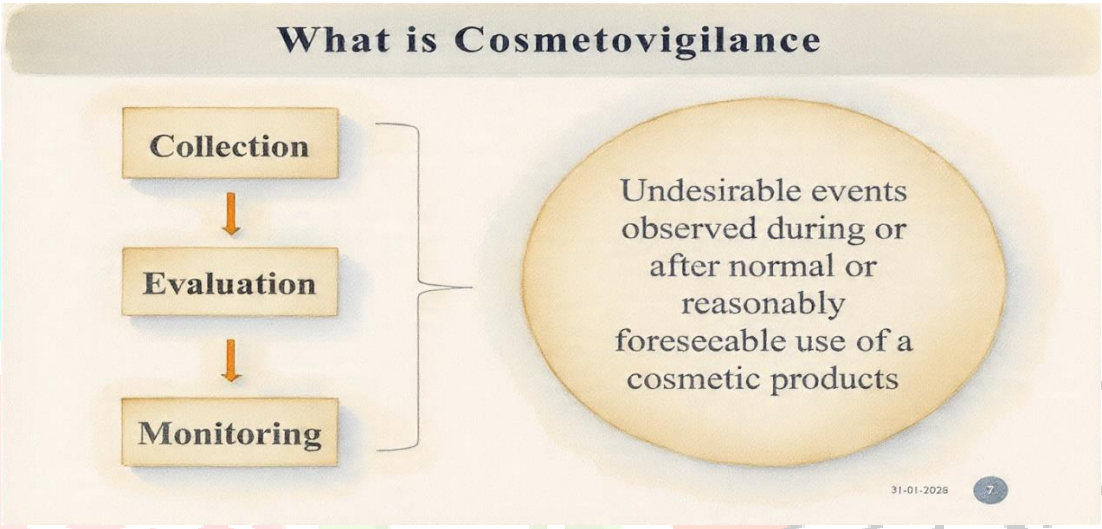

Fig 2: cosmotovigilance

III.REGULATION OF COSMETOVIGILANCE IN INDIA:

In India, cosmetic products are regulated under the Drugs and Cosmetics Act, 1940, along with the Drugs and Cosmetics Rules, 1945, the import and registration of cosmetics are addressed under Part XIII. Part XIV concerns the manufacture of cosmetics intended for sale or distribution, while Part XV deals with cosmetic labeling, packaging, and prescribed standards. India ranks as the fourth-largest cosmetics market in the Asia-Pacific region, following Japan, China, and South Korea. Adverse or unwanted reactions associated with cosmetic products are generally reported at a very low frequency or may remain unidentified because an adequately organized reporting system is lacking.

As early as 10,000 BC in Egypt, both men and women used scented oils and ointments for cleansing and softening the skin and for covering body odor. The Cosmetics Act, 1940is an Indian parliamentary legislation that governs the import, manufacture, and distribution of drugs in the country. Drugs and cosmetics marketed in India are required to be safe, effective, and compliant with prescribed quality standards. The associated Drugs and Cosmetics Rules, 1945, provide provisions for the classification of drugs under different schedules, along with requirements concerning their storage, sale, display, and prescription.

Under the Act, cosmetics are described as products intended for application to the human body for purposes such as beautification or cleansing. Similarly, the Federal Food, Drug, and Cosmetic Act defines drugs partly according to their intended purpose. These include articles intended for the

diagnosis, cure, mitigation, treatment, or prevention of disease, as well as articles, other than food, intended to influence the structure or any function of the body of humans or other animals.

