
ORIGINAL ARTICLE

Using Pharmaceutical and Cosmetic Products Beyond Expiry Date

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ABSTRACT

The expiry date for medicines is the specific moment when a product is no longer in a suitable condition to be deemed both effective and safe for the health of consumers. The study aimed to assess the acquisition, utilization, and utilization of expired medications by individuals in Saudi population. This study involved 500 Saudi individuals, aged 18 or older, who have used pharmaceutical and cosmetic products beyond their expiration dates. Participants will be recruited through internet platforms, social media marketing, and community outreach. They will be sent an electronic questionnaire hosted on a secure online platform like Qualtrics, which will gather data on demographic attributes, product usage patterns, perspectives on expiration dates, and instances of using products after their expiration dates. The questionnaire will have limited response options, allowing participants to contribute numerical data and subjective insights. Closed-ended questions will cover the frequency of using products past their expiration date, motivations behind such actions, perceived effectiveness and safety of expired products, and awareness of expiration dates. Open-ended questions will allow participants to provide additional facts or opinions. The quantitative data will be analyzed using descriptive statistics to provide a summary of participant characteristics, product usage patterns, and opinions towards expiration dates. Calculations for frequencies, percentages, means, and standard deviations will be performed as needed. Results revealed the broad use of expired cosmetic and pharmaceutical products beyond expiry date although the previous knowledge of possible risks associated with the use of expired products. The study findings shed the light on the importance of awareness campaigns through various channels.

Keywords: Pharmaceutical products, Cosmetic products, Expiry date, Microbial Contamination, Allergic reaction, Dermatitis

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INTRODUCTION

The expiration date of any pharmaceutical product is the last day it can be used for medicine which is the specific moment when a product is no longer in a suitable condition to be deemed both effective and safe for the health of consumers [1]. The expiration date of a product can be determined based on various factors, such as the time elapsed after manufacturing, dispensing, or opening of the manufacturer's container [2]. However, it is not a fixed concept that all pharmaceuticals deteriorate at the same pace or interval of time. Medicines, which belong to distinct synthetic or formed groups, have varying shelf-life positions. The World Health Organization states that pharmaceutical items are accompanied by a package insert that provides comprehensive information on the proper use of medicines, potential side effects, drug interactions, and expiration date [6].

Since 1979, the Food and Drug Administration (FDA) has mandated that pharmaceutical manufacturers provide expiration dates on all pharmaceutical items [3].

The expiration dates for most medications sold in the United States fall within a range of 12 to 60 months from the manufacturing date [4]. If pharmaceuticals are handled poorly, they may expire before their designated expiration date. Conversely, many studies have indicated that medications can remain effective much beyond their expiration date [5].

Women frequently ingest expired or utilized cosmetics without possessing a complete comprehension of their detrimental consequences [6]. In order to tackle this problem, it is imperative to evaluate women's

level of consciousness regarding the hazards linked to excessive utilization of cosmetics. One can accomplish this by utilizing formal channels, internet websites, social media platforms, and radio broadcasts. Informal educational institutions, including schools and universities, ought to develop health education initiatives aimed at enhancing women's understanding and perspectives of the hazards associated with excessive cosmetic usage. It is crucial to ensure proper utilization of these items, and it is advisable to promote the inclusion of the expiration date on cosmetic product packaging by health authorities [7].

The study aimed to assess the acquisition, utilization, and utilization of expired medications by individuals in the Saudi population.

MATERIAL AND METHODS

Procedure:

Participants: A cohort of 500 Saudi individuals will be enlisted for this study via convenience sampling. Participants will be chosen from a range of demographic backgrounds to guarantee variety in age, gender, socioeconomic level, and geographic location. The inclusion criteria will encompass persons who are 18 years of age or older and have utilized pharmaceutical and cosmetic items. The study will involve participants who have previous experience of utilizing products beyond their expiration dates.

The procedure involves inviting participants to take part in the study via internet platforms, social media marketing, and community outreach. Once participants show interest in the study, they will receive a link to an electronic questionnaire. This questionnaire will be hosted on a secure online survey platform such as Qualtrics. The questionnaire will be created to gather data on demographic attributes, patterns of product usage, perspectives on expiration dates, and instances of utilizing pharmaceutical and cosmetic products after their expiration dates.

