

COSMETOVIGILANCE: COSMETIC UTILISATION PATTERN, ADVERSE EVENTS AND AWARENESS ABOUT COSMETOVIGILANCE AMONG PARAMEDICS IN SOUTH KERALA

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Received on: 26/08/2020

Revised on: 16/09/2020

Accepted on: 06/10/2020

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ABSTRACT

Cosmetovigilance is an ongoing process and systematic monitoring of the safety of cosmetic in terms of human health. The aim of Cosmetovigilance is to detect the best effect of cosmetic product and to prevent adverse effects by taking appropriate measure. The study was conducted among pharmacy students and pharmacy graduate in Kerala by KAP questionnaire for a period of 6 month. Approximate 67 pharmacy students and pharmacy graduates were responded to this study. Among this 67 peoples, they use cosmetics to boost their confidence, for leisure purpose and without any indications, and they experiences the type of reactions were itching, burning sensation, hyper pigmentation, hair loss and running eyes. The process of Cosmetovigilance is evolving and coming up as a strong regulatory science to protect public health and beauty. In European Union, directive 76/768/EEC regulates the monitoring of cosmetics. The unwanted or adverse reactions due to cosmetic products are very low go unnoticed, or unde reported due to lack of proper organized reporting system. India can initiate to have formal Cosmetovigilance system. In future it could contribute to increased safety of cosmetics use which is important for the safeguard of public health.

KEYWORD: COSMETOVIGILANCE, ADR, COSMETICS, DRUGS.

INTRODUCTION

Drugs and Cosmetics 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 a component of cosmetic.”^[1,2] In India, cosmetics are regulated as per Drugs and Cosmetics Act 1940 and Rules 1945. Part-XIII (regulates import and registration of cosmetics), part-XIV (manufacture of cosmetic for sale or for distribution) and part-XV (regulates labelling, packing and standards of cosmetics). Rule 145 and 135 prohibits the use and import of arsenic and lead containing compounds. Cosmetics containing mercury are prohibited as per provisions of rules 135A and 145 D. Rule 134-A prohibits import of hexachlorophene containing cosmetic. Rule 134 specifies that cosmetic products should contain color, dye or pigment as per specified by schedule Q and Bureau of Indian Standards. Gazette notification G.S.R 426(E) divides cosmetics into 4 gross categories: 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), hair and scalp products, nail and cuticle products, and products for oral hygiene.^[2] With increased use of cosmetics, the rate of sensitization to many allergenic components has increased.^[3] Hair dye is reported as one of the most common causes of contact dermatitis in India.^[4] Kumkum dermatitis was highly prevalent in southern part of India. Sticker bindi use is also found to be an important risk factor for occurrence of contact dermatitis.^[5] Apart from the active product, other ingredients of cosmetic products are also implicated in adverse reactions following the use of cosmetics.^[6] Although lots of ADRs occur at the population level, reporting to the regulatory authority is very low. In a study with patients of contact dermatitis cases, most of the patients reported adverse reactions to cosmetic products. In their study, they found that in many patients suffering from contact dermatitis showed positive finding in patch test for cosmetics and they concluded that cosmetics are important etiological factors for occurrence of contact dermatitis.^[7] Cosmetic product-related adverse effect identification and analysis is mainly industry driven. Although lots of efforts are made by manufacturers, potential conflict of interest may bias the findings.^[8] The cosmetic products in India are regulated under the Drugs and Cosmetics Act 1940 and Rules 1945 and Labelling Declarations by the Bureau of