In another section, cosmetics are categorized according to their intended application as products designed to be rubbed, poured, sprinkled, sprayed onto, introduced into, or otherwise applied to the human body for cleansing, beautifying, enhancing attractiveness, or modifying appearance. Products included within this definition comprise skin moisturizers, perfumes, lipsticks, fingernail polishes, eye and facial makeup preparations, cleansing shampoos, permanent-wave products, hair colors, deodorants, and other substances intended to serve as components of cosmetic products.4

Adverse Effects of Various Cosmetics:

- **Hair cosmetics:**

The Preparations intended for placing in contact with the hair and scalp with the purpose of cleansing, promoting attractiveness, altering appearance and protecting them in order to maintain them in good condition. Hair cosmetics are classified two main categories: (2, 4, 5)

(a) Cosmetics with temporary effect on the hair: Shampoos, Conditioners, Sprays and Temporary colors.

(b) Cosmetics that produce permanent effect on the hair shaft: Permanent waves, Bleaches and Permanent colors.

- **Nail Cosmetics:**

Nail beautification is a big industry today with various nail cosmetics available ranging from nail hardeners, nail polishes, extensions, artificial/sculpted nails, nail polish remover and nail decorations. Adverse events may occur either during the nail-grooming procedure or as a reaction to the individual components of the nail cosmetics.

- **Hygiene Purpose:**

Hygiene is defined as the many practices that help people be and stay healthy. In society cleanliness is an important issue poor hygiene is seen as unacceptable and unhealthy. Good hygiene includes thoroughly and regularly washing one's body (especially hands), washing one's hair, brushing and flossing teeth and caring for gums. These grooming habits will reduce the threat of bacteria that constantly reside on the body. While a certain amount of bacteria are harmless and even beneficial to the body, a build-up of bacteria can harm a person's health. For hygienic purpose various cosmetics used such as Controlling body odor, deodorants, antiperspirants, perfumes, colognes, and scented soap**.**5

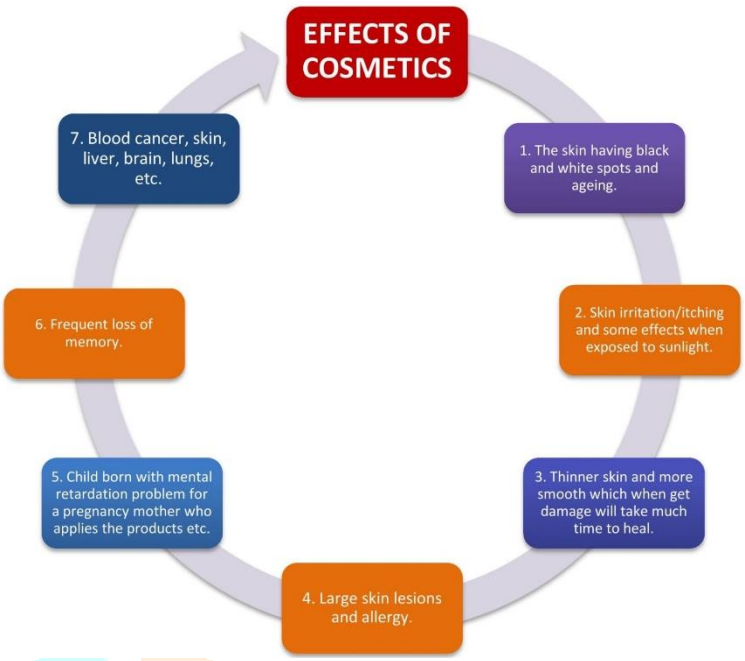

Fig 3; adverse effects of cosmetic

Pharmacovigilance, materiovigilance, hemovigilance, and cosmetovigilance are specialized disciplines concerned with monitoring the safety of different products within their respective areas.

