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Protecting Consumers as the Buyers and Users of Cosmetic Products in the Light of European Parliament and Council Regulation (EC) No 1223/2009 on Cosmetic Products

Abstract

The article focuses on the legal classification of cosmetic products and the protection of consumers as the buyers of cosmetics products. Provided under the international and the national legal systems, the protection is guaranteed by two equally valid legal bases: the Regulation of the European Parliament and of the Council (EC) of 30 November 2009, No 1223/2009 on cosmetic products and the Act of 30 March 2001 on cosmetic products. Due to the practical difficulties that attend classifying a product as a cosmetic or otherwise, the issue of determining the similarities and differences between a cosmetic product, a medicinal product and a medical device are discussed. Reference is made also to the issue of the qualifications of the persons providing cosmetic services, and who apply cosmetic products, and the liability that falls upon these individuals.

Keywords: cosmetic product, medicinal product, consumer, end user.
JEL Classification: K15.

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1. Introduction

Due to their statutorily designated purpose, cosmetics require special regulations. Because humans apply them directly to themselves, user safety must be assured. In the current legal state, the issues relating to cosmetic products are regulated by two legal instruments: the Regulation of the European Parliament and of the Council (EC) of 30 November 2009 No 1223/2009 on cosmetic products and the Act of 30 March 2001 on cosmetic products. Because the regulation is applied directly, the provisions of the Act on cosmetic products apply only to a marginal extent. Both international and national legislation differentiates, apart from cosmetic products, medicinal products and medical devices. Because of their similar scope of application, medicinal products are often wrongly classified as cosmetics or vice versa. Moreover, there are cases of unauthorised use of drugs to perform cosmetic services. This may make the cosmetic service performed with the use of a medicinal product threatening to the health of the consumer. The service may also exceed the competence of the person providing the service. This may introduce a level of chaos that must be cleared up. Protecting buyers of cosmetic products is crucial both on account of the scope and manner of protection resulting from the regulation as well as the general protective principles stemming from the Civil Code and consumer protection law.

2. Cosmetics Law – a Historical Overview

The cosmetic products market developed rapidly in the second half of the twentieth century. New cosmetics categories prompted the need for common European regulations on cosmetic products. The result of the work undertaken was the European Council Directive of 27 July 1976 harmonising the national legislation of the Member States – Directive 76/768/EEC on the approximation of the laws of Member States relating to cosmetics products (Cosmetics Directive). Although the Cosmetics Directive has been amended on several occasions and from 2013 was replaced by the Cosmetics Regulation, the mere idea of adopting it was important. The primary purpose of the Cosmetics Directive was to protect public health. Its preamble stressed that this protection must take into account economic and technological requirements. In this perspective, it emphasised the importance of the economic side of the cosmetics market, which, as it was soon to become clear, was one of the fastest growing European markets (Borkowski 2015, p. 40).

Another equally important objective of the Directive was to harmonise the regulations and to establish common rules in respect of the ingredients, labelling and packaging of cosmetic products. It was of utmost importance that the

Cosmetics Directive introduced a definition of a cosmetic product. Appendix I, which contained an illustrative list of cosmetic products, divided into respective categories, clarified the definition. The text of the document referred to the safety of cosmetic products and Appendix II set forth the substances whose use was banned. In the opinion of the European Economic and Social Committee on the Regulation of the European Parliament and of the Council on cosmetic products COM (2008), 49, it was indicated in the final version, in point 3.1, that one of the objectives of transforming the Cosmetics Directive and replacing it with a new act of law was to eliminate legal uncertainties and inconsistencies resulting from the numerous amendments. Due to the considerable number of amendments, there had arisen a need to introduce a new form of regulation. In connection with the work undertaken, the Cosmetics Directive ceased to apply. It was replaced by the Regulation of the European Parliament and of the Council (EC) of 30 November 2009 No 1223/2009 on cosmetic products. The choice of the regulation was not accidental, as in section 2 of the introduction it was shown that it is a document that does not provide Member States with the possibility of diverging transpositions of clear and detailed provisions of the Regulation.

In the Polish legislation, as in the EU legislation, Regulation 1223/2009 is of utmost importance for cosmetics products. At the same time, when the Cosmetics Directive was still valid, in 2002, the Act of 30 March 2001 on cosmetic products entered into force[1]. Due to the legal nature of Regulation 1223/2009, all internal regulations, including in particular the provisions of the Act on cosmetics, apply currently only to the extent that they are not contrary to EU legislation and in the area not regulated by the Regulation. Because the provisions of the Act on cosmetics were based on the Cosmetics Directive, their significance is presently strongly marginalised because the Regulation entered into force.

