REVIEW ARTICLE

CONTENTS

Modern approaches to the development of recommendations on the safety of sun protection products use and the need to control their composition and labelling

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ABSTRACT

Aim: To enhance the effectiveness and safety of sun protection product use by developing recommendations based on an analysis of the Ukrainian SPF product market.

Materials and Methods: A literature review was conducted using publications indexed in the databases Google Scholar, Web of Science, and Scopus, and the PubMed and ToxNet search engines. A structured search was conducted using relevant keywords and their logical combinations, including: "skin cancer" and "ultraviolet radiation", "sunscreens", "SPF products", "sunscreen cosmetics", "efficacy and safety of sunscreens", and others. Information about sunscreens contained only on the official websites of the manufacturers was used. Information from unofficial sources was not considered. The review is based mainly on recent studies; however, selected scientific sources (2011-2018) were intentionally included to highlight the evolution of scientific knowledge in this field. The analysis used formal-logical and systemic-complex methods, which ensured a comprehensive and critical synthesis of the available evidence.

Conclusions: Ultraviolet radiation is the main factor in the development of melanoma, basal cell carcinoma, and squamous cell carcinoma of the skin. The increasing incidence of skin cancer prompts health professionals to encourage the population to use sunscreens. Sun protection factor (SPF) serves as the main criterion for choosing the necessary level of protection in conditions of insolation. International recommendations support the use of preparations with high SPF indices, but in practice, frequent cases of inaccurate information provided by cosmetic manufacturers have been recorded. At the same time, cosmetic sunscreens, even with the same SPF value, demonstrate different levels of effectiveness under insolation conditions. The Ukrainian cosmetic market offers hundreds of SPF products in the form of creams, sprays, oils, milks, or foams. In addition to well-known brands from France, the USA, Italy, Switzerland, Germany, Poland, and Ukraine, dozens of brands from lesser-known manufacturers, especially from Korea, are now available thanks to online shopping. As a rule, such resources do not indicate the exact SPF used in the product but instead declare marketing characteristics such as "lightest" or "safest." Today, their use is gaining popularity among the population; however, the need for legislative control over them must be addressed.

KEY WORDS: skin cancer, melanoma, sun protection products

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INTRODUCTION

Every year in May, many countries around the world observe Skin Cancer Awareness Month, as skin cancer is one of the most common groups of oncological diseases. The World Health Organization (WHO) reports that more than 1.5 million new cases of skin cancer were detected in 2022, among which melanoma – the most dangerous malignant tumour of the skin, developing from pigment cells (melanocytes) – was diagnosed. In 2022, an estimated 330,000 new cases of melanoma were diagnosed worldwide, and almost 60,000 people died from the disease. There are large geographical variations in melanoma incidence rates across countries and world regions. In most world regions, melanoma occurs more frequently in men than in women [1].

According to the National Cancer Registry, in Ukraine, the total number of new cases of non-melanoma skin cancer in 2021 was 11,109; incidence – 15.7 per 100,000 population (standardized rate, world standard), mortality – 0.5 per 100,000 population (standardized rate, world standard). In 2022–2023, 5,051 cases of melanoma were detected for the first time, and by the beginning of 2023, more than 31,000 people with this diagnosis were registered [2].

It is well established that solar ultraviolet (UV) radiation is the main cause of melanoma, basal cell carcino-

ma, and squamous cell carcinoma of the skin [3]. The most noticeable increase in the incidence of melanoma occurs among the fair-skinned populations of countries with a moderate level of insolation. For example, the Danish Cancer Registry documented one case of melanoma per 100,000 population in 1950, three cases per 100,000 population in 1970, and the forecast figure for 2036 is 50–70 cases per 100,000 population [4].

A similar trend is observed in many European Union (EU) countries, the USA, the United Kingdom (UK), and others. Understanding the urgency of the issue, a working group of experts, which included clinicians and researchers from Africa, America, Asia, Australia, and Europe, together with scientific societies (European Association of Dermato-Oncology, Euromelanoma, Euroskin, European Union of Medical Specialists, and Melanoma World Society) jointly formulated scientifically based recommendations on photoprotection as a strategy for preventing skin cancer. Specifically, people with fair skin, especially children, should minimise exposure to UV radiation, and it is recommended to take protective measures when the UV index reaches 3 or higher (the UV index is a standard international indicator of UV radiation. Its values start from "0" and can exceed "10"; the higher the number, the greater the likelihood of skin and eye damage and the shorter the time required to cause harm) [5, 6].