Pharmacovigilance emerged during the middle of the twentieth century, following several incidents associated with medicines, particularly the thalidomide catastrophe during the 1950s and 1960s. These events increased awareness of the importance of systematic monitoring of drug safety. The incident demonstrated the necessity for comprehensive medicine-safety surveillance and encouraged regulatory authorities worldwide to establish systems for assessing and monitoring the safety of pharmaceutical products. With the establishment of various regulatory agencies and systems for reporting adverse drug reactions (ADRs), the concept and practice of pharmacovigilance continued to develop. The World Health Organization (WHO) played an important role in promoting international cooperation in the field of pharmacovigilance. With technological progress and increasing globalization, pharmacovigilance has incorporated data-mining techniques, safety databases, and electronic reporting systems for detecting potential medication-related safety concerns. Organizations such as the International Conference on Harmonization of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH) have developed guidelines to harmonize pharmacovigilance practices across different geographical regions. Marketing authorization holders are required to submit Periodic Safety Update Reports (PSURs) to regulatory authorities at regular intervals. PSURs summarize the available information regarding the safety profile of a drug, including adverse drug reaction reports, clinical trial findings, and other relevant information. Regulatory authorities use PSURs to assess the benefit-risk ratio of a medicine and to take appropriate regulatory decisions.

In comparison with pharmacovigilance, materiovigilance is a relatively recent field. It is concerned with monitoring the safety of medical technologies, including implants, diagnostic equipment, and other medical devices.6

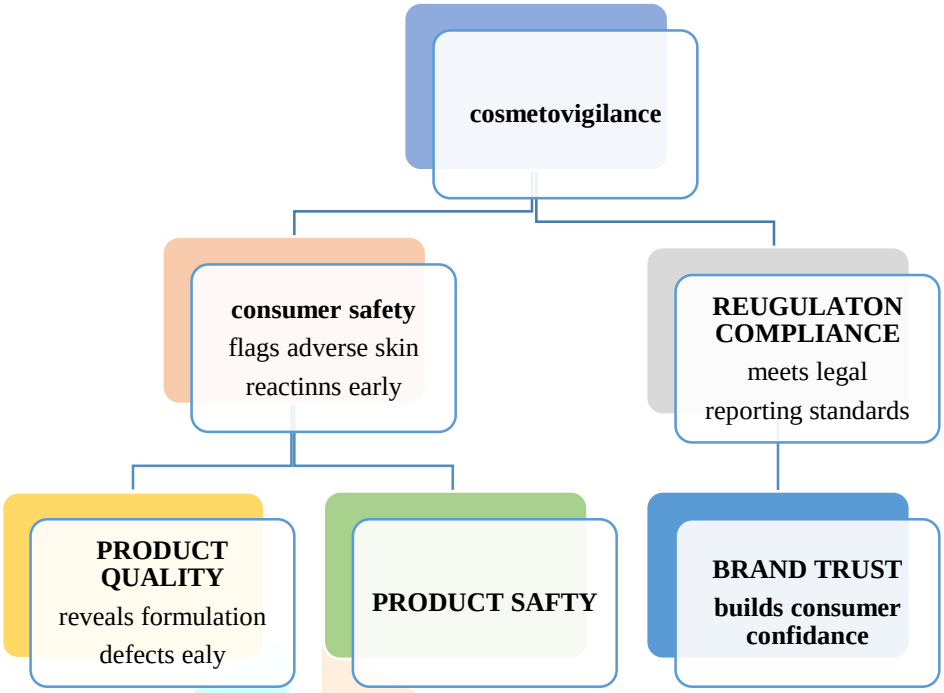

Fig 4: Workflow of cosmotovigilance

Medical equipment got more intricate and varied, materiovigilance became necessary. System monitoring and safety evaluation was spurred by problems including device malfunctions, failures, and negative responses The Medical Device Reporting (MDR) standards were developed in 1984 by the Food and Drug Administration (FDA) in the United States. These regulations mandate that manufacturers, importers, and device user institutions record adverse occurrences associated with medical devices. In the same way, the European Union created guidelines and directives that controlled the functionality and safety of medical devices, leading in the 2021 implementation of the Medical Device Regulation (MDR). With the introduction of laws like the Medical Device Regulation (MDR) of the European Union, which requires strict monitoring of medical device safety throughout its lifespan, materiovigilance has become more and more important. Concerns about the safety of blood transfusions prompted the development of hemovigilance. In the past, receiving blood transfusions was linked to dangers including infection transmission and negative responses. The 1980s saw the onset of HIV/AIDS, which highlighted the significance of transfusion safety as well as the possible hazards of infectious disease transmission via blood transfusions. The late 20th and early 21st century saw the establishment of formal hemovigilance systems in a number of nations. These systems include the methodical gathering, examination, and distribution of information on unfavorable outcomes connected to blood transfusions. To increase transfusion safety globally, international organizations like the World Health Organization (WHO) and the International Society of Blood Transfusion (ISBT) have encouraged cooperation in hemovigilance.