3. The Concept of a Cosmetic Product in the European Legislation

3.1. General Remarks

Though the Cosmetics Directive is no longer binding, it was the first legislation to define a cosmetic product: "a cosmetic product was any product intended for contact with the external parts of the human body (skin, hairs, nails, lips and external genital organs) or with the teeth and mucous membranes of the oral cavity

[1] The Act came into force in 2002, repealing an earlier act of law, dating back to before the Second World War, namely the Regulation of the Minister of Social Welfare of 18 January 1939, which was issued in consultation with the Minister of Industry and Trade on the supervision over cosmetics products and their circulation, Journal of Laws 1939, No 13, item 72.

with a view exclusively or mainly of cleaning, perfuming them or protecting them in order to keep them in good condition, change their appearance or correct body odours" (art. 1 of the Cosmetics Directive). Its complement was Appendix I, which contains an illustrative list of cosmetics by category.

The Act on cosmetics of 2001, modelled on the Cosmetics Directive, does not use the term "cosmetic product" but rather a "cosmetic", which, according to art. 2 paragraphs 1 is "any chemical substance or mixture, intended for external contact with the human body: skin, hair, lips, nails, external genital organs, teeth and mucous membranes of the oral cavity, where the sole or primary purpose is to keep them clean, care for, protect, perfume them, change the appearance of the body or improve its smell".

Because Regulation 1223/2009 on cosmetics entered into force, the binding definition is that of a "cosmetic product" contained in this Regulation. According to art. 2 paragraph 1 point a of Regulation 1223/2009, "a 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". This definition differs minimally from the definition of the cosmetic products contained in the Cosmetics Directive. The main difference comes down to the precise definition of the concept of a cosmetic product by showing the two basic forms one can take: a substance or a mixture. Consequently, according to art. 2 paragraph 1 point b of the Regulation, "a substance means a chemical element and its compounds in the natural state or obtained by any manufacturing process, including any additive necessary to preserve its stability and any impurity deriving from the process used but excluding any solvent which may be separated without affecting the stability of the substance or changing its composition". In turn, the definition of a mixture is a logical-linguistic error which causes it not to entirely explain the essence of a mixture, defining it by a pleonasm as follows: "mixture" means a mixture or solution composed of two or more substances (art. 2 paragraph 1 point c). According to the preamble to the Regulation, the term "mixture" should have the same meaning as the term "preparation" previously used in the Community legislation. Referring to the Cosmetics Directive, the term "preparation" was used twice there: first, in the introduction, in which it was indicated that the Directive does not apply to pharmaceutical preparations; and second, in art. 5a point 1, which referred a cosmetic ingredient as, among others, a chemical preparation of synthetic or natural origin, which is part of the cosmetic product. As M. Borkowski pointed out (Borkowski 2015, p. 48), the term "preparation" under the Cosmetics Directive is closer to the concept of a substance

under Regulation 1223/2009, while a cosmetic product can only be a "substance" or a "mixture". In addition, the Regulation uses the term "ingredient of a cosmetic product" to refer to the extended group of obligations regarding the provision of information on cosmetic products (art. 19 paragraph 1 point g).

The definition of a cosmetic product highlights three basic elements, namely product forms, the place of application of the product and the aim of its use. From the perspective of the form, a cosmetic product is a substance or a mixture. The cosmetic product defined in such a manner may be used only for external contact with the human body or parts of the mouth, whereas the catalogue of applications is closed, just like the catalogue of the basic functions of the cosmetics (Starzyk & Zachwieja 2010, p. 20–21). The primary function of the cosmetic product may be to clean one's body, to care, protect, perfume or change the appearance of the body or to improve body odour. In addition to the functions indicated in the definition of a cosmetic product, Cosmetics Regulation 1223/2009 does not refer directly to other functions of the cosmetic product than those set forth above. In turn, in art. 19 relating to the labelling of the cosmetic products, it is indicated that the containers and outer packaging of the cosmetic product should contain information about the product's function (art. 19 paragraph 1 point f). The same provision excludes the need to place information about the function of the product when that information results from the product's presentation.

