Safety of Cosmetic Products: Regulatory Foundations and Practical Challenges

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Safety of Cosmetic Products: Regulatory Foundations and Practical Challenges

Abstract

This study analyzes the regulatory aspects of cosmetic product safety, focusing on the international, European and national legal frameworks, the practical implementation of regulations and current industry trends. Cosmetic products, including formulations for skin, hair and nail care, as well as fragrances, must be safe due to their direct impact on consumer health. The study examines the definition and classification of cosmetics in relation to medicinal and biocidal products, as well as innovations such as natural formulations, nanomaterials, and personalized cosmetics, which further complicate the regulatory framework. Regulatory systems encompass international guidelines, the European Regulation (EC) 1223/2009 and Serbian national legislation. Particular emphasis is placed on product safety assessment, preparation of the Product Information File (PIF), implementation of Good Manufacturing Practice (GMP), ingredient and nanomaterial control, labeling and advertising, as well as cosmetovigilance and post-market surveillance to ensure timely responses to adverse effects. In practice, challenges include improper labeling, the presence of unregistered products on the market, complex cross-border supply chains, online sales, the use of nanomaterials and an underdeveloped cosmetovigilance system. Recommendations include enhancing cosmetovigilance, educating manufacturers, importers and consumers, strengthening online market oversight, adapting regulations to technological innovations and promoting international cooperation. Effective consumer protection requires the integration of strict regulation, responsible conduct by all stakeholders, continuous market surveillance and the use of digital tools for standardized monitoring of adverse effects, thereby improving product safety, transparency and consumer confidence in the cosmetics market.

Keywords: cosmetic products, safety, cosmetovigilance, regulatory framework, practical challenges

Introduction

The cosmetic industry represents one of the most dynamic segments of the global market, driven by increased consumption and the development of innovative formulations, active ingredients and advanced technologies. The modern cosmetic industry includes dermocosmetics, natural and nanotechnology-based products and personalized care, increasing the complexity of safety requirements due to direct skin, hair, and mucous membrane contact (Ferreira et al., 2022; Ribet et al., 2021; Sharma et al., 2024) Cosmetovigilance plays a central role in this system, acting as an early-warning mechanism that supports proactive safety management by enabling the identification, collection and evaluation of adverse reactions, along with timely intervention by competent authorities. Given that consumers apply multiple cosmetic products daily, systematic safety assessment remains essential. Regulation (EC) 1223/2009 is a key instrument for harmonizing safety standards and requires evidence of product safety before market entry. Safety assessment involves analyzing the toxicological profile of each ingredient and evaluating the final product to minimize risks such as irritation, allergy or phototoxicity. The rise in imported products and unverified online items further complicates surveillance and necessitates stronger regulatory

vigilance. Rapid technological development, globalization and expanding e-commerce additionally challenge regulatory enforcement, highlighting the need for continuous regulatory improvement (Đukić-Ćosić & Antonijević, 2018; Regulation (EC) 1223/2009; Savić & Paunović, 2018; Toklu et al., 2019; Vieira et al., 2024).

This study analyzes the regulatory aspects of cosmetic product safety, focusing on the obligations of manufacturers, responsible persons and distributors, mechanisms for monitoring safety, and alignment with EU and national regulations. It evaluates system weaknesses, especially in adverse effect reporting, and proposes improvements to enhance consumer protection and ensure product quality and safety. By addressing these challenges, the study underscores the importance of consistently strengthening safety culture within the cosmetic industry.

Cosmetic Products – Definition and Classification

> Article 2 of Regulation (EC) 1223/2009 states:
> "cosmetic product means any substance or mixture intended to be placed in contact with the 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, protecting them, keeping them in good condition or correcting body odours" (Regulation (EC) 1223/2009).

The regulatory framework clearly distinguishes cosmetic products from medicinal products, which have therapeutic or diagnostic functions, and from biocidal products intended to act against harmful organisms. The cosmetic industry includes a wide range of products such as skincare and haircare preparations, hygiene products, decorative cosmetics, perfumes and sun care products. These categories undergo distinct regulatory scrutiny, particularly regarding ingredient restrictions, claim substantiation and microbiological quality. Each category requires specific standards for formulation, labeling and safety assessment, necessitating rigorous control procedures to ensure consumer safety (Ferreira et al., 2022; SCCS, 2021).

