

Dietary Supplement vs Medicinal Product

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Abstract

The article is intended to present research on the comparison of a dietary supplement versus a medicinal product. The demarcation of these issues is not an easy task. This paper attempts to do so, along with the presentation of relevant legal acts and judgments of competent judicial authorities, relating to the issue indicated.

Keywords

Dietary supplement, medicinal product, food law, food, health.

1. Introduction. Dietary supplement

Separating the issues of dietary supplements and medicinal products is very challenging, despite increasingly detailed regulations supported by emerging technological capabilities. The differences between these products are difficult to grasp due to the fact that they often contain the same ingredients and their qualification depends on the dose. What seems most important, however, is the effect of the above products on human health and often life. This is especially relevant in the case of medicinal products, which are intended to cure a person or stop the progression of a disease.

A dietary supplement does not carry such significance, and the purpose of taking it is the desire to maintain a person's health (the body's homeostasis) for as long as possible. It is therefore used regularly and preventively to supplement the regular diet. The fad of taking dietary supplements, which is associated with their easy availability, competitive price and large choice on the market is a response to human interest in healthy eating and an active lifestyle. The dietary supplement market is also growing because more and more food products, year after year, are becoming less valuable in terms of nutrient content. What's more, globalization is influencing the appearance on store shelves of products from different corners of the world, qualified as new foods, often with health-promoting properties, and these are attracting consumer interest. Such ingredients, in concentrated form, very often appear as dietary supplements.

Dietary supplements, to be approved for marketing, do not have to meet as restrictive requirements as medicinal products. An entrepreneur who wants to put a dietary supplement on the market must meet a formal condition, that is, notify the Chief Sanitary Inspector, and can immediately start selling a particular product without waiting for the authority's response. It is therefore crucial to comprehensively regulate the dietary supplement market, especially at the Community level. This will protect consumers from consequences resulting from the wide availability and low prices of these products, such as unjustified and excessive consumption. Despite the differences, often including those that are difficult to grasp at first glance, medicinal products and dietary supplements have many features in common. These are primarily a similar form of administration and health-promoting properties.

Poland, as a member state of the European Union, had to adapt its national law to the requirements of EU legislation. All regulations in force at the Community level and concerning food, due to the principle of priority, had to be adopted into national law. The Food and Nutrition Safety Act is an expression of the transposition of EU regulations. Undoubtedly, it is not an exhaustive act, so it is necessary to simultaneously apply the law in question and its corresponding national regulations, as well as the relevant directives and regulations at the Community level, as far as food in its broadest sense is concerned. Thus, the definitions of dietary supplements in individual national legislation differ from the basic one contained in the EU Directive. The differences also

apply to dietary supplement ingredients other than those indicated on the list (annex to the directive). As a result, we are faced with an inconsistent legal status in this regard in all (currently 28) EU member states¹.

In accordance with the general principles and requirements of food law contained in Regulation 178/2002/EC, which sets out the basic principles and rules of food safety², a dietary supplement is considered a certain type of food (foodstuff), that is, a substance or product, whether processed or not, that is intended for, or expected to be consumed by humans. Thus, it must meet the definition of food. The purpose of consuming such food is to supplement the normal diet with nutrients or substances that produce a nutritional or physiological effect. In addition, due to this classification, a dietary supplement, as a food, is a product available to the general public. Regulation 178/2002/EC makes it clear that a food (foodstuff) is not considered a medicinal product (Article 3(d)), i.e., products defined as medicinal products in pharmaceutical legislation. Such an exclusion is also contained in the Directive on the approximation of the laws of the Member States relating to food supplements in Article 1 point 2 "This Directive shall not apply to medicinal products as defined by Directive 2001/83/EC of the European Parliament and of the Council of November 6, 2001 on the Community code relating to medicinal products for human use."