3.2. Cosmetic Products, Medicinal Products, Medical Devices and Biocidal Products

In addition to the basic functions arising from the definition of a cosmetic product, additional functions may also come into play, e.g. bacteriostatic action or controlling glands, for example with antiperspirants. A cosmetic product may not be used to treat or prevent diseases or function as a biocide. In addition, a cosmetic cannot be used to modify physiological functions of the body, for example, fat reduction or weight loss, since these are reserved for medicinal products.

The overlap between what constitutes a cosmetic product and what a medicinal product is recognised in the Cosmetics Directive, the preamble to which indicates that its scope concerns only cosmetics, and not pharmaceutical or medicinal products. Therefore, it stresses the need to determine the scope of the application of the Directive by distinguishing firmly between cosmetics and medicinal products. This limit was determined by the exact definition of cosmetics, which related both to the place as well as to the purposes of their use. In addition, the preamble of the Directive clearly set forth that the Directive did not apply to products which meet the definition of a cosmetic product but are exclusively intended to protect from disease.

In this regard, paragraph 6 of the preamble to the Regulation 1223/2009 is crucial. It highlights that the Regulation applies only to cosmetic products and not to medicinal products, medical devices or biocidal products. The paragraph indicates that this delimitation follows from the detailed definition of cosmetic products, which refers both to the areas of their application as well as to the purposes of their use. In addition, it was indicated that the assessment of whether a product is a cosmetic product has to be made on the basis of an individual assessment of the product, including all of its features.

Article 2 paragraph 2 of Regulation 1223/2009 clearly indicates that a cosmetic product may not be suitable for application other than externally. This section of the Regulation establishes that a cosmetic product is not ingested, inhaled, injected or implanted into the human body. Such a definition of the area and the form of application of a cosmetic product has far-reaching effects. Particularly, often the purpose and the method of application of the products widely used in various types of cosmetic services are inconsistent with the law. This is crucial for those using a particular product in professional activity, and is further addressed later in this article.

Medicinal products, medical devices and biocidal products, which fall outside of the scope of the Regulation on cosmetic products, are defined in separate laws. According to art. 2 section 32 of the Act of 6 September 2001 – Pharmaceutical Law, "a medicinal product is a substance or mixture of substances presented as having properties for treating or preventing disease in human beings or animals or given in order to make a diagnosis or to restore, correct or modify physiological body functions by exerting a pharmacological, immunological or metabolic action". The Act indicates the types of medicinal products, including homeopathic medicinal products (art. 2 section 29), and herbal medicinal products (art. 2 section 33a). A medicinal product defined in such a form remains in compliance with art. 2 paragraph 2 of Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use, according to which the provisions of the Directive apply when, while taking into account all the characteristics of a medicinal product, the product may fall within the definition of a medicinal product and within the definition of a product covered by other Community legislation. The Directive also defines the purpose of the application of the product, describing it – as does art. 2 point 32 of the Pharmaceutical Law – very broadly. What is of particular importance is that the statutory definition emphasises the pharmacological effect of the medicinal product, the occurrence of which determines the proper classification of a product as a cosmetic product and not a drug. This problem is significant given that, in a situation where the product meets both the criteria for a medicinal product and the criteria for another product, e.g. a cosmetic, according

to art. 3q of the Act on cosmetic products in connection with art. 2 paragraph 2 of the Directive 2001/83, such a product is subject to the regulations on medicinal products. According to art. 1 paragraph 2 of Directive 2001/83/EC, a medicinal product is: a) any substance or combination of substances presented for treating or preventing disease in human beings, b) any substance or combination of substances which may be administered to human beings with a view to making a medical diagnosis or to restoring, correcting or modifying physiological functions in human beings.

The second of the exemptions set out in Regulation 1223/2009 applies to medical devices, to which the provisions of the Act of 20 May 2010 on medical devices apply. According to art. 2 paragraph 1 point 33, a medical device is "any instrument, apparatus, appliance, software, material or other item, whether used alone or in combination with the software intended by its manufacturer to be used specifically for diagnostic or therapeutic purposes and necessary for its proper application, intended by the manufacturer for use in humans in the statutory purpose". This Act is in compliance with Council Directive 93/42/EEC of 14 June 1993 concerning medical devices (OJ L 169, 12/07/1993). In its judgment of 22 November 2012, the Court of Justice of the European Union, when addressing the question referred for a preliminary ruling about the interpretation of the term "medical device", stressed that on account of the context of art. 1 paragraph 2 point a) of Council Directive 93/42 concerning medical devices and due to the goals indicated therein, the term "medical device" covers an object created by a manufacturer for use in humans in order to study the physiological process, only if it is intended for medical purposes (CJEU judgment of 22 November 2012).