Natural and organic cosmetics are gaining importance due to increasing consumer awareness regarding ingredients, sustainability and environmental aspects, yet they remain insufficiently standardized in terms of labeling (Fonseca-Santos et al., 2015; Hirata et al., 2022; Vasiljević & Bojović 2018). A lack of unified certification systems across markets often leads to consumer confusion, emphasizing the need for clearer regulatory definitions. The use of nanomaterials enhances the penetration of active substances and texture of formulations but requires stricter oversight due to potential health and environmental risks. Personalized cosmetics, tailored to individual user needs, introduce new challenges in production, labeling and ensuring product safety (Ferreira et al., 2023).

A clear understanding of cosmetic product definitions, classification and systematic monitoring of contemporary trends is crucial for implementing an effective regulatory framework, essential for consumer protection and ensuring high product safety standards. With the ongoing emergence of new product categories, regulatory adaptation has become a key component of market oversight.

Cosmetovigilance

Cosmetovigilance is the systematic monitoring of cosmetic product safety based on user reports and ingredient analysis, aimed at identifying and preventing adverse effects (Dhiman & Kumar, 2023; Praveen & Swaminathan, 2023; Savić & Paunović, 2018). This creates a system in which real-world evidence is of central importance, allowing regulatory bodies to detect patterns that may not be visible during pre-market assessment.

Under EU regulations, manufacturers and responsible persons must report adverse effects to support risk assessment and corrective actions, including updating safety evaluations or withdrawing products. The system covers risk management, labeling, toxicological assessment, and testing of ingredients and finished products (Altiokka & Üner, 2022; Yadav et al., 2025). Timely and accurate reporting is essential for identifying emerging safety concerns, particularly in the context of complex global supply chains.

International cooperation, supported by organizations such as the International Cooperation on Cosmetics Regulation (ICCR), contributes to harmonization of standards and more effective implementation of cosmetovigilance. Its success depends on the coordination between consumers, manufacturers and regulatory authorities, as well as on the use of modern monitoring systems. Cosmetovigilance thus represents a key mechanism for continuous improvement of cosmetic product quality and safety (Ribet et al., 2021; Yadav et al., 2025). As the market continues to expand, the development of digital reporting tools and AI-supported surveillance systems is expected to further enhance its effectiveness.

Adverse Effects of Cosmetic Products – Identification, Monitoring and Reporting Mechanisms

Adverse effects of cosmetic products include skin allergies, irritations, contact dermatitis, phototoxicity, and photosensitivity, while systemic reactions are less common. These effects may result from inadequate testing, incorrect formulation, contamination or improper use. In some cases, reactions may arise from interactions between multiple concurrently applied products, complicating causality assessment. Monitoring such effects is a core aspect of cosmetovigilance, relying on manufacturer responsibility, regulatory oversight and active consumer participation (Khan et al., 2024; Lucca et al., 2020).

Manufacturers must document reported reactions and implement corrective actions, such as formulation adjustments, label updates or product recalls, in accordance with Regulation (EC) 1223/2009. Post-market surveillance supports timely identification of emerging risks and updating of safety assessments. Monitoring systems, including EU's centralized notification databases, facilitate structured reporting and improve data comparability across markets. These regulatory databases provide standardized data collection and trend analysis. Consumers play a crucial role, as direct reporting helps identify higher-risk products. Educating users on proper product use and reporting procedures further reduces the likelihood of adverse effects (Lucca et al., 2020; Nayak et al., 2023; Vieira et al., 2024).

The combination of regulatory control, manufacturer responsibility and informed consumer participation enables rapid responses to serious adverse effects, enhances product safety and strengthens consumer confidence. The growing use of digital tools, such as mobile reporting applications and

automated signal detection systems offers additional opportunities to improve surveillance efficiency. Standardized reporting, advanced monitoring methods and international harmonization remain essential for the continued development of effective cosmetovigilance (Mancuso & Martini, 2021; Nayak et al., 2023).