The questionnaire will comprise of questions with limited response options, enabling participants to contribute both numerical data and subjective insights regarding their experiences and perceptions. Closed-ended questions will encompass inquiries regarding the frequency of using products past their expiration date, the motivations behind such actions, the perceived effectiveness and safety of expired products, and the level of awareness regarding expiration dates. Utilizing open-ended questions enables participants to expand upon their responses and offer supplementary facts or opinions.

Data Analysis:

The quantitative data gathered from the questionnaire will be examined using descriptive statistics to provide a summary of participant characteristics, product usage patterns, and opinions toward expiration dates. Calculations will be performed for frequencies, percentages, means, and standard deviations as necessary.

RESULTS

Table 1: Demographic characteristics of individuals participating in the questionnaire were included in the study

| Variable | Item reduction sample |
|--|-----------------------|
| Age | |
| Age: mean± (SD) | 33.91±4.94 |
| Gender | |
| Sex, female: (%) | 73.30% |
| Education Level | |
| Prefer not to say (%) | 6.70% |
| Not specified Secondary Education, (%) | 3.30% |
| High school graduate (%) | 3.30% |
| Bachelor's Degree (%) | 16.70% |
| Master's Degree (%) | 16.70% |
| Doctoral Degree (%) | 56.70% |
| Employment Status | |
| Currently employed. (%) | 90.00% |
| Not employed Student (%) | 3.30% |
| Jobless (%) | 6.70% |
| Geographical Location | |
| Suburban (%) | 3.30% |
| Rural (%) | 10.00% |
| Urban (%) | 68.70% |

According to Table No. (1), the sample used during the questionnaire consisted of a group of individuals, 73.3% of them are women, on average Aged 39.1 years (SD = 4.9) and their ages range between 24 to 55 years. According to the geographical division, the percentage of those living in urban areas was (68.70%), **Suburban** 3.30%(and those living in rural areas, and various other areas was (10.00%), but in terms of the level of education, the percentage of those who obtained pre-university education was (3.30%), and university education was (16.70%), and those who obtained master's degrees was (16.70%), the doctorate percentage was (56.70%), while Al-Aid refused to disclose and their percentage was (6.70%) out of the total sample. In terms of work, the percentage of those with a job was (90%), and for those without a job or job the percentage was (6.70%).

Table 2: internal consistency of subscales

| Domains | Number of items | Cronbach's alpha | % variance explained* |
|---|-----------------|------------------|-----------------------|
| Objective and Utilization | 3 | 0.848 | 76% |
| Cognizance and Understanding | 3 | 0.788 | 78% |
| Process of making choices | 4 | 0.94 | 74% |
| Waste Management and the Environment | 2 | 0.854 | 75% |
| Contemplation and Future Plans: | 9 | 0.858 | 75% |
| Overall score | 20 | 0.966 | 74% |

Cronbach's alpha: the tau equivalent reliability scale or alpha coefficient, is a reliability coefficient (0:1) f= variance explained

According to table (2) Internal consistency refers to the extent to which items within a subscale measure the same underlying concept. In other words, it evaluates whether respondents who score high on one item in a subscale are also likely to score high on the other items in that subscale, and vice versa. The most common metric for assessing internal consistency is Cronbach's alpha. This coefficient ranges from 0 to 1, with higher values indicating greater internal consistency. Generally, values above 0.7 are considered acceptable, but the threshold can vary depending on the research field and study context. The Cronbach's coefficient and alpha For Objective and Utilization was (0.848) , variance explained f=(76%), , The Cronbach's coefficient and alpha For Cognizance and Understanding was (0.788) , variance explained f=(73%), , The Cronbach's coefficient and alpha For Process of making choices was (.094, variance explained f=(74%), The Cronbach's coefficient and alpha For Waste Management and the Environment was (.0854), variance ex Contemplation and Future Plans: plained f=(75%), The Cronbach's coefficient and alpha **Contemplation and Future Plans** was (0.855), variance explained f=(75%), and for Overall score The Cronbach's coefficient and alpha (0.966), variance explained f=(74%)