The third exception applies to biocidal products referred to in the Regulation to the Act of 9 October 2015 on biocidal products. The Act does not contain a definition of biocidal products. Hence one refers to the Regulation to determine the categories and groups of biocidal products. One of the groups consists of biocidal products for personal hygiene, which include: products used for human hygiene purposes, applied on the human skin or scalp, or in contact with the skin, for the primary purpose of disinfecting the skin or scalp.

The above premises for classifying a product as a cosmetic product and the occurring difficulties in finding its proper form in the light of the confluence of the qualifying criteria mean that in certain situations determining a reasonable basis for the liability of service providers requires judicial intervention.

4. Protecting the Consumer – the Purchaser of Cosmetic Products

Cosmetic products are most often bought by consumers, though they are also used by people who provide cosmetic services. Thus, the Regulation on cosmetic products uses a broader definition than that of consumer – namely, the end user, which may be understood, according to art. 2 paragraph 1 point f, both as the consumer and as a person who uses a cosmetic product to pursue professional activity. The Regulation emphasises the aspect of the application and use of a cosmetic product, yet when referring to the consumer, it does not define the latter. This means that the concept of the consumer used in the Regulation requires a reference to the general legislation. The Regulation includes both the provisions of the Civil Code, i.e. the Act of 20 May 2014 on consumer rights and the Directive of the European Parliament and of the Council of 25 October 2011, 2011/83/EU on consumer rights.

According to art. 22^1 of the Civil Code, "a consumer is any natural person undertaking with a trader a legal action not directly related to its business or professional activity". The doctrine emphasises that the location and content of this provision indicate that the intention of the legislature was that art. 221 of the Civil Code provides the general definition of the consumer, which is binding for the entire legal system (Pazdan 2011, pp. 114–115). A narrow definition of the consumer, as included in the Civil Code, remains in compliance with the dominant European trend of limiting the scope of the application of this concept to the individual and to the activities in no way related to its economic or professional activity, although it is also possible to encounter a different position in the doctrine (Malarewicz 2009, p. 112). A similar approach of applying such a narrow definition of the consumer can be found in the Directive of the European Parliament and of the Council of 25 October 2011, 2011/83/EU on consumer rights. According to art. 2 paragraph 1 of the Directive, "*consumer* means any natural person who, in contracts covered by this Directive, is acting for purposes which are outside his trade, business, craft or profession". At the same time, as underlined in recital 17 of the Directive's preamble, the definition of the consumer provided for by this Directive, shall be also applied "in the case of dual purpose contracts, where the contract is concluded for purposes partly within and partly outside the person's trade and the trade purpose is so limited as not to be predominant in the overall context of the contract". The Consumer Protection Act, which constituted the implementation of Directive 2011/83/EU, adopted the same narrow approach to the concept of the consumer.

In conclusion, according to Regulation 1223/2009 and of the Act on cosmetic products, a consumer is a natural person who acquires and independently applies cosmetic products. In addition, because the Regulation has been extended to

cover the end user, the protection it affords will also be granted to the person who pursues the profession of cosmetic technician or cosmetologist who, when purchasing cosmetic products, applies them in the performance of cosmetic services. It is my view that the unambiguous limitation of the status of a consumer to legal transactions undertaken in order to carry out one's own activities, remaining beyond any economic or professional activity, is a narrow approach to the concept of a consumer, similarly to the definition set forth in art. 22^1 of the Civil Code.

Despite the rather broad approach to the concept of the consumer Directive 2011/83/EU takes, clearly differentiating between the consumer and the person using the cosmetic product in the course of their professional activities, as provided in Regulation 1223/2009, makes it impossible to grant the status of consumer to other end users than pure consumers. However, on account of the contractual relation between both entities, namely the contract to provide cosmetic services, their status as the contracting parties does not seem to raise major doubts. The literature emphasises that the legal classification of civil law relations between the consumer and the trader is determined by the definition of the consumer and the entrepreneur provided by the Civil Code. A different approach is presented by M. Borkowski, who maintains "the consumer is also the beautician who purchases cosmetic products which he or she will use for the cosmetic treatments applied to customers" (Borkowski 2015, p. 64).