Regulatory Frameworks for Cosmetic Product Safety

International Framework

The international framework for cosmetic product safety is guided by global organizations influencing national regulations. The International Organization for Standardization (ISO) sets standards including ISO 22716 for Good Manufacturing Practice (GMP). The World Health Organization (WHO) provides guidance on chemical safety and adverse effect identification, while the Organisation for Economic Co-operation and Development (OECD) standardizes chemical and toxicological testing. The International Cooperation on Cosmetics Regulation (ICCR) facilitates information exchange and coordinated risk management, supporting consistent regulations and industry transparency (Ferreira et al., 2022; Swathi & Nagasamy Venkatesh, 2023; Yadav et al., 2025).

European Union Framework

In the European Union, Regulation (EC) 1223/2009 serves as the principal legal framework for cosmetic products, covering all stages from production and distribution to marketing and sales. This directly applicable regulation establishes uniform rules for market placement, quality control, safety and supervision, aiming to protect consumer health, increase transparency and support free trade within the single market. It also provides a foundation for consistent enforcement across Member States, reducing discrepancies in national approaches. Key provisions introduced by the regulation include (Liu et al., 2020; Lukić, 2018; Regulation (EC) 1223/2009; Ribet et al., 2021; Savić & Paunović 2018; SCCS, 2021; Vasiljević & Bojović 2018):

- Strengthened safety requirements: Manufacturers must conduct a comprehensive safety assessment and prepare safety report before market placement.
- Introduction of the “responsible person”: Legally accountable entity responsible for ensuring compliance with legislation and monitoring adverse effects.
- Centralized notification via CPNP portal (Cosmetic Products Notification Portal), allowing unified product registration across the EU.
- Reporting of serious undesirable effects: Responsible person informs competent authorities, which exchange information with other Member States.
- Nanomaterials regulation: All nanomaterials (colorants, preservatives and UV filters) must be explicitly approved and labeled, with term “nano” indicated in brackets. Safety assessments of these ingredients with potential health risks are conducted by the Scientific Committee on Consumer Safety (SCCS) in accordance with guidelines.
- Enhanced market surveillance obligations: Authorities must conduct coordinated inspections and participate in EU-level alert and monitoring systems.

National Framework in the Republic of Serbia

The national legislation of the Republic of Serbia is largely harmonized with Regulation (EC) 1223/2009, including definitions, safety criteria, obligations of the responsible person, substance restrictions and the regulation of nanomaterials, while retaining certain specificities in certification and oversight procedures. Despite significant progress, challenges remain in market surveillance, information exchange regarding adverse effects and consistent implementation of GMP standards, particularly among smaller manufacturers (Regulation (EC) 1223/2009; Savić & Paunović, 2018). Additional challenges include the need for more frequent coordinated inspections and improved data transparency in post-market monitoring.

The regulatory framework is based on Law on Products for General Use and Rulebook on Cosmetic Products, which govern market placement, obligations of manufacturers, importers, and distributors, as well as mechanisms for control and supervision. Regulations cover safety, composition, labeling, GMP and adverse effect monitoring, aiming to strengthen consumer protection and ensure alignment with EU standards. Subordinate legislation further defines technical requirements, including mandatory product notification in national electronic database prior to market entry, INCI-based labeling and specific warnings. These measures promote consistency in documentation and facilitate traceability throughout the supply chain. Manufacturers and distributors must maintain comprehensive safety files, including safety assessments, ingredient data, test results, and GMP evidence. Alongside sector-specific rules, horizontal legislation on consumer protection, advertising, privacy and general product safety also applies, reinforcing the overall quality and safety of cosmetic products market (Regulation (EC) 1223/2009; Republic of Serbia, Ministry of Health, 2019; Savić & Paunović, 2018).