Indian Standards (BIS). BIS sets the standards for cosmetics for the products listed under Schedule 'S' of the Drugs and cosmetics Rules 1945. BIS has also provided the specification for Skin Creams and Lipstick in the Indian Standards (IS) 6608:2004 and 9875:1990 respectively. According to IS 6608:2004, all the raw materials requiring test for heavy metals have been so tested and comply with the requirements, then the manufacturer may not test the finished cosmetic for heavy metals and arsenic. The Rule 134 of Drugs and Cosmetics Rules has laid down restrictions on use of cosmetics containing dyes, colours and pigments other than those specified by the Bureau of Indian Standards (IS: 4707 Part 1 as amended) and Schedule Q. The Rule 145 of the Drugs and Cosmetics Rules prohibits use of lead and arsenic compounds in cosmetics for the purpose of colouring. Rule 135 prohibits import of cosmetics in which a lead or arsenic compound has been used for the colouring purpose. Rule 145 D and 135 A prohibits manufacture and import respectively of cosmetics containing mercury compounds. A Gazette Notification G.S.R 426(E) dated 19th May 2010 has been issued by the Government of India for amending the Drugs & Cosmetics Rules, 1945 providing for registration of import of cosmetics into the Country. This provision was to come into effect from the 1st April, 2011. But in view of the various possible difficulties apprehended by the stakeholders, its implementation was deferred till the 31st March, 2013. All cosmetic products that are imported for sale in India now need to be registered with the Central Drugs Standard Control Organisation (CDSCO) which has been appointed as the licensing authority for the purpose of these rules. This new 'registration' requirement is primarily to regulate indiscriminate import of beauty and personal care products by traders with no accountability for contents and no mechanism to fix responsibility in case a consumer is not satisfied with the quality. The new regulation is an attempt to check the sale of sub-standard cosmetic products and also to harmonise import requirements with products manufactured in India.

METHODOLOGY

The study was conducted among pharmacy students and pharmacy graduate in Kerala by KAP questionnaire for a period of 6 months.

Tab: 1

Cosmetic using pattern			Reason for cosmetic use	
Daily	44	65.7%	Boost the confidence	46.3%
Occasionally	23	34.7%	Leisure Purpose	23.9%
			No reason	29.9%

5. MAIN SOURCE OF COSMETIC PURCHASE AND FACTORS INFLUENCING COSMETIC PURCHASE

Among the 67 candidates 85.07% were purchased the cosmetics from the cosmetics or department store, 10.4% from online platform and only 4.5 % from drug store or

Objectives:

1. Pattern of cosmetics use in Pharmacy graduates.
2. Prevalence of adverse cosmetics effects.
3. Assess the knowledge of Pharmacy graduate about cosmetovigilance.

Study Design: Prospective observational study.

Sample Size: A Questionnaire was distributed among 200 paramedics among them 67 candidates were positively responded.

Inclusion Criteria:

1. Candidates from Pharmacy background.
2. Willing to co-operate with the study.

Exclusion Criteria:

3. Candidates from non pharmacy background.
4. Not willing to co-operate with the study.

SOFTWARE USED: SPSS and R

RESULTS AND DISCUSSIONS

1. AGEWISE DISTRIBUTION

Among the 67 candidates 71.8% belongs to 20-25 years of age, 9.4% belongs to 15-20 years of age, 15.5% belongs to 25-30 years of age, 2.4 % belongs to 30-35 years of age and only 1.2% belongs to above 35 years of age group.

2. SEXWISE DISTRIBUTION

Among 67 Pharmacy candidates 82.1% (55) were females and 17.9% (12) were male representants that majority of candidates are females.

3. EDUCATIONAL BACKGROUND OF RESPONDENT

Among 67 pharmacy graduates 1.49% were PhD Holders, 14.9 2% were Pharm.D graduates, 71.64% were Pharm.d students and 11.94% were M.Pharm graduates.

3. COSMETIC USING PATTERN AMONG THE CANDIDATES AND REASON FOR USE.

Among 67 candidates based on their responds 65.7% were using cosmetics daily and 34.7% were using as occasionally. They used cosmetics for boost their confidence (46.3%), leisure purpose (23.9%) and without any reasons(29.9%).

chemist shop. Their are number of factors influencing the purchasing pattern of cosmetics, they are 34.01% looking for the quality of cosmetics, 23.12% looking for the brand value, 12.24% looking for price, 15.64% based on the recommendations from friends and colleague, 8.16% prefer the package quality and 6.80% candidate select

the cosmetics from the special offer category. Among that only 58.2% read and understand the contents of

cosmetics, remaining 16.4% were not interested to read the content and 25.4% sometimes.