To prevent skin cancer, international organizations support the use of sun protection products (products containing Sun Protection Factor [SPF]) with high sun protection values. However, manufacturers of such cosmetics do not always provide reliable information about the actual sun protection properties of their products or their safety for consumers, as revealed by a comparative analysis of the sun protection product market.

AIM

The aim of the research was to enhance the effectiveness and safety of sun protection products use by developing recommendations based on an analysis of the Ukrainian market of SPF products.

MATERIALS AND METHODS

A literature review was conducted using publications indexed in the databases Google Scholar, Web of Science, and Scopus, and the PubMed and ToxNet search engines. A structured search was conducted using relevant keywords and their logical combinations, including: "skin cancer" and "ultraviolet radiation", "sunscreens", "SPF products", "sunscreen cosmetics", "efficacy and safety of sunscreens", and others. Information about sunscreens contained only on the official websites of the manufacturers was used. Information from unofficial sources was not considered. The review is based mainly on recent studies; however, selected scientific sources (2011-2018) were intentionally included to highlight the evolution of scientific knowledge in this field. The analysis used formal-logical and systemic-complex methods, which ensured a comprehensive and critical synthesis of the available evidence.

ETHICS

Since this study was conducted exclusively as a systematic review of the available scientific literature obtained from open sources, permission from the ethics committee was not required. All data included in the review were previously published and freely available, and their use was carried out exclusively for scientific purposes.

During the preparation of the article, the principles of academic integrity were observed, including proper citation of sources in accordance with the established requirements. The authors did not use unreliable or falsified data, and also avoided any manifestations of plagiarism.

When preparing the review, the provisions of international ethical guidelines were taken into account, in particular the recommendations of COPE (Committee on Publication Ethics) and PRISMA (Preferred Reporting Items for Systematic Reviews and Meta-Analyses), which ensures transparency, reliability and scientific quality of the presented material.

FRAMEWORK

The study was performed as a fragment of the Scientific Department of Scientific Basis of Chemical Factors Risk Assessment (State Enterprise «L.I. Medved's Research Center of Preventive Toxicology, Food and Chemical Safety of the Ministry of Health of Ukraine (state enterprise) «Scientific Substantiation of Measures for the Toxicological Safety of the Human Environment in the Health Care System» (state registration number 0123U102087; term: 2023-2027).

REVIEW AND DISCUSSION

The increasing incidence of skin cancer is prompting health professionals to encourage the use of sun protection products among the population. The SPF index is the main criterion for selecting the necessary level of protection under insolation conditions: the higher the SPF, the greater the level of protection. It has been estab-