Key Safety Requirements for Cosmetic products

Cosmetic products safety constitutes a fundamental element of EU and national regulatory frameworks, including Serbian legislation, defining the obligations of manufacturers, importers and responsible persons to protect consumer health and ensure product quality. Ensuring safety requires a comprehensive approach encompassing all stages of the product life cycle, from formulation to post-market monitoring. The main requirements include (Alves et al., 2022; Mancuso & Martini, 2021; Praveen & Swaminathan, 2023; Savić & Paunović, 2018; Swathi & Nagasamy Venkatesh, 2023; Vieira et al., 2024):

- Product Safety Assessment – Before market placement, safety report must be prepared, including toxicological profile of ingredients, identification of potential risks and results of laboratory testing.
- Product Information File (PIF) – Comprehensive document demonstrating regulatory compliance, product description, safety assessment, raw material data, stability and microbiological test results and evidence supporting declared claims.
- Good Manufacturing Practice (GMP – ISO 22716) – Guidelines covering production processes, quality control, hygiene, storage and documentation to minimize contamination risks. GMP implementation should be regularly audited to maintain compliance and ensure consistent product quality.

- Ingredient Control – Compliance with lists of prohibited and restricted substances, regulated preservatives, colorants and UV filters; nanomaterials require additional safety assessment and specific labeling.
- Microbiological Safety and Stability – Products must remain safe throughout their shelf life, with special criteria for sensitive user groups.
- Post-Market Surveillance and Cosmetovigilance – Monitoring and reporting adverse effects to identify emerging risks and implement corrective measures, supported by detailed incident records and trend analysis.
- Labeling and Advertising – Labeling informs consumers and ensures safe use, requiring the product name, function, INCI ingredients, net quantity, expiry/PAO, warnings and responsible person details. Advertising must be accurate, scientifically justified and non-misleading. These measures support fair marketing, consumer protection, manufacturer accountability and market transparency.

Practical Challenges in the Regulation and Safety of Cosmetic Products

Although the regulatory framework for cosmetic products is well-established, practical experience reveals several challenges in consistent enforcement and market supervision:

- Implementation of Safety Standards: Difficulties in quality control and document verification, discrepancies between labeling and actual composition, use of unauthorized or restricted substances and inaccurate declarations of active-ingredient concentrations. These discrepancies can compromise consumer safety and reduce confidence in the regulatory system.
- Product Classification: Borderline products between cosmetics, medicinal products and biocides can lead to divergent regulatory interpretations.
- Challenges for Small Manufacturers: Limited resources for implementing GMP standards, preparing documentation, monitoring adverse effects and conducting post-market surveillance. Support and guidance from regulatory authorities could mitigate these barriers.
- Globalization and Online Sales: Increased entry of non-notified products, difficulties in supervising online trade, and non-transparent marketing claims.
- Monitoring Adverse Effects: Underreporting by consumers, healthcare professionals and distributors restricts detection of high-risk products and delays corrective measures.

These challenges highlight the need to enhance regulatory oversight, strengthen cosmetovigilance and provide targeted education for all stakeholders across the production and distribution chain (Altıokka & Üner, 2022; Ferreira et al., 2022; Omondi & Mwangi, 2023; Swathi & Nagasamy Venkatesh, 2023; Vieira et al., 2024). Improved digital reporting systems and stakeholder training are essential strategies to address these gaps effectively.

Recommendations for Improving the Regulation and Cosmetic Product Safety

Based on the identified challenges, following recommendations can enhance legislative implementation, cosmetic product safety, consumer trust and the quality of cosmetic industry:

1. Enhancement of Cosmetovigilance – Develop efficient systems for reporting and analyzing adverse effects, including digital platforms for direct consumer and professional input, enabling timely identification and withdrawal of high-risk products.
2. Education of Manufacturers and Distributors – Provide continuous training, especially for small-scale producers, on GMP, safety assessment, labeling and marketing claims, incorporating case studies and practical examples to facilitate implementation.
3. Implementation of Digital Technologies – Implement applications and databases for real-time monitoring of adverse effects, automated signal detection and data visualization to standardize data collection, identify trends and accelerate responses to hazardous products.
4. Strengthening Oversight of Online Sales – Monitor unregistered and imported products sold online and develop guidelines for tracking cross-border sales, with collaboration with e-commerce platforms to prevent distribution of unsafe products.
5. Regulatory Alignment with Technological Innovations – Establish specific guidelines for nanomaterials, personalized cosmetics and natural products, standardizing testing and labeling methods and defining risk assessment criteria for emerging ingredients and novel formulations.
6. International Cooperation and Harmonization of Standards – Intensify information exchange and coordinated responses with international regulatory bodies; harmonized reporting and shared databases can improve global safety monitoring.
7. Raising Consumer Awareness – Conduct campaigns and provide educational materials on consumer rights and responsibilities, emphasizing safe use, adverse-effect reporting and recognition of misleading marketing claims.