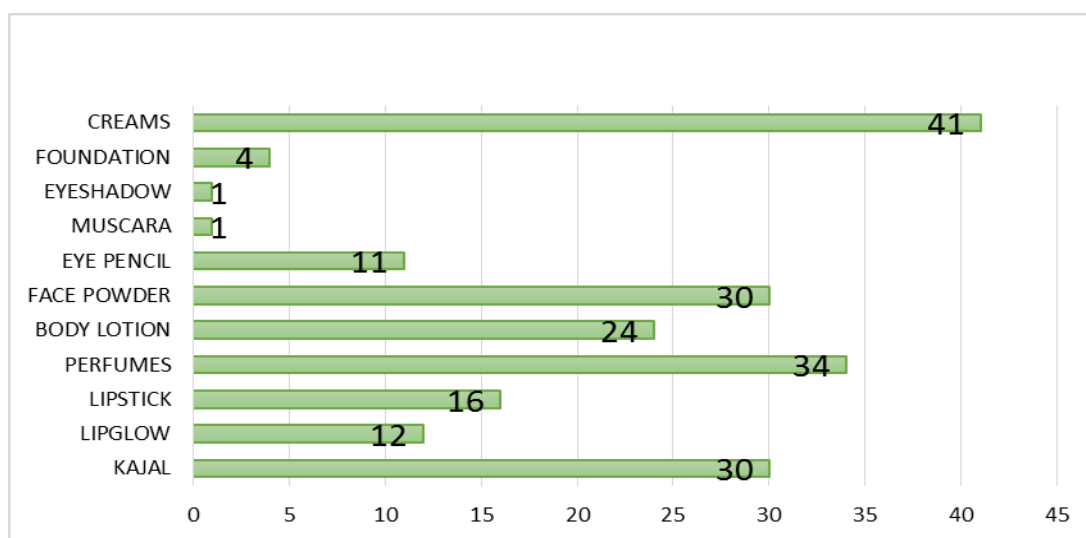
Tab:2

Main Source of cosmetic purchase	Main Source of cosm	
Cosmetic store	57	85.07%
Drug store	3	4.5%
Online	7	10.4%
Factors influencing cosmetic purchase		
Quality	34.01%	
Brand	23.12%	
Price	12.24%	
Package	8.16%	
Special Offer	6.80%	
Recommedation	15.64%	
Read the content of cosmetics		
Yes	58.2%	
No	16.4%	
Maybe	25.4%	

6. COSMETIC USING PATTERN AMONG PARAMEDICS

From Graph:1 indicate the usage pattern of cosmetics among 67 candidates. Some of them were used single cosmetics and some of them were used more than one cosmetics per day. In that 74.4% spend approximately 1000 rupees per month for purchasing the cosmetics,

19.5% spend 1000-2000 RS/month, 3.7% spend 2000-3000 RS/ month and only 2.4% spends 4000-5000 RS/month for purchasing the cosmetics. These amonth will go to the national economy and manufacturer so ensuring the cosmetics safety will be the responsibility of both the nation and the manufacture.