Legal regulations on dietary supplements in Polish legislation have found their place in the Act of 25.8.2006 on food and nutrition safety, and the Regulation of the Minister of Health of 9.10.2007 on the composition and labeling of dietary supplements. Polish legislation on dietary supplements is an expression of the transposition of Directive 46/2002/EC. According to the statutory definition in Article 3, paragraph 3, item 39, a dietary supplement is "a foodstuff the purpose of which is to supplement a normal diet, being a concentrated source of vitamins or minerals or other substances having a nutritional or other physiological effect, whether single or combined, marketed in a dosage format in the form of: capsules, tablets, dragees and in other similar forms, sachets with powder, ampoules with liquid, bottles with dropper and in other similar forms of liquids and powders intended to be consumed in small, measured unit quantities, excluding products that have the characteristics of a medicinal product as defined by pharmaceutical law."

According to the above definition, the purpose of taking dietary supplements is to complement the diet, not to treat or prevent disease as in the case of taking a medicinal product. A dietary supplement is distinguished from a medicinal product in that it is not aimed at either treating or preventing disease. Its action cannot modify physiological functions in the process of treatment or prevention of disease, but only influence them³. Moreover, Article 27(1) of the Food and Nutrition Safety Law indicates that dietary supplements may include in their composition vitamins and minerals found in food and consumed as part of food. This also applies to other substances normally found in food. They must exhibit a nutritional or other physiological effect.

Consumers choose to use dietary supplements because of their lifestyles or other considerations, supplementing their food with them. Other than vitamins and minerals, substances that might be included in dietary supplements can be divided into 6 groups.

These are amino acids, enzymes of plant and animal origin, probiotics and prebiotics, oils and fatty acids, plant raw materials and preparations derived from them, as well as many other substances such as glucosamine, soy isoflavones or coenzyme Q10, among others.

No detailed definition of the so-called "normal diet" can be found in legal acts. However, it is pointed out that such a diet includes the nutrition standards developed in medical science, determining the amount of energy and essential nutrients that constitute the daily requirements of one person. It is also necessary to take into account differences in the need for the above components, depending on age, gender, health and physical activity, as well

¹M. Korzycka, P. Wojciechowski, System prawa żywnościowego, Rozdział III, Zakres przedmiotowy prawa żywnościowego, Wolters Kluwer, Warszawa 2017, pp.180-181.

² Regulation (EC) No. 178/2002 of the European Parliament and of the Council of January 28, 2002, laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in the field of food safety (OJ EU. L. of 2002, No. 31, p. 1, as amended).

³ M. Korzycka-Iwanow, Prawo żywnościowe. Zarys prawa polskiego i wspólnotowego. Warszawa 2007, p.56.

as living conditions and lifestyle⁴. Complementation of the ingredients contained in dietary supplements is therefore associated with various life situations during which certain deficiencies may arise. This may be due, for example, to where one lives, taking products that cause deficiencies of certain minerals in the long term or finding oneself in a stressful situation. A contradiction, however, is the provision indicating that a normal diet is a complete diet, and then indicating that dietary supplements can supplement such a normal diet.

Regulated at the European Union level only the vitamins and minerals specifically indicated in the annex to Directive 46/2002/EU are considered to be nutritional substances and they are found in specific forms, also listed in the annex. The list of the above-mentioned ingredients is contained in the Regulation of the Minister of Health on the composition and labeling of dietary supplements. The area not regulated by the aforementioned directive, namely vitamin and mineral substances not included in the lists and other substances showing a nutritional or physiological effect, is covered by the national laws of individual member states. Based on Article 3 of the Treaty on the Functioning of the European Union (TFEU)⁵, competent authorities of individual member states may restrict in their territory the sale of foodstuffs (dietary supplements) registered in another European Union country, referring to the protection of human health and life. However, restrictions imposed by national law must not harm the fundamental freedoms of the European Union's single market, such as the principle of free movement of goods or the principle of proportionality.

The European Commission, together with the member states, is still in the process of preparing regulations for the remaining substances that currently are not covered by Directive No. 46/2002/EU. The catalog of vitamins and minerals included in this directive is not a closed list, which means that the definition of a dietary supplement as well as the legal regulations on this matter differ in each EU member state. To date, the European Commission has also not set maximum levels (doses) of substances that can be components of a dietary supplement⁶.