TABLE 3: General analysis of residual variance

| Source of variance | Sum of squares of variance | Degrees of freedom | F | P |
|-----------------------|----------------------------|--------------------|-------------|--------------|
| Between groups | 14.2 | 19 | 3.05 | 0.048 |
| Within groups | 20.2 | 4 | | |
| sum | 34.4 | 23 | | |

F: F for One-way ANOVA test,

p: p-value for comparing between the three studied groups

According to Table (3) In the analysis of variance (ANOVA) test, the P value and F indicate two main measures to evaluate the significance of the results: P value, small P values (less than 0.05) indicate statistical significance, while large P values (Higher than 0.05) indicates that there is no statistical significance. It represents the ratio of the variance (f) between the data sets to the variance within the data sets. If this value is large, it indicates that there is a large difference between the data sets, while small values indicate that there is no significant difference. As shown in the table the p-value was (0.024), which means that there is statistical significance. Also, the value of (f) = p.05, showed that the differences and variance are also statistically significant.

Table 4: Descriptive statistics for the DermaSat scales and overall score according to

| | Valid % | Missing | Mean | SD | min | max | min | max |
|---|-------------|-----------|--------------|-------------|----------|------------|----------|-----------|
| Objective and Utilization | 100% | 0% | 0.99 | 0.1 | 0 | 100 | 4 | 8 |
| Cognizance and Understanding | 100% | 0% | 0.82 | 0.18 | 0 | 100 | 2 | 10 |
| Process of making choices | 100% | 0% | 0.826 | 0.18 | 0 | 100 | 2 | 8 |
| Waste Management and the Environment | 100% | 0% | 0.88 | 0.12 | 0 | 100 | 2 | 8 |
| Contemplation and Future Plans: | 100% | 0% | 0.514 | 0.54 | 0 | 100 | 2 | 8 |
| Overall score | | | 0.806 | 0.25 | 0 | 100 | 2 | 10 |

SD = Standard Deviation, Min = Minimum, Max = Maximum, Lower =min point, Upper cat = max point

Table No. (4) presents descriptive statistics for the DermaSat scales and the overall score according to to evaluate the effects of using expired products previously for the survey respondents, A score was assigned to each individual in the questionnaire according to the standards, The table shows that the value of the major assessment is 100% and the minor assessment is 0%, noting that all individuals answered all questions, and for Objective and Utilization, the average rating of the grades was (94%), the lowest grade obtained by the individual was (4), and the highest grade obtained was (8), noting that the grades were evaluated from zero to ten for each question. For Cognizance and Understanding, the average rating of the grades was (82%), the lowest grade obtained by the individual was (2), and the highest grade obtained was (10), for the Process of making choices, the average rating of the grades was (82.6%), the lowest grade obtained by the individual was (2), and the highest grade obtained was (8), For Waste Management and the Environment, the average rating of the grades was (88%), the lowest grade obtained by the individual was (2), and the highest grade obtained was (8), For the Contemplation and Future Plans, the average rating of the grades was (51.4%), the lowest grade obtained by the individual was (2), and the highest grade obtained was (8), and For the Overall score, the average rating of the grades was (80.6%), the lowest grade obtained by the individual was (2), and the highest grade obtained was (10),

Table 5: Validity Concerning Known Groups

| | mean± (SD) | min-max | Median (IQR) | p | f |
|---|-----------------|--------------|---------------|------------------|-------------|
| Objective and Utilization | 99± 1.6 | 80-94 | 90(2) | <0.001 | 1.9 |
| Cognizance and Understanding | 82±1.99 | 65-96 | 77(18) | 0.003 | 1.05 |
| Process of making choices | 82±1.78 | 65-96 | 88(11) | <0.001 | 2.05 |
| Waste Management and the Environment | 82±1.65 | 61-82 | 82(10) | <0.001 | 3.02 |
| Contemplation and Future Plans: | 82±2.05 | 67-92 | 71(18) | <0.005 | 3.1 |
| Overall score | 80.6±1.9 | 61-96 | 81(11) | 0.024 | 3.05 |