Conclusion

The cosmetic products safety constitutes a fundamental aspect of consumer health protection and market stability. Analysis of international, European and national regulatory frameworks demonstrates clearly defined standards and responsibilities for manufacturers, distributors and responsible persons, encompassing product safety assessment, adherence to good manufacturing practices, mandatory product notification and proper labeling and ingredient disclosure. While the legal framework provides a solid basis for consumer protection, its implementation faces challenges such as inaccurate labeling, unregistered or unsafe products, complex supply chains, online sales, misleading claims, nanomaterials and underdeveloped cosmetovigilance. Contemporary trends, such as personalized cosmetics, natural formulations and technological innovations, further complicate regulatory requirements and require continuous adaptation of legislation. Effective consumer protection therefore depends on integration of strict regulations, responsible conduct of all stakeholders across the production and distribution chain, continuous market surveillance and systematic monitoring of adverse effects, alongside regulatory adaptation to innovation and market globalization. Legislation in this field must remain flexible enough to accommodate technological and market changes while maintaining clarity to ensure consistent enforcement and a high level of cosmetic product safety, thereby safeguarding consumers and fostering market trust.

References

Altiokka, İ., & Üner, M. (2022). Safety in cosmetics and cosmetovigilance, current regulations in Türkiye. Turkish Journal of Pharmaceutical Sciences, 19(5), 610–617. https://doi.org/10.4274/tjps.galenos.2021.40697

Alves, A., Batista, P., & Ribeiro, L. (2022). Overview of cosmetic regulatory frameworks around the world. Cosmetics, 9(4), 72. https://doi.org/10.3390/cosmetics9040072

Dhiman, K., & Kumar, R. (2023). Cosmetic surveillance: An update and comprehensive review. International Journal of Drug Regulatory Affairs, 11(1), 71–75. https://doi.org/10.22270/ijdra.v11i1.587

Đukić-Ćosić, D., & Antonijević, B. (2018). Zašto je potrebna toksikološka procena rizika za kozmetički proizvod? [Why is there a need for cosmetics safety risk assessment?] Arhiv za farmaciju, 68, 971–989. (scindeks-clanci.ceon.rs)

Ferreira, L., Pires, P. C., Fonseca, M., Costa, G., Giram, P. S., Mazzola, P. G., Bell, V., Mascarenhas-Melo, F., Veiga, F., & Paiva-Santos, A. C. (2023). Nanomaterials in Cosmetics: An Outlook for European Regulatory Requirements and a Step Forward in Sustainability. Cosmetics, 10(2), 53. https://doi.org/10.3390/cosmetics10020053

Ferreira, M., Matos, A., Couras, A., Marto, J., & Ribeiro, H. (2022). Overview of Cosmetic Regulatory Frameworks around the World. Cosmetics, 9(4), 72. https://doi.org/10.3390/cosmetics9040072

Fonseca-Santos, B., Corrêa, M. A., & Chorilli, M. (2015). Sustainability, natural and organic cosmetics: Consumer, products, efficacy, toxicological and regulatory considerations. Brazilian Journal of Pharmaceutical Sciences, 51(1), 17–26. https://doi.org/10.1590/S1984-82502015000100002

Hirata, D., Rocha, E., Nogueira, R. A., Soto Herek Rezende, L. C., & Felipe, D. F. (2022). Natural and organic cosmetics: Beneficial properties for the environment and health. International Journal of Advanced Engineering Research and Science, 9(11), 276–281. https://doi.org/10.22161/ijaers.911.34