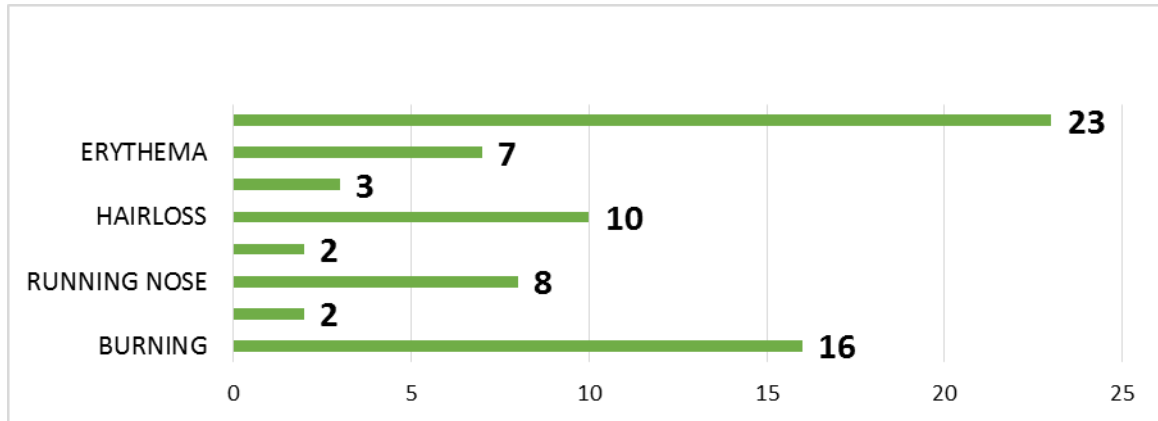


Graph: 1

7. DETAILS OF REACTIONS

In Graph 2: represent the nature of adverse effects. Among 67, 23 of them suffered by itching, 16 by burning, about 10 people had hairloss, 8 of them felt running eyes, 2 of them affect hyperpigmentation 3 of them affected blistering, 7 by erythema and 2 of them affected by scaling.many of them suffered by multiple

reactions. Among that only 9.9% of candidates went for treatment due to the adverse effect and the remaining 90.1% stop the cosmetics as apart of self treatment or home remedy and some of them were spend (2.9%) 4000RS/MONTH for a period for treatment. That will leads to a economic burden of people.

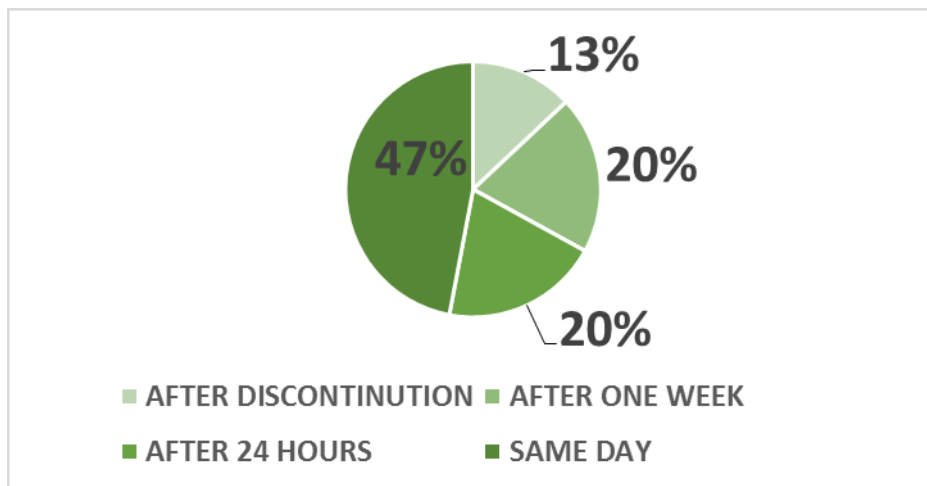


Graph 2.

8. TIME OF OCCURANCE OF ADVERSE EFFECTS

Graph 3, represents the time of occurrence of adverse effect. About 47% of adverse effect were occurred in the

same day of first use. Next 20% were affected after 24 hours. Remaining 13% occurred after the discontinuation of particular cosmetics.



Graph 3.

9. TYPE OF COSMETICS ADVERSE EFFECTS

In that 10.80 % of adverse effects were found to be serious and the remaining 89.20 % were found to be non serious type reaction.