IQR: Inter quartile range

SD: Standard deviation

F: F for One-way ANOVA test,

p: p-value for comparing between the three studied groups

According to Table (5) In the analysis of variance (ANOVA) test, the P value and F indicate two main measures to evaluate the significance of the results: P value, small P values (less than 0.05) indicate statistical significance, while large P values (Higher than 0.05) indicates that there is no statistical significance. It represents the ratio of the variance (f) between the data sets to the variance within the data sets. If this value is large, it indicates that there is a large difference between the data sets, while small values indicate that there is no significant difference. As shown in the table the p-value was (0.024), which means that there is statistical significance. Also, the value of p =0.05, showed that the differences and variance are also statistically significant. The P-value within all groups was less than 0.005, for Objective and Utilization was (<0.001), variance explained f=(1.9), For Cognizance and Understanding was p =(0.003), variance explained f=(1.05), for making choices p= (<0.001), variance explained f(2.05), For Waste Management and the Environment p was ((<0.001)), variance f=(3.02), Contemplation and Future Plans p was (<0.005), variance explained f=(3.1), and for Overall score p was (0.024), variance explained f was(3.05)

The results of the study revealed high frequency of using pharmaceutical products among study population where 53.3% of the respondent reported their use of the products every day. 46.7% of the respondent reported their efforts to verify expiry date. While 36.7% reported that they sometimes verify expiry date. Concerning the intentionally use of medicinal or cosmetic product that has beyond its expiry date, 50% of the respondents reported that they use the expired products intentionally (figure1).

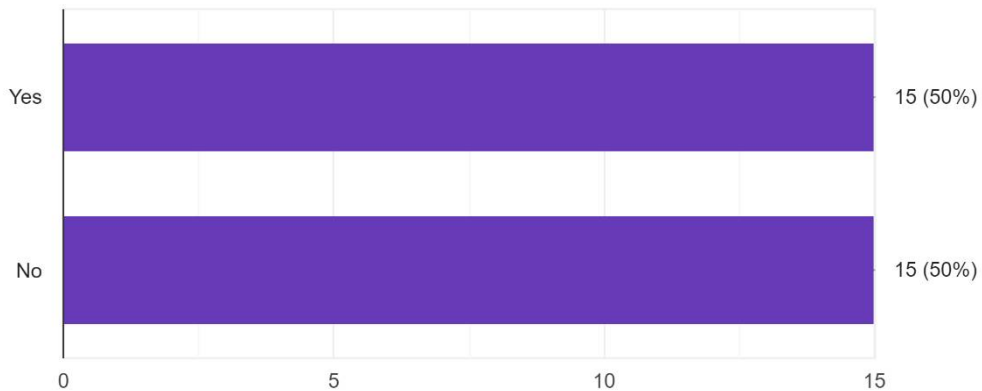


Figure 1: percentage of respondent who intentionally used cosmetic and pharmaceutical products beyond expiry date.

Concerning the knowledge about the possible hazards 46.7% reported that they are somewhat aware with the possible hazards while 30% of them were very aware with the possible hazards. Concerning obtaining information about safety and efficacy of medical and cosmetic products 56.7% of the respondent reported that they get their information either from the healthcare professionals and from the internet. Concerning the aware about the hazards associated with the use of the products beyond expiry date, 80 % reported that reduced effectiveness is the major risk followed by allergic reactions, bacterial contamination while decreased potency came last. Figure (1) show the percentages of each hazard. Increased potency