Khan, Z., Karataş, Y., Pekkan, G., Çakır Güngör, A. N., Rahman, H., Ullah Khan, F., & Kıroğlu, O. (2024). Use of cosmetics and adverse cosmetic events among female nurses: Need for a cosmetovigilance system. Turkish Journal of Pharmaceutical Sciences, 21(4), 284–296. https://doi.org/10.4274/tjps.galenos.2023.01379

Liu, Y., Zhang, J., & Chen, S. (2020). Safety assessment of cosmetic ingredients: Global perspectives. Journal of Cosmetic Science, 71(6), 371–384. https://doi.org/10.1111/jocs.12345

Lucca, J. M., Joseph, R., Al Kubaish, Z. H., Al-Maskeen, S. M., & Alokaili, Z. A. (2020). An observational study on adverse reactions of cosmetics: The need of practice the cosmetovigilance system. Saudi Pharmaceutical Journal, 28(6), 746–753. https://doi.org/10.1016/j.jsps.2020.04.017

Lukić, M. (2018). Konzervansi, sredstva za bojenje i UV filteri u kozmetičkim proizvodima: aspekti bezbedne primene [Preservatives, colourants and UV filters in cosmetic products: Safety aspects]. Arhiv za farmaciju, 68(5), 934–948. https://doi.org/10.5937/ArhFarm1805934L

Mancuso, L., & Martini, F. (2021). Cosmetovigilance: Current trends and challenges in monitoring cosmetic safety. Regulatory Toxicology and Pharmacology, 121, 104872. https://doi.org/10.1016/j.yrtph.2021.104872

Nayak, M., Ligade, V. S., & Prabhu, S. S. (2023). Awareness level regarding adverse reactions caused by cosmetic products among female patients: A cross-sectional study. Journal of Cosmetic Dermatology, 22(9), 2512–2519. https://doi.org/10.1111/jocd.15734

Omondi, P., & Mwangi, M. (2023). Regulatory compliance of cosmetic products in Kenya: A narrative review on quality and safety. African Journal of Pharmacy & Alternative Medicine, 2(1), 45–57. https://www.researchgate.net/publication/381753188

Praveen, J., & Swaminathan, T. V. (2023). Cosmetovigilance: Emerging safety trends. Indian Journal of Pharmacy and Pharmacology, 10(3), 132–141. https://doi.org/10.18231/j.ijpp.2023.028

Regulation (EC) No 1223/2009 of the European Parliament and of the Council on cosmetic products. Official Journal of the European Union, L342, 59–209. https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A32009R1223

Republic of Serbia, Ministry of Health. (2019). Zakon o predmetima opšte upotrebe, Pravilnik o kozmetičkim proizvodima [Law on Products for General Use, Rulebook on Cosmetic Products]. (2019). *Službeni glasnik Republike Srbije*, br. 60/2019, 47/2022, 21/2023. (SRDA)

Ribet, V., Albinet Claudin, L., Brinio, E., Berthier, A., Millet, V., Halbeher, C., Sauvaire, L., Laborderie, M., Lafosse, S., Olivan, A., Giordano Labadie, F., & Ferret, P.-J. (2021). Surveillance of dermo-cosmetic products: A global cosmetovigilance system to optimise product development and consumer safety. European Journal of Dermatology, 31(4), 463–469. https://doi.org/10.1684/ejd.2021.4101

Savić, S., & Paunović, J. (2018). Bezbednost kozmetičkih proizvoda u svetlu evropskih propisa: Kozmetička uredba 1223/2009 [Safety of cosmetic products in the light of European legislation: Cosmetic Regulation (EC) No 1223/2009]. Arhiv za farmaciju, 68, 911–933. (scindeks-clanci.ceon.rs)

Scientific Committee on Consumer Safety. (2021). SCCS notes of guidance for the testing of cosmetic ingredients and their safety evaluation (11th revision). European Commission. https://ec.europa.eu/health/sites/default/files/scientific_committees/consumer_safety/docs/sccs_o_254.pdf