Compared to the other fields listed, Cosmetovigilance is a relatively recent one. It focuses on keeping an eye on the safety of cosmetics, skincare, and hair care products. Concerns about the safety of cosmetic goods and growing consumer knowledge have led to an increase in the demand for Cosmetovigilance. Many nations' regulatory bodies have created systems for documenting and assessing negative responses to cosmetics. Historically, rather than post-market monitoring of adverse effects, the regulation of cosmetics has concentrated largely on matters like product safety, labelling, and marketing claims. Cosmetics were not subject to the same degree of regulatory supervision as drugs or medical devices in many nations. With the passage of the Cosmetics Directive in 1976, cosmetics regulation in the European Union advanced significantly. The growth of Cosmetovigilance programs has been aided by the substantial role that social media and internet platforms have played in increasing consumer reporting of adverse reactions and bringing attention to concerns about the safety of cosmetics.7

IV. HERE'S WHY EACH OF THESE MATTERS IN PRACTICE:

Consumer safety Cosmetovigilance systems capture reports of irritation, allergic reactions, or unexpected side effects once a product is in real-world use across millions of different skin types, conditions, and combinations with other products things pre-market testing can't fully anticipate.

Regulatory compliance Regions like the EU (under the Cosmetic Products Regulation) and other markets require manufacturers to report serious undesirable effects to authorities within set timeframes. A weak vigilance system risks fines, product recalls, or loss of market authorization.

Product quality Patterns in adverse event reports often point to a specific batch, ingredient, or manufacturing issue, letting companies fix the root cause rather than just responding to isolated complaints.

Brand trust Companies that respond quickly and transparently to safety signals tend to retain consumer confidence, while those that ignore or hide problems face reputational damage that's much harder to repair than the original issue.6

- **How to Health Care Professionals Use Cosmotovigilance Practice**

Since the 2004 Public Health Law, any health professional in France shall report serious undesirable effects - or those he deems serious connected to the use of cosmetic products, whether they are from misuse or not. The mission of the Cosmetovigilance investigation will then be to assess case causality. In Germany, Belgium, the Nether lands, Italy and Portugal, Cosmetovigilance is available to all health care professionals, although reporting to Cosmetovigilance is not mandatory. The notification can be made on a sheet of plain paper or using the notification form that can be downloaded from the websites of the competent authorities: ANSM in France, the Ministry of Health in Belgium... The following information should be mentioned: 1/ name of the reporter, 2/ name of the user affected by the undesirable effect (first three letters of the surname, first name, gender and date of birth), 3/ name of the cosmetic product concerned (full name, brand, use and, when possible, batch number). The product must be kept for further potential analyses. The undesirable effect must be described providing detailed chronological and semi logical elements as well as detailed evolution over time. The notification must be carried out when the undesirable effect occurs and will then possibly be complemented later by the results of useful additional tests or by data on evolution. The same notification can be sent to the person responsible for marketing the product. Notification to Revidal-Gerda only occurs when the undesirable effect is an allergic undesirable effect; this notification can be carried out by any European dermatologist/allergist. Although the 2004 Public Health Law does not mention consumers, professional users and industrialists, it seems that they can also make reports the ANSM website or the websites of the competent authorities of Member States, as these websites provide specific tabs for them. In practice, health care professionals use Cosmetovigilance mainly through case notification reporting undesirable effects linked to cosmetic product use. Here's how it works: 8