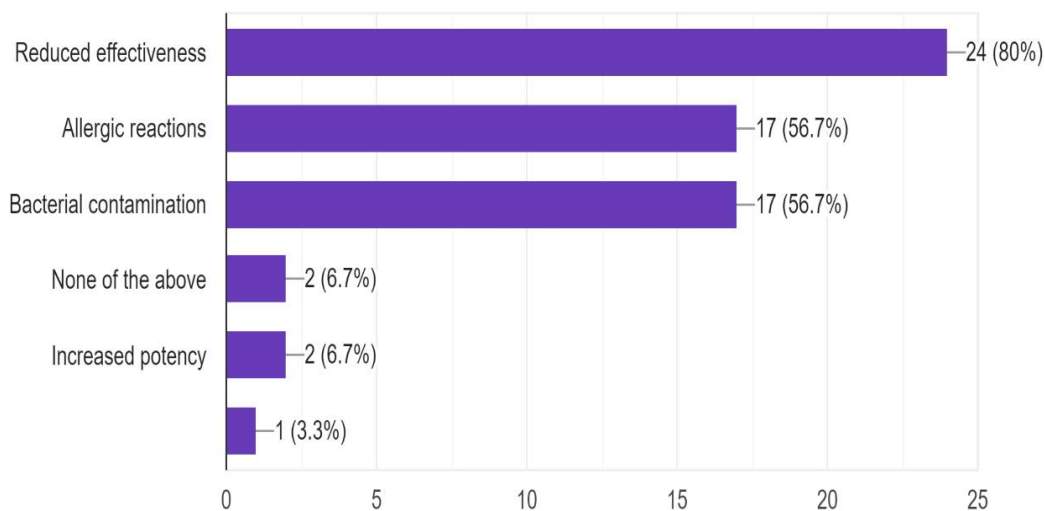


Figure 2: percentage of respondents' expected hazards of using expired products.

Seeking information or updates on the potential risks of using expired medical and cosmetic products was reported to be occasionally by 46.7% of the correspondents while 43.3 % of them reported that they rarely seek updates on potential risks. Concerning the variables that impact the respondent's choice to use the products beyond expiry date; 70% of the respondents choose healthcare professionals. The respondents also reported that they haven't any peer pressure that impact their decision for using the products beyond expiration. Figure (3). Concerning the disposal of expired cosmetic and medical products 96.7% of the respondents reported that they dispose the products in

trash, the respondents also reported that they don't prioritize environmental responsibility while disposing the products.

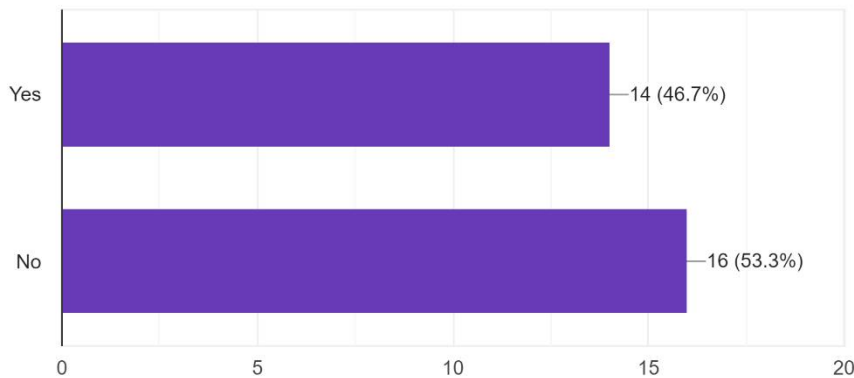


Figure 3: shows the percentage of respondents for peer pressure impact Regarding the consequences that the respondents had when using expired products 83% of the respondents reported that they didn't experience any detrimental consequences.