The key to defining what a dietary supplement is, especially in comparison to a medicinal product, and what properties to attribute to it, turned out to be the CJEU ruling in the case of *Commission v. Germany*⁷. The above case involved garlic capsules sold under the name "garlic extract powder capsules." Each capsule contained 370 mg of garlic extract, including 0.95% to 1.05% allicin. Such amount is equivalent to 7.5 g of fresh garlic. German authorities concluded that it was a medicinal product. After an analysis on both function and presentation the court pointed out that the physiological effect is not solely attributed to medicinal products, but is one of the criteria used to define a food supplement⁸. In further arguments in the same ruling, examining a preparation containing garlic extract, the Court pointed out that if the manufactured product has the same properties as a product of natural origin consumed in reasonable quantities, it cannot be considered a medicinal product.⁹

The differences between qualifying products as either dietary supplements or medicinal products were addressed by the Provincial Administrative Court in Warsaw in its judgment VII SA/Wa 2111/14, indicating that "a foodstuff, including a dietary supplement, differs from a medicinal product. This difference in particular relates to the "different physiological effect," which in the case of a dietary supplement should be understood as optimization of normal physiological functions of the body (maintenance, support, optimization), and not restoration, reconstruction, prevention, or modification of physiological functions inherent in a medicinal product."¹⁰

⁴ M. Ożóg, Rozdział VIII Reklama produktów leczniczych, aptek i punktów aptecznych. w: System handlu produktem leczniczym i produktami pokrewnymi. Problematyka prawna. Wydawnictwo Prawnicze Lewis Nexis, 2009.

⁵ Treaty Establishing the European Economic Community OJ of 2004. No. 90, item 864/2 as amended).

⁶ Scientific Editor Paweł Czechowski, Prawo rolne, Rozdział XXVIII. Prawo żywnościowe, Małgorzata Korzycka-Iwanow, Paweł Wojciechowski, Warszawa 2015 p. 463.

⁷ Judgment of November 15, 2007 in *Commission v. Germany*, C-319/05.

⁸ Ibid.

⁹ Ibid.

¹⁰ Judgment of the Provincial Administrative Court in Warsaw dated May 29, 2015, VII SA/Wa 2111/14.

Importantly, the fact that dietary supplements occur in dosage form, i.e. capsules, dragees or tablets, does not automatically qualify them as a medicinal product. The definition of a dietary supplement indicates that it comes in the same forms as pharmaceutical products. Such forms distinguish it from ordinary food. According to the example given in the judgment in question, the capsule form is not specific only to medicinal products. Foodstuffs often contain this form in order to facilitate consumption by consumers. "Therefore, this indication alone is not sufficient for assuming that the product in question is a medicinal product according to the manner of presentation"¹¹. The Court of Justice of the European Union has clearly indicated that the above product is not a medicinal product either in terms of presentation or function. The Court's assertions seem reasonable and logical, but despite the passage of years, there is still a problem in drawing the line between a dietary supplement and a medicinal product. There is still no legal act to establish a threshold for the effects of individual substances to unambiguously determine when the nutritional and other physiological effects end and the metabolic and other effects attributed to medicinal products begin.

The detailed conditions for the composition and labeling of dietary supplements are set forth in a regulation of the Minister of Health. It contains the provisions indicated in Directive 46/2002/EC on the list of minerals and vitamins and the chemical forms that can be used in their manufacture. General regulations on the labeling of dietary supplements are set forth in the Food and Nutrition Safety Act, with the exception of the specific provisions contained in the regulation in question. According to Article 5 (2) of the above regulation, the following information must be included on the packaging of a dietary supplement:

- 1) the designation "dietary supplement",
- 2) the names of the categories of nutrients or substances that characterize the product or an indication of their properties,
- 3) indication that the dietary supplement cannot be used as a substitute for a varied diet,
- 4) about the portion of the product recommended for consumption during the day,
- 5) a warning not to exceed the recommended daily portion,
- 6) recommendation to keep it away from small children.

The labeling of dietary supplements must take into account the provisions of the Food and nutrition Safety Act, the Ordinance of the Minister of Agriculture and Rural Development of 10.7.2007 on the labeling of foodstuffs, as well as Regulation EC No. 1924/2006 P of 20.12.2006 on nutrition and health claims made on food and Regulation 1169/2011 on the provision of food information to consumers.