V. WHAT INFORMATION GOES INTO THE REPORT?

The affected user's identifying details (first three letters of the surname, first name, sex, date of birth) The product involved (full name, brand, intended use, and batch number if available A detailed account of the adverse effect: chronology, clinical/semi logical features, and how it evolved over time Professionals are also expected to keep the physical product on hand in case further lab analysis is needed later. Timing and follow-up the initial report should be filed as soon as the reaction occurs, and can be updated afterward with additional test results or information on how the patient's condition progressed. Where else a report can go the same report can also be sent directly to the company marketing the product. If the reaction is specifically allergic, any European dermatologist or allergist can additionally notify Revidal-Gerda, a dedicated allergy-focused network. Once a case is reported, the Cosmetovigilance system's job is to assess causality -essentially determining how likely it is that the product actually caused the reported effect. So functionally, a clinician who suspects a cosmetic-related adverse reaction acts as the frontline reporter, feeding structured case data into a system that authorities and manufacturers then use to evaluate product safety signals- sometimes with parallel reporting to allergy-specific networks for hypersensitivity,9

Given flowchart traces the path from spotting reaction all the way to the causality verdict. A few things worth noting alongside it:

•The initial notification and the product retention step can happen in parallel-the clinician doesn't need to wait for one to file the other.

•The parallel routes (marketing company, Revidal-Gerda) are optional add-ons, not replacements for the official notification to the competent authority.

•Causality assessment is where the system does its real work — deciding how likely it is that the product, rather than something else, caused the effect. The loop back to complementary data reflects that Cosmetovigilance reporting isn't a one-shot event.10

In another survey study in Brazil, 38% of the participants declared an ADR with a cosmetic product used in the past 2 years. Soap, shampoo, and deodorants were told to cause the majority of mild to moderate adverse effects. Less than 10% of the ADRs were severe.

In a recent survey study conducted in Ethiopia with 600 participants, 61% of them reported that they experienced adverse effects (i.e. allergic reaction, acne, and hirsutism) with the cosmetics they use. The number of products and the frequency of use were found to be associated with ADRs. Even though the results represent a small community, this study is of importance to demonstrate the prevalence and factors for cosmetic-related adverse events.11

VI.NEED OF COSMETOVIGILANCE IN INDIA:

Population of India is huge and similar is the market of cosmetics. Contact dermatitis and other dermatitis are common in India and cosmetics are implicated in the same. Adverse reactions to traditional agents are also commonly reported, for example, kajal and kokum dermatitis. Import of cosmetics tested in animals is prohibited in India as per se action 135 B of Drugs and Cosmetics Act. Like other diseases, disorders related to cosmetics also lead to pharmacoeconomic loss. Hence besides proper regulation of these agents, a proper vigilance system is also required to protect health of Indian population. Going with words of Vigan and Castilian, 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.12