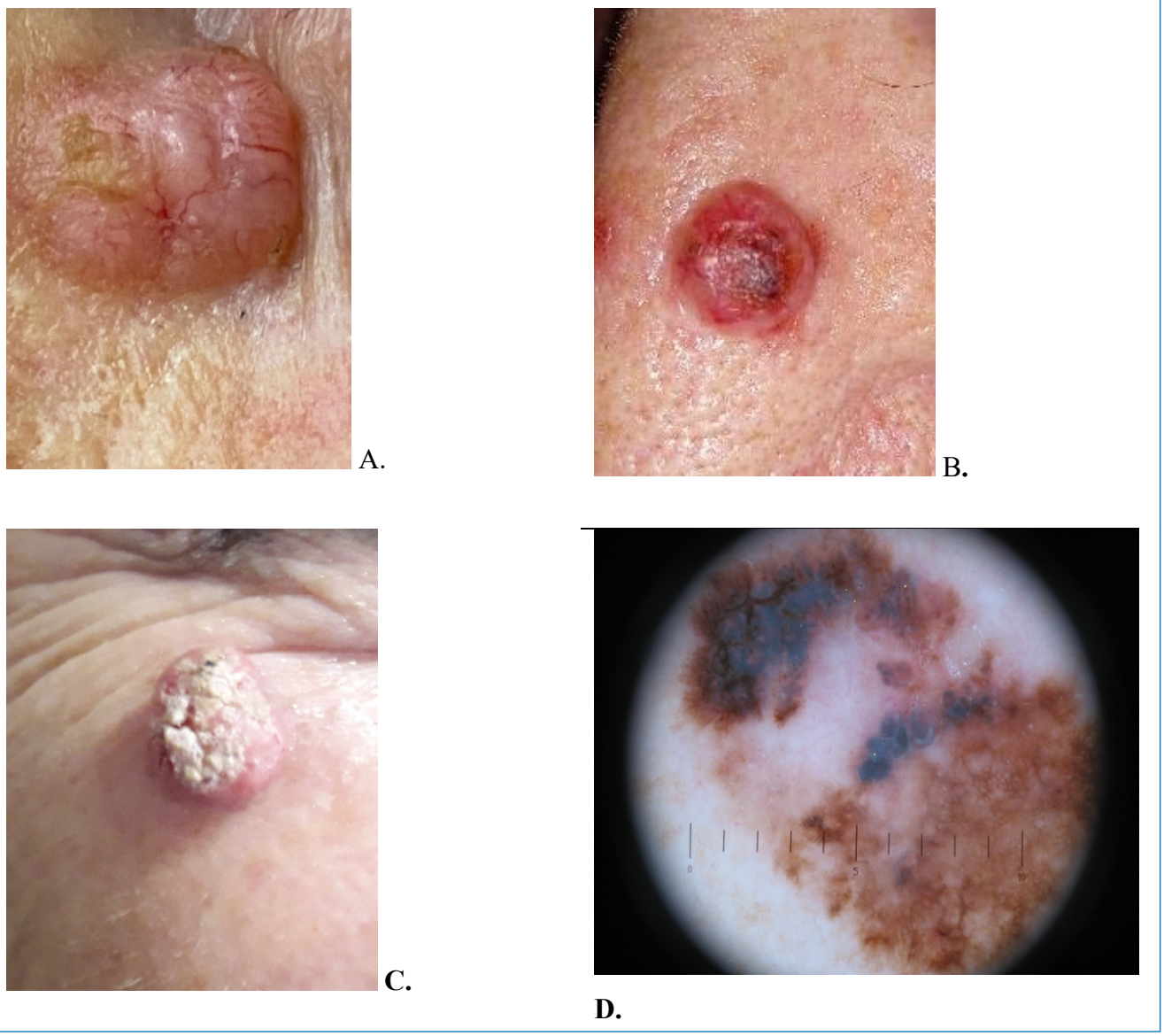

Fig. 1. Examples of keratocytic skin cancer (A, B, C) and melanoma (D) (photo by O. Havrylyuk): **A.** Basal cell carcinoma, nodular form periocular face skin area, woman 74 years old; **B.** Basal cell carcinoma, nodular form, wing of the nose skin, woman 68 years old; **C.** Squamous cell carcinoma, verrucous form, upper mandibular facial skin area, woman 61year old; **D.** Melanoma of the skin. Dermatoscopy, Heyne Delta, woman, 27 years old
Pictures taken by the authors

lished that the incidence and mortality from melanoma among individuals with light skin is significantly higher than among those with darker skin. The risk is classified according to the scale developed by American dermatologist Thomas B. Fitzpatrick, ranging from I to IV [7].

Thus, keratinocyte carcinoma (Fig. 1) has higher prevalence rates among individuals with light skin compared to those whose skin is less sensitive to the sun and of a darker shade. At the same time, the highest density of melanocytes per unit area of skin is observed in areas most frequently exposed to the sun, such as the face, head, and neck.

Experts estimate that in fair-skinned populations, up to 95% of keratinocyte skin cancers and 70–95% of cutaneous melanomas are caused by UV radiation. Therefore, a significant proportion of skin cancers can be prevented by reducing excessive exposure to UV radiation through effective sun protection [6].

When characterising the effect of solar radiation on humans, it should be noted that UV radiation (100–400 nanometres, nm) accounts for only 5–10% of terrestrial sunlight. Of this, the B spectrum – UVB (280–315 nm) – is considerably more harmful, accounting for 5%, while the remaining 95% is represented by the A spectrum – UVA (315–400 nm). Both UVB and UVA spectra adversely affect the skin, but UVB is more active. Although less aggressive, the UVA spectrum is constantly present. Therefore, for optimal protection, SPF products must provide a high level of defence against both UVA and UVB rays. SPF products have also been shown to

be effective, with varying degrees of efficacy, in preventing actinic keratosis, squamous cell carcinoma, photoaging, basal cell carcinoma, and melanoma [8].

The main active components of cosmetic SPF products are compounds that absorb, scatter, or reflect UV radiation, known as sunscreens. These are divided into two categories: chemical sunscreens (chemical UV absorbers of both old and new generations) and physical sunscreens, which form a protective layer that acts like a mirror, reflecting and scattering UV rays.