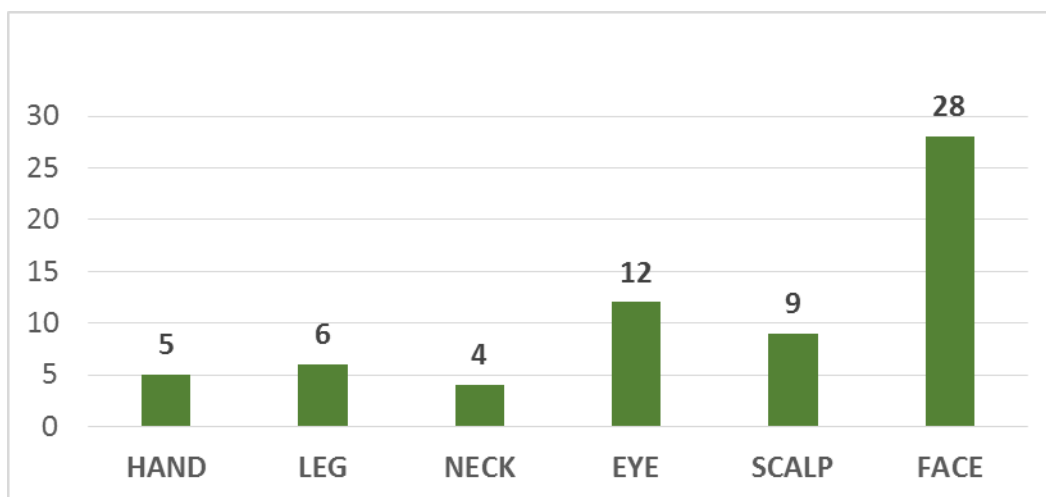
Tab:3

NON SERIOUS	89.20%
SERIOUS	10.80%

10. SITE OF REACTIONS

In graph: 5, 28 persons were affected on their face, 12 on their eye, 9 on their scalp, 6 on legs, 5 on their hand and 4 on their neck portions. Number of candidates

experience adverse effect related with hydroquinone content. The adverse effect on face ie, hyperpigmentation affect the candidates pscologically that leads to over conciousness about the appearance in publics.



Graph 4

13. KNOWLEDGE ABOUT COSMETOVIGILANCE

Among 67 candidates, 41 persons were heard about cosmetovigilance and their source of information were 22 from internet 12 from teachers 5 from friends and 2 from journal. Remaining 26 were unaware about cosmetovigilance. This unawareness reveal the lack of

proper and updated curriculam. In that Out of 41.33 % were replied that the reporting authority is manufacturers 25 % replied the reporting authority is hospital /doctor and 42 % were unaware about the reporting authority. All candidates recommend the need of cosmetovigilance center, 12% recommend central reporting and 88% recommend statewise reporting authority.

Tab:4

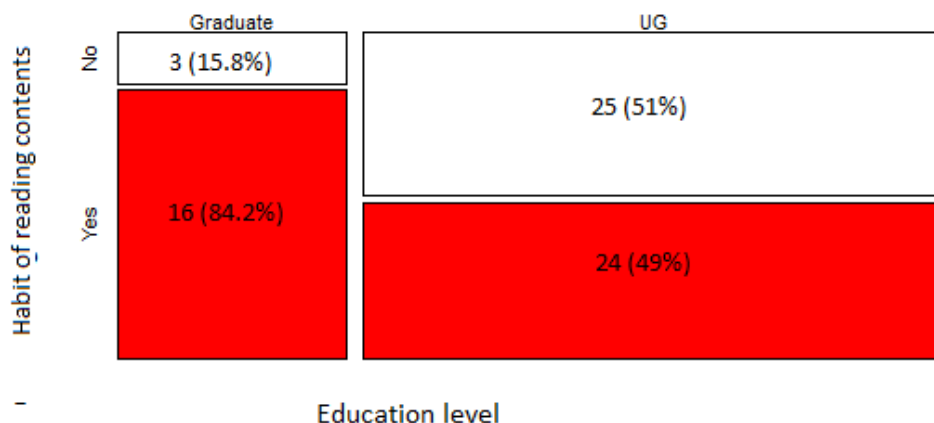
Knowledge About Cosmetovigilance		
Yes	41	
No	26	
Participants Knowledge On Reporting Authority		
Manufacturer	33%	
Hospital/ Doctor	25%	
Don'T Know	42%	
Information Source		
Friends	5	
Teacher	12	
Internet	22	
Journal	2	
Demand Of Reporting Authority		
Central Reporing Authority	12%	
Statewise Reporting Center	88%	