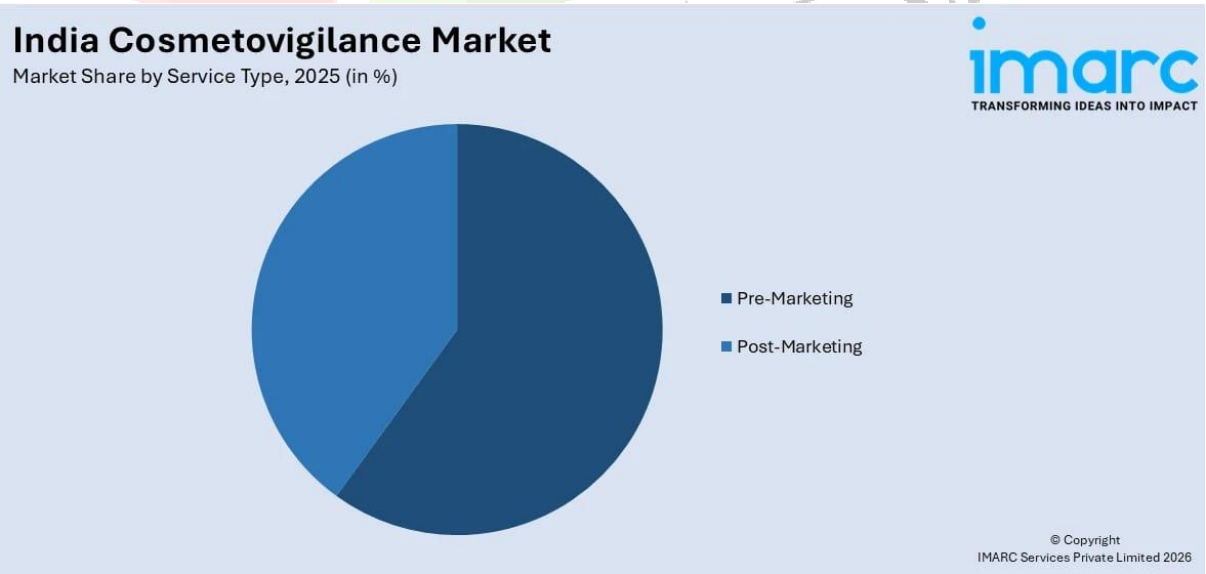

Fig 5: Indian cosmetovigilance market

India’s massive cosmetic user base leads to a statistically higher volume of adverse reactions. Environmental Factors: A tropical climate, sweating, and pollution increase the risk of allergic and irritant contact dermatitis. Traditional & Herbal Usage: Everyday items like Kajal, Mehdi, and Butane often contain undeclared heavy metals (lead, mercury), leading to issues like Kajal conjunctivitis. Misuse of OTC Products: The misuse of bleaching agents and fairness creams containing steroids without dermatologist advice causes severe skin damage. Imported & Spurious Goods: E-commerce brings untested international products and counterfeit items with harmful ingredients directly to consumers. Lack of Animal Testing Data: With animal testing banned under Section 135B of the Drugs and Cosmetics Act, post-market human safety data is crucial. High Economic Burden: Treating cosmetic-induced skin conditions (dermatomes) leads to high medical expenses and lost work hours.2. Current Status Regulatory Body: Cosmetics are regulated by the Central Drugs Standard Control Organization (CDSCO) under the Drugs and Cosmetics Act, 1940.The Gap: Unlike the EU's mandated systems, India currently lacks a dedicated, mandatory, centralized reporting database specifically for cosmetic adverse events. The Need: Experts urge the expansion of the Pharmacovigilance Programmed of India to systematically track and monitor cosmetic safety.3. Benefits of a Dedicated System Early Signal Detection: Catches toxic or harmful ingredients (e.g., high mercury or PPD) before widespread public harm. Consumer Awareness: Empowers the public through safety bulletins, proper labeling, and patch testing instructions. Global Alignment: Helps Indian cosmetic brands align with international standards, making it easier to export products to the EU and US.13

VII.THE FUTURE OF COSMETOVIGILANCE EU REGULATION 1223/2009

Ten community pharmacies distributed in the Naples' urban (6) and extra-urban (4) area were involved. Ten pharmacy graduates from our Faculty (25-27-year-old females), were trained to submit a structured nineteen items question-naira to all the customers (15-75 years old) of the pharmacy. A poster was hung on the shop-window of the pharmacies in order to inform the customers that interviews were not carried out for commercial profit. It outlined the target of the survey and the institution by whom it was conducted. The first four questions of the questionnaire covered a description of the interviewed (age, sex, school-attendance, profession). The next two items regarded the reasons for entering the pharmacy, while the next three questions were aimed to investigate the use of cosmetics (type of cosmetic utilized, frequency of use and place where they were gen-really bought). The other ten questions regarded suspected ACEs experienced by consumers (previous experience of ACEs or not, type of cosmetics responsible for ACEs and their brands, type of reported ACEs (cutaneous or systemic and, for cutaneous events, their localization), frequency and length of reported events); type of consultation requested in the presence of suspected ACE (none, general practitioner, dermatologist, pharmacist, beautician, others); the relative measure adopted (cosmetic withdrawal or change, drug treat-mint, others); dechallange and recalling. The interviews took place for two weeks, from 1 to 15 June 2004, between 09:00 a.m.-01:00p.m. and 04:00 p.m.-08:00p.m. The filled questionnaires were recorded in a database and data were analyzed. Among the sample who experienced ACE, different denominators were considered: the whole number of people; the number of used cosmetics related to adverse events; the whole number of adverse events. Indeed people might report adverse events because of the use of more than one cosmetic and, for each cosmetic, more than one adverse event might occur.