Physical sunscreens are represented by titanium dioxide (Latin: *Titanium Dioxide)* and zinc oxide (Latin: *Zincum Oxide*). Titanium dioxide and zinc oxide are usually incorporated into SPF products formulations as ultra-fine (20-50 nm) particles, called micro reflectors. Particles, which are smaller than 10% of the wavelength of incident light, scatter light according to Rayleigh's law, which states that the intensity of scattered light is inversely proportional to the fourth power of the wavelength. As a result, they scatter UVB light (wavelengths between 280 and 320 nm) and UVA light (wavelengths between 315 and 400 nm) more than visible light with longer wavelengths, preventing sunburn while remaining invisible on the skin [6, 8]. Physical sunscreens use solid particles to scatter and reflect UV radiation, although some modern products with metal oxide nanoparticles are also able to absorb it. Titanium dioxide and zinc oxide are chemically inert metal oxides. Physical sunscreens protect against the UVB spectrum and to some extent against visible UVA radiation. Physical sunscreens are usually thick, opaque, can have a «whitening» effect on the face, and are cosmetically unacceptable to many people [8].

The Ukrainian cosmetic market is represented by many brands that use physical sunscreens. According to open sources and information provided directly by manufacturers, physical filters in SPF products are actively used by many companies. However, these products may have unsatisfactory organoleptic properties, cause skin whitening and unacceptable aesthetic results. Therefore, recently, formulations with micronized or nanoparticle components with a diameter of less than 100 nm have begun to appear, which improves the transparency and cosmetic acceptability of physical filters in sunscreens [9-11]. Today, there are no regulatory restrictions on the use of chemical filters in Ukraine, as cosmetic products that meet international requirements is expected to be sold on the market starting from August 3, 2026, in accordance with the Technical Regulations on Cosmetic Products, approved by the Resolution of the Cabinet of Ministers of Ukraine No. 65 of January 20, 2021 [12].

A lot of brands represented on the Ukrainian cosmetics market continue to use toxic filters in their products, which poses a potential threat to consumer health.

In contrast to the abovementioned, new generation chemical filters have been developed taking into account modern requirements of efficiency and safety. They guarantee a wide spectrum of protection against UV radiation (UVA and UVB); have better photo stability and a lower risk of adverse reactions. Additionally, local photolyases and antioxidants (vitamin C, vitamin E, selenium and polyphenols contained in green tea extract) appear as potential agents of local photo protection [13].

Products containing such components are gradually entering the Ukrainian market, but their share remains insignificant. Instead, products manufactured in the Republic of Korea (South Korea) constitute a significant segment of cosmetics, having gained popularity due to their favourable organoleptic properties and affordability [14].

The Ukrainian cosmetic market offers hundreds of SPF products in the form of creams, sprays, oils, milks, or foams. In addition to well-known brands from France, the USA, Italy, Switzerland, Germany, Poland, and Ukraine, online shopping has made dozens of brands from lesser-known manufacturers, especially from Korea, readily available. As a rule, such products do not indicate the actual SPF value but promote "marketing" characteristics such as the lightest, safest, etc. [15].

In our opinion, this situation in Ukraine has arisen because there are currently no regulatory restrictions on the use of SPF filters. Cosmetic products that comply with European requirements are expected to be allowed on the market starting from 3 August 2026. In Ukraine, the profit from the SPF products market in 2025 is projected to reach 21,53 million US dollars, with the market expected to grow annually by 4,74% (CAGR 2025–2030), driven by increasing public awareness of the harmful effects of UV radiation and a surge in demand for SPF 50+ products [16].

The above highlights the necessity of introduction of stricter quality control for cosmetic products, in particular sun protection products, to ensure their effectiveness and safety for consumers, since among the adult population, the main sources of information about skin health are Internet resources, social networks, and to a lesser extent, people receive knowledge from medical professionals, who have more reliable data on the composition of cosmetic products.

The European Commission monitors the effectiveness and safety of sun protection products, which are classified as cosmetic products and must comply with the EU Cosmetics Regulation 1223/2009 [17].

In the United States, manufacturers must follow strict testing protocols to confirm the effectiveness and safety of SPF products before they become available to consumers. The American Academy of Dermatology recommends the widespread use of SPF products in skincare, especially during outdoor recreational activities. Although the FDA oversees and regulates the production of sun protection products, their ingredient profiles still require improvement. The FDA classifies SPF products as over-the-counter drugs,

meaning they are subject to more rigorous testing for safety, stability, compatibility, and efficacy than conventional cosmetics [18].