Regardless of whether the purchaser of a cosmetic product is a consumer or a person who purchases the product for use in their professional activities, the Regulation protects the purchase and application of a cosmetic product. This protection is extended to ensure users' health and safety and is realised on several levels. According to art. 3 of Regulation 1223/2009, in order to minimise potential health risks, the safety of a cosmetic product is affected by suitable product presentation, labelling and accompanying information in the form of instructions for use and disposal, and other instructions necessary for the safe use of the product. In the same context, the safety of a cosmetic product is determined by art. 4 paragraph 1 of the Act on cosmetic products, which emphasises that the safety of cosmetic products also depends on their being applied correctly, i.e. their application is compatible with their intended use and in reasonably foreseeable conditions.

Apart from the detailed procedures related to the implementation of a cosmetic product, the Regulation indicates the substances whose application in cosmetic products is prohibited or restricted and subject to a detailed assessment – for example, nanomaterials used in cosmetic products. Of particular importance for consumer safety is packaging information with respect to the product's composition, weight, shelf life, usage, specific place of application, the person

responsible, as well as the product's documentation (art. 19 paragraph 1 of Regulation 1223/2009 in conjunction with art. 6 of the Act on cosmetics). All of the information pointed out in both these acts of law, placed on the packaging, must be indelible, easily legible and visible. In exceptional circumstances, where for practical reasons it is not possible to put the information directly on the packaging of the cosmetic products, the information is appended to an attached leaflet, label, tape, tag or card. Some products may even provide information in a condensed version. The liability for the safety of a cosmetic product burdens the responsible person, namely the manufacturer, importer or distributor, whose responsibilities are defined in articles 5–7 of the Regulation.

Due to the functions of cosmetic products – providing care, aesthetics and safety – their role is particularly important not only in the cosmetic services industry but also in medical treatment and rehabilitation (Wąsik 2016, pp. 11 and 22). Hence, it is of utmost importance, as indicated in point 2.1s, to distinguish between cosmetic products, medicinal products and medical devices. The considerations relating to the basis of the differentiation and classification of a product as a cosmetic or a medicinal product are reflected in situations where the user of the product is a provider of cosmetic services operating within the framework of its economic activity. Cosmetic services are most commonly provided by cosmetic services technicians or cosmetologists. Both professional groups can apply cosmetic products when providing their services, but they are not authorised to use medicinal products (including OTC medicinal products and herbal medicinal products) or medical devices. These professions do not perform the role of medical professionals, who are qualified to apply medicinal or other products, which must be considered as such, because in addition to meeting the criteria of cosmetic products, they also fulfill the requirements of medicinal products.

The same applies to medical devices, in which both cosmetic and medicinal products can be used. Even if a cosmetologist has been professionally trained to use a specific medical device, which in practice often occurs, he does not have the legal right to use them. Although the Act on medical devices does not directly indicate the entities authorised to use medical devices, their use is defined in the instructions, which may preclude some types of individuals from using them. The problem is not in fact the preparation and the service or the use of a medical device, but the lack of competence to assess the health of the patient to use the medical device. The literature indicates, in particular, the risks associated with the use of implants (especially tissue implants, which restore the permanent or temporary volume of tissue) and acidic substances (including hyaluronic acid), which are classified in accordance with the Regulation of the Minister of Health of 5 November 2010 on the classification of medical devices as being of a class III risk. This class includes invasive medical devices, including, for example, invasive

surgical devices intended for transient and short-term use, e.g., tissue implants, which in practice are also used in cosmetic services.

A detailed distinction and proper classification of the product and service as a cosmetic or medicinal product or services has further consequences in the scope of protection as set out in Regulation 1223/2009 and in the Act on cosmetics. In the case of the consumer, the purchaser of a cosmetic product or cosmetic service, this protection is additionally strengthened on the basis of the Consumer Rights Act. When a medicinal product or medical device is purchased, the protection is provided on the basis of the provisions provided for in all three of the above regulations. With health services, in most cases, the entity entitled to protection is not the consumer but the patient whose special status and the rules for his protection are governed by the medical acts law. While the Consumer Rights Act, referred to in art. 3 paragraph 1 point 7 of the Act, cannot be applied to health services, the status of the patient as a consumer and the protection related therewith is not excluded, depending on the type of health services called for and the entity providing them (Michałowska 2015, p. 210).