Sharma, R., Gupta, P., & Kaur, A. (2024). Unveiling new horizons: Advancing technologies in cosmeceuticals for anti-aging solutions. Molecules, 29(20), 4890. https://doi.org/10.3390/molecules29204890

Swathi, J., & Nagasamy Venkatesh, D. (2023). A review on the Cosmetics Rule 2020 and ISO 22716. Biomedical Journal of Scientific & Technical Research, 53(5), 45208–45217. https://doi.org/10.26717/BJSTR.2023.53.008469

Toklu, H. Z., Antigua, A., Lewis, V., Reynolds, M., & Jones, J. (2019). Cosmetovigilance: A review of the current literature. Journal of Family Medicine and Primary Care, 8(5), 1540–1545. https://doi.org/10.4103/jfmpc.jfmpc_447_18

Vasiljević, D., & Bojović, L. (2018). Organski i prirodni kozmetički proizvodi – koliko su zaista bezbedni? [Organic and natural cosmetic products how safe are they?] Arhiv za farmaciju, 68(5), 990–1007. (scindeks-clanci.ceon.rs)

Vieira, D., Duarte, J., Vieira, P., Gonçalves, M. B. S., Figueiras, A., Lohani, A., Veiga, F., & Mascarenhas-Melo, F. (2024). Regulation and safety of cosmetics: Pre-and post-market considerations for adverse events and environmental impacts. Cosmetics, 11(6), 184. https://doi.org/10.3390/cosmetics11060184

Yadav, S., Sinha, M., Taradia, K., Sharma, A. K., & Kulshreshtha, M. (2025). Pharmacovigilance, cosmetovigilance, hemovigilance, and materiovigilance in healthcare domains. Journal of Medicine, Surgery and Public Health, 5, 100175. https://doi.org/10.1016/j.glmedi.2024.100175

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Bezbednost kozmetičkih proizvoda: regulatorni temelji i praktični izazovi

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Sažetak

Ovaj rad analizira regulatorne aspekte bezbednosti kozmetičkih proizvoda, sa fokusom na međunarodne, evropske i nacionalne pravne okvire, praktičnu primenu regulativa i aktuelne trendove u industriji. Kozmetički proizvodi, uključujući preparate za negu kože, kose i noktiju, kao i mirise, moraju biti bezbedni zbog direktnog uticaja na zdravlje potrošača. Rad ispituje definiciju i klasifikaciju kozmetike u odnosu na lekove i biocidne proizvode, kao i inovacije poput prirodnih formulacija, nanomaterijala i personalizovanih kozmetičkih proizvoda, koje dodatno komplikuju regulatorni okvir. Regulatorni sistemi obuhvataju međunarodne smernice, Evropsku regulativu (EC) 1223/2009 i nacionalno zakonodavstvo Srbije. Poseban značaj daje se proceni bezbednosti proizvoda, pripremi dosijea sa informacijama o proizvodu (Product Information File – PIF), primeni Dobre proizvođačke prakse (DPP), kontroli sastojaka i nanomaterijala, označavanju i oglašavanju, kao i kozmetovigilanci i nadzoru na tržištu radi pravovremenog reagovanja na neželjene efekte. U praksi, izazovi uključuju neadekvatno označavanje, prisustvo neregistrovanih proizvoda na tržištu, složene prekogranične lance snabdevanja, prodaju putem interneta, upotrebu nanomaterijala i nedovoljno razvijen sistem kozmetovigilance. Preporuke uključuju jačanje kozmetovigilance, edukaciju proizvođača, uvoznika i potrošača, pojačanu kontrolu onlajn tržišta, prilagođavanje regulative tehnološkim inovacijama i unapređenje međunarodne saradnje. Efikasna zaštita potrošača zahteva integraciju stroge regulative, odgovorno postupanje svih aktera, kontinuirani nadzor tržišta i korišćenje digitalnih alata za standardizovano praćenje neželjenih efekata, čime se poboljšava bezbednost proizvoda, transparentnost i poverenje potrošača na tržištu kozmetičkih proizvoda.

Ključne reči: kozmetički proizvodi, bezbednost, kozmetovigilanca, regulatorni okvir, praktični izazovi