14. DISTRIBUTION OF COSMETOVIGILANCE & EDUCATION AND COSMETOVIGILANCE & READ THE CONTENT OF COSMETICS

Among the graduates 16 (84.2%) read and understand the contend of cosmetics before purchase and only 3(15.8%) wont have the habbit of reading the content of cosmetics what they were purchased. In the case of under

graduates and students 24 (49%) had the habbit of read and understand the content and 25 (51%) wont spend their time to understand the content of cosmetics with the statistical value of x-squared= 6.4318, df=2, Pvalue= 0.04012. This reveals the importance of proper education and awareness program about cosmetics safety.

Education level and habit of reading contents of a cosmetic product

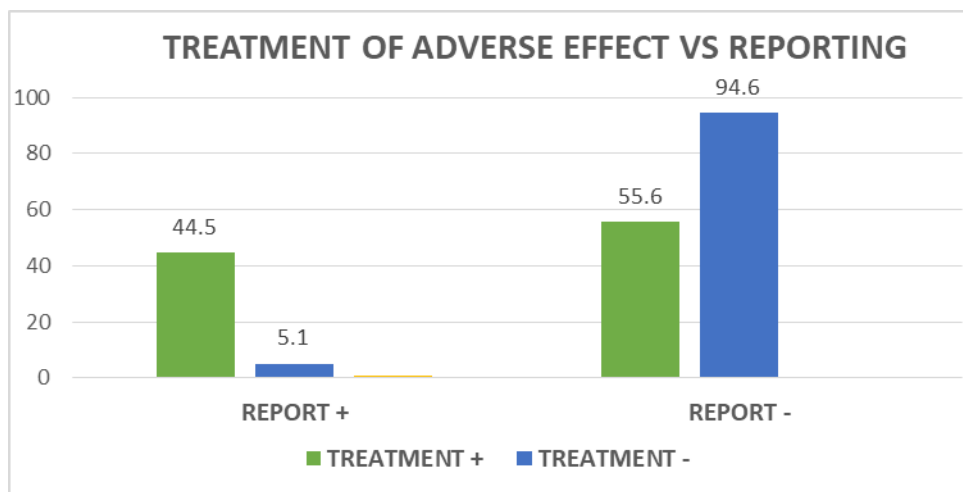


Graph: 5

15. DISTRIBUTION OF TREATMENT OF ADVERSE EFFECT AND REPORTING PATTERN

The data analysed by R software, explain the reporting pattern and treatment of adverse effect of cosmetics. 44.5% of affected candidates undergone treatment and reported the adverse effect to hospital/manufacturer and 55.6% of undergraduates also went for treatment and not

reported the adverse effect. About 5.1% never went for treatment but they reported to the available authority but 94.6% of adverse effect affected population never went for treatment and not reported to the available authority with the statistical value calculated by Pearson's chi squared test with Yates continuity correction χ^2 9.1847, df=1 and p value 0.002.



Graph: 6.

CONCLUSION

Cosmetic industry in India is mature and growing in terms of product developments and marketing because user's preferences are changing from only cosmetic, to more functional, advanced and specialised products. India is fourth largest cosmetic market in Asia Pacific region. But the unwanted or adverse reaction due to cosmetic products goes unnoticed due to lack of proper organised reporting system. In India, the pharmacovigilance system monitors the adverse drug reactions and recently consideration is also being given to medical device, blood products, biologics, and special nutritional and natural products, however adverse

reaction related to cosmetic products have still remained unmarked. It is time that India should also initiate to have a formal cosmetovigilance system. This could contribute to increase the safe use of cosmetics which is important for the safeguard of public health. The process of Cosmetovigilance is evolving and coming up as a strong regulatory science to protect public health and beauty. In European Union, directive 76/768/EEC regulates the monitoring of cosmetics. The unwanted or adverse reactions due to cosmetic products are very low go unnoticed, or under reported due to lack of proper organized reporting system. India can initiate to have formal Cosmetovigilance system. In future it could

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