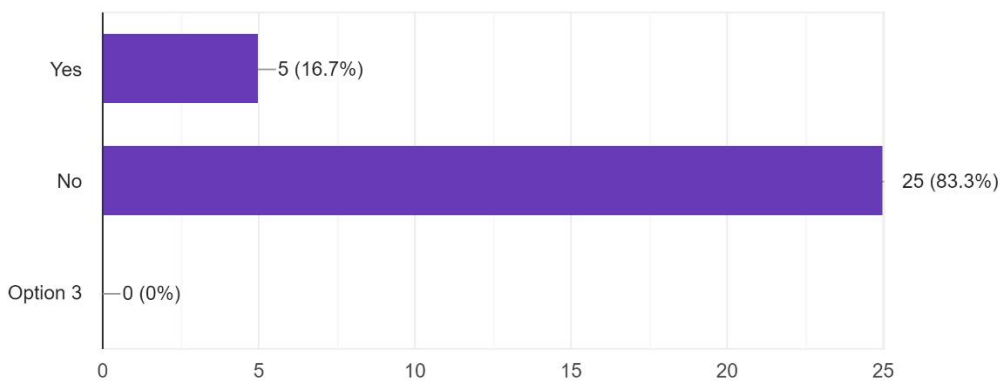


Figure 4: respondent percentage regarding detrimental consequences when using expired products. Upon asking the respondents about their intentions to modify their behavior regarding using expiry products, 66.7% of the respondents reported that they will not change their behavior. On the other hand; upon asking about the challenges, they may have to obtain precise information about the expiry date of the products, 63.3% of them reported that they didn't face any challenges. Regarding the improved labelling, 60% of them reported that improved expiry date labelling will impact their choice to use or dispose the expired products where 60% of them agreed to that.

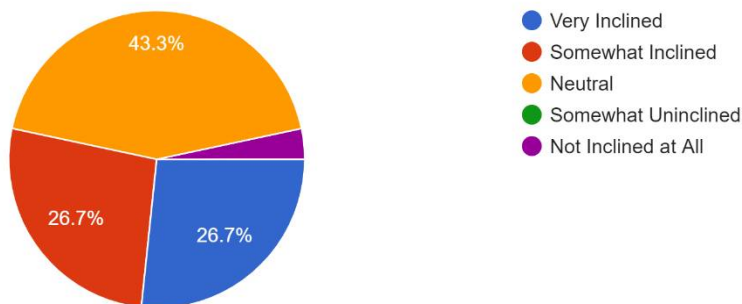


Figure 5: respondents' percentages regarding acquiring information about expiry date

Figure (5) shows that 43.3% of the respondents were neutral regarding acquiring information about the expiry date of the products. Asking the respondents about their knowledge toward the risks of using expired cosmetic and pharmaceutical products, 70 % of them reported their previous knowledge about the possible risks. Upon asking them about their intentions to inform others with the risks of using expired products, 80% of them reported they are intended to inform others about the possible risks. Upon asking them about their opinion toward the benefits of the awareness initiatives, 60% of them reported that it is very beneficial while 33.3% reported that they are somewhat beneficial.



Figure 6: represents the respondent suggestion to improve public understanding about the hazards of using expired products.

Upon asking them about their suggestions to improve public understanding about the hazards of using expired products; the answers came as follow: collaborate with healthcare professionals for public awareness programs (13.3%), Implement sticker regulation and labelling requirements on product packaging (13.3%), launch educational campaigns through social media platform (16.7%),enhance accessibility to educational resources online (6.7%), utilize television and radio advertisement for outreach (6.7%), 40% of the respondents choose all of the above.

Discussion

The phrases "best before," "expiry date," and "shelf-life" are frequently used in reference to pharmaceutical products, but they are also frequently used in reference to food, drink, chemicals, and cosmetics [8]. For the majority of pharmaceutical items, the expiration date indicates the quality of the product because, following the expiration, contamination is indicated by elevated microbiological index levels or moisture contents, which may also affect the use of such medications [9]. Loss of potency, safety, efficacy, and the creation of hazardous byproducts are among the negative impacts of expired medications [10]. The study aimed to assess the acquisition, utilization, and utilization of expired medications by individuals in Saudi population.

According to the Consumer Healthcare Products Association, the retail sales of over-the-counter medications (OTC) in the United States have increased twofold from USD 16.8 billion to USD 35.2 billion between 2008 and 2018[18].

Furthermore, according to Variant industry Research, an Indian-based business specializing in data mining and information research, it has been projected that the global over-the-counter (OTC) industry will have a significant growth from USD 125 billion in 2016 to USD 273 billion by the year 2024 [20].

Simultaneously, the German Federal Ministry for the Environment has documented that pharmaceutical businesses in both developed and developing nations are manufacturing a diverse range of synthetic chemicals at an annual production volume of 100,000 tons [11]. Only a small share is being used, while the majority will eventually be unused or expired, leading to a significant amount of pharmaceutical waste [12].