UV filters, which provide SPF products with their protective properties, are considered "active ingredients," and only FDA-approved UV filters may be included in sun protection products. However, only some older-generation physical and chemical filters are permitted in the US. These filters tend to whiten the skin and can increase sebum production, making them cosmetically less acceptable. Consequently, manufacturers are limited to selling products based solely on older-generation physical or chemical filters. By comparison, the European Union allows the use of twenty-seven active ingredients to block the harmful effects of sunlight and prevent skin damage, whereas the FDA has approved only seventeen. FDA approval of UV filters lags significantly behind other countries, as no new UV filters have been added to the FDA's approved list since 2002. The number of available ingredients is important because not all filters are easily incorporated into formulations that satisfy both skincare and organoleptic requirements [19].

The American Academy of Dermatology recommends the daily use of sun protection products with an SPF of 30 or higher for people of all skin types. The Canadian Dermatology Association also recommends the use of broad-spectrum sun protection products with an SPF of 30 or higher [6, 19]. Health Canada does not recommend the use of SPF products for infants under six months of age due to the theoretical risk of increased absorption of sunscreen ingredients, which is associated with a thinner epidermis and a higher skin surface area-to-body volume ratio [20].

SPF 50 products provide protection against approximately 98% of UV radiation and are considered the most appropriate for use. However, SPF filters with values above 50 offer virtually no additional protection against sunburn or UVB radiation [6]. It should be noted that most SPF products do not provide permanent sun protection, as organic sunscreens can degrade under the influence of light or be adversely affected by other components of the product when exposed to UV radiation. The protective effect of SPF products against skin damage caused by UV radiation has been confirmed in numerous studies, and their effectiveness against sunburn is unequivocally determined by the SPF value [8].

Following the detection of regulatory violations, the FDA ordered stricter quality control and recalled several sunscreens from the market [22]. This is why many Korean brands are not available on cosmetic markets in Europe and the United States, whereas most remain accessible in Ukraine due to the lack of proper regulation [23].

In practice, the situation can be significantly different, as many sun protection products have not been tested to meet the stated standard. In 2020, Korean-made cosmetic products were the subject of critical reports from laboratories and scientific institutes. Those were related to the actual SPF level in popular products.

The Korean Institute of Dermatological Sciences released data on the product, which, after being tested, showed an average SPF of 28,4±3,2, even though the packaging stated SPF 50/PA++++. Those findings had a huge impact on consumers and raised concerns about the reliability of Korean SPF products [24, 25].

It has been found that the problem is not limited to a single brand. A similar situation was observed during testing of a popular cream (SPF 50/PA++++), which demonstrated significantly lower SPF values in an in vivo study. According to the report on the determination of the degree of protection against UV radiation of a cosmetic product No. EU/121/10/2023 (SPF 50/PA++++), the average protection factor was 44.8. For another popular Korean product (SPF 50+ PA++++), the average SPF was 45.8. It is noteworthy that some samples showed significantly lower SPF values, down to 15.7, which does not meet international recommendations for the required level of sun protection. This finding raises concerns regarding the reliability of information provided by individual manufacturers and the quality of their products, as the study of the UV protection factor was conducted in accordance with the Recommendation of the Commission of the European Communities of 22 September 2006 on the effectiveness of sunscreen products and claims made thereon (document number C (2006) 4089, 2006/647/EC) and ISO 24444:2020/A1:2022 [14, 23–25].

The prospects for further research are driven by the relevance of identifying effective and consumer-safe methods for skin protection against ultraviolet radiation, as confirmed by the work of Ukrainian scientists [26, 27]. The continuous expansion of the cosmetic market for various sunscreens capable of mitigating the harmful effects of ultraviolet radiation on human skin underscores the need to improve measures for quality control and consumer safety. One current priority is to establish regulatory oversight of sunscreens at the legislative level [28].

CONCLUSIONS

1. Ukraine has a disappointing statistic on the incidence of skin cancer among the population, so the availability of high-quality sun protection products on the domestic market and objective information about them is the key to increasing the effectiveness of skin protection from the harmful effects of UV radiation.
2. SPF products available on the Ukrainian market from various countries and manufacturers do not consistently indicate the SPF index, which is the primary indicator of the effectiveness of SPF products; there are also frequent cases of discrepancies between the

data declared by the manufacturer and the indicators obtained under experimental conditions.
3. The public health service of Ukraine should be tasked with informing the population about the need to use SPF products and the rules for their selection in accordance with their availability on the existing SPF product market.
4. The State Service of Ukraine on Food Safety and Consumer Protection must carry out regular random control over the compliance of consumer qualities of SPF products with the manufacturer's information about them indicated on the product labelling.

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CONFLICT OF INTEREST

The Authors declare no conflict of interest

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