In order to group cosmetics the Italian National Health Institute classification (legislative decree, DL April 24, 1997 n 126, law 723/86) was used.14

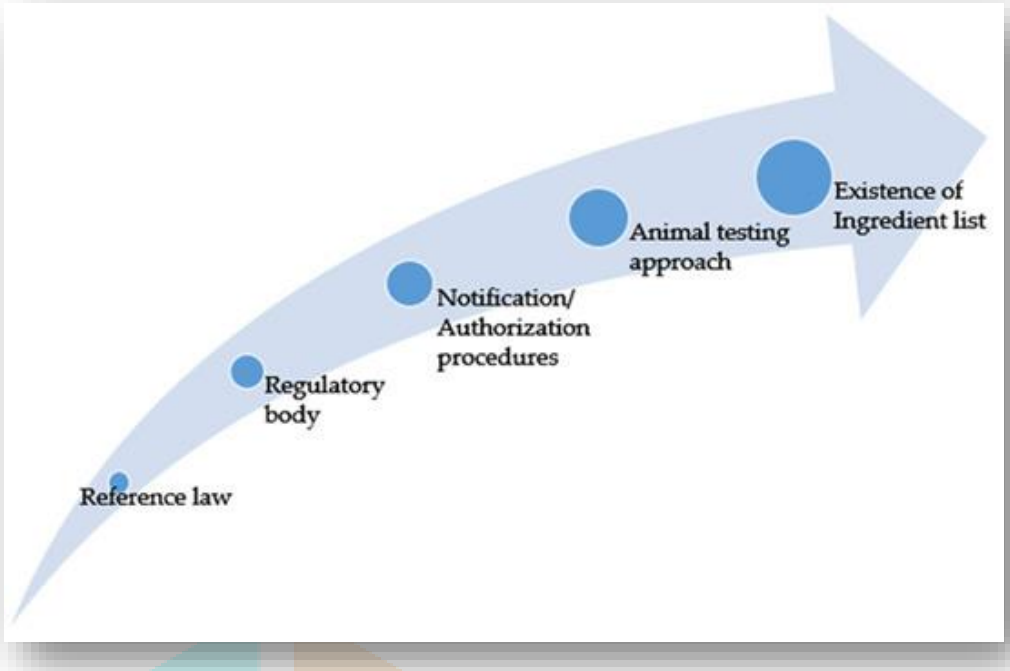

Fig 6: regulatory requirements of exporting cosmototic products

- **Causality assessment Problems yet to be solved:**

The definition of causality assessment is slightly different for AFSSAPS and Colipa: For AFSSAPS, causality "assesses the cause and effect relationship between a cosmetic product and a specific clinical and/or preclinical manifestation" (2010). As investigations, recommendations on the proper use of the product, or regulations at national or European level (restrictions on use, warnings on packaging labels, limited concentration or prohibition).15

The French Agency for Sanitary Safety of Health Products (AFSSAPS, 2010) defines causality as the determination of a direct link between a cosmetic item and an observed clinical or preclinical reaction. To support safety monitoring, regulatory decisions, and usage guidelines, several analytical frameworks have been established:

Colipa Framework: Relies on a decision tree that integrates three core factors clinical symptoms, time-to-onset (chronology), and specific test results to assign one of three causality tiers (questionable, likely, or very likely).