The results of this study have revealed wide use of expired cosmetic and pharmaceutical products by the participants despite their awareness of the possible risks associated with the use of expired products. Due to their diminished efficacy, expired medications may prove ineffective in the treatment of both mild ailments such as headaches or colds, as well as more severe conditions like diabetes or heart disease [5]. In the study conducted by [13]. He analyzed donated expired cosmetic products. The donated used products were subjected to microbial culture and identification to determine their microbiological contents. Approximately 79-90% of the utilized products exhibited bacterial contamination, with

bacterial loads varying from 102 to 103 colony-forming units per milliliter (cfu/ml). Notably, beauty blenders displayed an average load exceeding 106 cfu/ml. The identification of *Staphylococcus aureus*, *Escherichia coli*, and *Citrobacter freundii* was observed. Enterobacteriaceae and fungi were found in all categories of products, with beauty blenders having the highest prevalence at 26.58% and 56.96% respectively. A significant majority of beauty blenders, specifically 93%, had not undergone cleaning, while 64% had been spilled on the floor and remained in use.

The European Cosmetics Regulation guarantees that cosmetics are manufactured to a stringent standard to guarantee the safety of consumers. It is important to conduct testing to evaluate the physical and chemical properties, stability, and microbiological and toxicological attributes of the product [3].

According to legislation in the United States, it is not anticipated that cosmetics will be completely devoid of microorganisms upon initial use or throughout consumer usage. Additionally, cosmetics don't need to be sterile; yet, the presence of microbial contamination can potentially endanger health [13].

The determination of expiration dates for cosmetic items is contingent upon the duration during which the preservatives incorporated within the product possess the ability to effectively manage contamination. If the package contains an expiry date, it is presented as a symbol that resembles an open pot. The sign is centered around the number of months the product can be used, which can be either 3M, 6M, 12M, 18M, 24M, or 36M [14].

Based on the findings derived from our research, it is posited that the propensity of customers to utilize expired products could potentially be impacted by the strategic pricing strategies employed by specific cosmetic enterprises [15]. These organizations can employ exclusive promotional strategies or execute price reductions on items that are approaching their expiration date. This particular approach enables organizations to effectively manage their inventory, enhance sales performance, and mitigate potential losses prior to the expiration of their products. Nevertheless, it is imperative for consumers to exercise prudence while acquiring reduced-priced goods in proximity to their expiration date and to ascertain that the product is within acceptable quality parameters prior to utilization.

The utilization of expired cosmetics can potentially result in adverse reactions as a consequence of various factors, over the course of time, the chemical composition of cosmetics has the potential to undergo alterations, resulting in the emergence of novel compounds or the deterioration of preexisting ones [16]. The chemical transformations can lead to the generation of irritants or allergens that have the potential to elicit allergic responses upon dermal application [17].

The concentration or acidity of expired cosmetics may increase as they undergo degradation, leading to heightened skin sensitivity and an increased risk of allergic responses [18]. Expired cosmetics may potentially contain allergies originating from several sources, including dust or debris, particularly if they have been inadequately preserved. The application of the substance to the skin can potentially heighten the likelihood of allergic responses [19].

The application of expired products can cause symptoms like redness, itching, burning, or stinging, as well as dermatitis, a rash, blisters, or swelling at the skin's contact area. These reactions are triggered by the immune system's response to specific allergens in cosmetics, resulting in skin inflammation and pain [1].

Only 500 respondents of the Saudi population participated in this study which resembles a bias limitation. The conducted questionnaire only focused on the attitude toward the use of expired medical and cosmetic products.

Based on our study findings, the suggestions of the participants have shed light on the importance of collaborating with healthcare professionals for public awareness programs, implementing sticker regulation and labeling requirements on product packaging, launching educational campaigns through social media platforms, enhancing accessibility to educational resources online, utilize television and radio advertisement for outreach.

CONCLUSION

This research investigates the utilization of expired pharmaceutical and cosmetic products, elucidating the potential hazards and underlying incentives associated with this conduct. The study revealed that a considerable proportion of customers partake in this behavior, frequently driven by financial factors, product accessibility, or perceived low levels of risk. Nevertheless, the study highlights the significance of recognizing the possible dangers, such as reduced effectiveness, heightened likelihood of negative responses, and microbial pollution, which provide substantial health risks.

CONFLICT OF INTEREST: No conflict of interest.

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