The distinction between the two types of products – cosmetics and medicines – and an appropriate qualification of the services rendered with their application is also fiscally reflected on the basis of tax on goods and services. A tax on goods and services does not apply to medical services rendered. According to the Act of 11 March 2004 on tax on goods and services, medical care services provided by a doctor and dentist, nurse and midwife, psychologist and persons practicing medicine are exempt from a goods and services tax. The provisions of the VAT Act indicate that the tax exemption shall not apply to medical services which are not intended to protect health. These include services for preventing, preserving, restoring and improving health. Accordingly, the condition of tax exemption is the occurrence of the therapeutic purpose indicated in the Act, for example, rehabilitation.

This approach raises a number of questions, because making the possibility of using the exemption conditional upon the objective rather than the character of the activity significantly broadens the conceptual scope of the therapeutic purpose of medical services, and that scope is not always consistent with the assessment of the tax authorities. In the case of cosmetic services, the taxpayer is charged the 23% VAT rate. In order to avoid taxation, taxpayers qualify the cosmetic service as a medical service, which unfortunately is not always intended for medical therapy. Rehabilitation is an example of such a service, though it may not fall within the professional status granted to the entities which claim to carry it out. That is to say, these entities may lack the appropriate authorisation to claim a tax exemption. A noteworthy example would be providers of cosmetic services in the form of SPA salons qualifying massage as rehabilitation, promoting a good mood and improved

body aesthetics – and thus exempting them from paying VAT. Often the purpose of the massage and the person performing it do not satisfy the conditions for the tax exemption. A similar qualification applies to physiotherapy services. Finally, with regard to the taxation on products, the VAT rate for cosmetic products is 23%, while for medicinal products found in the Register of Medicinal Products it is, at 8%, roughly a third of that.

5. Conclusions

Protecting consumers, the buyers of cosmetic products, is an interesting and complicated issue. Cosmetic products are covered by Regulation 1223/2009 and the Act on cosmetics, which attach primary importance to defining a cosmetic product and determining the border between cosmetic products and other products. That border is crucial for how a product is classified and distributed and the protection its users are extended. Due to the relatively flexible boundaries between a cosmetic product and other products, which are sometimes attributed the status of cosmetics, it is extremely important to demarcate the border between them and to identify their distinctive elements. It should be emphasised that medicines and cosmetics are two different products.

The need to correctly classify products has to do with ensuring safety and protecting the purchaser and user of the product, as specified in the legal provisions. Entities that apply cosmetic products, the end users/consumers and the people who use cosmetic products for their professional activities are covered by the protection provided in Regulation 1223/2009 and the Act on cosmetics. However, end users specified in the Regulation are entitled to another protected status. Similarly, another scope of protection applies to consumers who are also patients, or when, because a medical service is being provided, consumers are categorized as patients. The distinction between a consumer and other types of entities is also reflected in VAT tax liability. Accordingly, when a given type of service is qualified in a manner incompatible with the facts, additional tax consequences may apply.

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Ochrona konsumenta nabywcy i użytkownika produktu kosmetycznego w świetle Rozporządzenia Parlamentu Europejskiego i Rady (WE) nr 1223/2009 dotyczącego produktów kosmetycznych

(Streszczenie)

W artykule zwrócono uwagę na zagadnienia prawnej kwalifikacji produktu kosmetycznego oraz ochrony konsumenta – nabywcy produktu kosmetycznego. Zapewniona międzynarodowym i krajowym porządkiem prawnym ochrona gwarantowana jest dwoma równorzędnie obowiązującymi podstawami prawnymi, tj. Rozporządzeniem Parlamentu Europejskiego i Rady (WE) z dnia 30 listopada 2009 r. nr 1223/2009 dotyczącym produktów kosmetycznych oraz Ustawą z dnia 30 marca 2001 r. o produktach kosmetycznych. Z uwagi na praktyczne trudności kwalifikacji produktu jako kosmetyku podjęto wątek ustalenia relacji produktu kosmetycznego, produktu leczniczego i wyrobu medycznego. Odniesiono się również do zagadnienia kwalifikacji osób świadczących usługi kosmetyczne, wykorzystujących w nich produkty kosmetyczne, oraz do zakresu ich odpowiedzialności.

Słowa kluczowe: produkt kosmetyczny, produkt leczniczy, konsument, użytkownik końcowy.