PLM-Integrated Flowchart Model: Processes reported cases immediately upon intake within a Product Lifecycle Management workflow. By evaluating temporal and sociological data, it categorizes reports across six potential designations (irrelevant, insufficient information, unlikely, possible, likely, or very likely).16

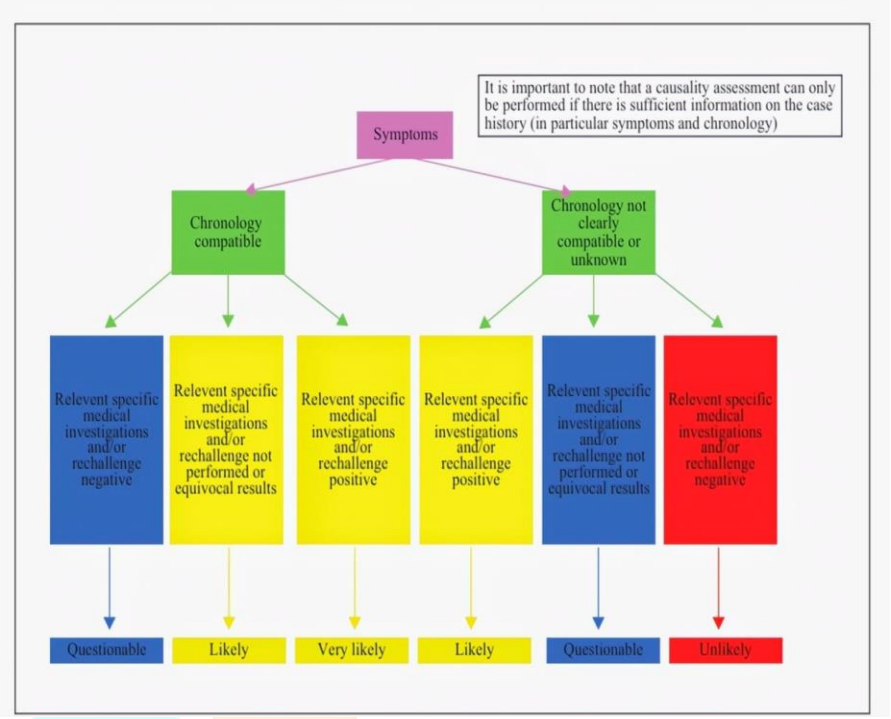

Fig 7: **Cosmotovigigilance causality assement algorithm**

VIII. CONCLUSION

Cosmetovigilance is an increasingly developing field of research within pharmacovigilance in India. This study examines the patterns of cosmetic use and the related adverse drug reactions reported by individuals. The US Food and Drug Administration (FDA) defines cosmetics as "articles used for beautification, cleansing, or modification of physical appearance" (U.S. Food and Drug Administration, 2018). The use of personal care products (PCPs) has been increasing over the past several decades, largely due to the growing importance placed on physical appearance worldwide, which has directly contributed to the emergence and expansion of the cosmetic industry. Prolonged exposure to these products may result in considerable accumulation within the body and may contribute to various adverse health effects. These effects may present as redness, scaling, and blisters, while in some cases there may be no visible changes. More serious manifestations may include hair loss, brittle nails, and contact dermatitis. Available data indicate that hair dyes are among the major causes of contact dermatitis in India. Counterfeit cosmetics are fraudulent or imitation beauty products manufactured to resemble authentic and well-established brands. Such counterfeit products are commonly manufactured and distributed without authorization or approval from the original brand or relevant regulatory authorities. The presence of impurities, including high concentrations of heavy metals such as lead, cobalt, cadmium, mercury, and aluminum, has been reported in several cosmetic products, including lipstick, lip glosses, eye shadow, and hair dye. These contaminants may present specific health risks such as hand dermatitis, asthma, and infertility, which are commonly observed among hair and salon technicians.17

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