2. Enriched food

The Food and Nutrition Safety Act regulates foods enriched with vitamins and minerals, right next to dietary supplements. Enriched foods are foods to which specific vitamins and minerals are intentionally added during production. A dietary supplement cannot be treated as an enriched food, it is a separate foodstuff, regulated in detail in other legal acts. As Article 28(1) of the above law indicates, vitamins and minerals may be added to foodstuffs in accordance with Regulation No. 1925/2006 on the addition of vitamins and minerals and certain other substances to food. In Poland, enriched foods are regulated by the Regulations of the Minister of Health on enriching substances added to food. It defines foods to which vitamins and minerals will be added, a list of minerals and vitamins, and establishes their maximum levels in individual products and the chemical forms that can be used. Such foods, like dietary supplements, must be properly labeled. It is important to inform the consumer in an understandable way about the properties of a particular food product¹². The most common example of such foods are children's fruit juices fortified with vitamin C, with clear information about its addition on the product

¹¹ Judgment of November 15, 2007 in *Commission v. Germany*, C-319/05, item 53.

¹² M. Grochowska, *Bezpieczeństwo żywności i żywienia*, Gdańsk 2007, p.38.

label.

3. Medicinal product

The basis of any medicinal product is one or more active substances that determine its proper action. Moreover, such a product includes additional substances (excipients), which do not have a pharmacological effect, but which give the product its proper form, stability and pharmaceutical and biological availability¹³. In accordance with Directive 2001/83/EC¹⁴, a substance is any matter regardless of its origin, which can be human, animal, plant and also chemical. Active substance and excipient are defined in detail in the directive. An active substance is considered to be one "which is intended to be used in the manufacture of a medicinal product and which, when used in its manufacture, becomes the active ingredient of that product, intended to produce a pharmacological, immunological or metabolic effect to restore, improve or modify physiological functions or to make a medical diagnosis" (Article 1, point 3a). *A contrario*, an excipient is anything that an active substance is not, i.e. another substance, as well as packaging material. This definition covers a very broad catalog of substances, both natural and artificial.

Synonyms for medicinal product in legislation and literature are terms such as pharmaceutical product, pharmaceutical agent, drug. These terms do not have legal definitions in legal acts, but taking into account the semantic rules, it is assumed that they are synonyms of the product¹⁵.

A medicinal product under Polish law, according to the act of 6.9.2011 Pharmaceutical Law is "a substance or mixture of substances, presented as having properties for the prevention or treatment of diseases occurring in humans or animals or administered for the purpose of making a diagnosis or for the purpose of restoring, improving or modifying physiological functions of the body through pharmacological, immunological or metabolic action." The current wording of this provision was introduced by the amendment to the Pharmaceutical Law of 30.11.2007 when the relevant provision of Directive 2004/27/EC was implemented. Therefore, any consideration of a medicinal product in EU law is valid with respect to the definition of this product in Polish legislation¹⁶. This scope has been established by the legislator very broadly, so that the provisions of the pharmaceutical law are impossible to circumvent. Thus, a drug can be a product that has a therapeutic effect, but also such a product that is only attributed with such properties¹⁷.

In the Polish law, the concept of medicinal product refers both to humans and to animals. In European legislation, there are two separate directives relating for humans and animals, respectively. Other types of medicinal products, such as herbal medicinal products (Article 2(33a)), generic medicinal products, homeopathic medicinal products (Article 2(29)), immunological medicinal products (Article 2(30)), blood products (Article 2(31)), veterinary medicinal products (Article 2(34)), radiopharmaceuticals (Article 2(35)), as well as medicinal products for special nutritional purposes are also listed in Article 2 of the Pharmaceutical Law.

The definition of medicinal product according to Article 1 point 2 of Directive 2001/83/EC indicates that such product is:

- 1) any substance or combination of substances presented as having medicinal or disease-preventing properties in humans,
- 2) any substance or combination of substances capable of being used or administered to humans for the purpose of recovering, improving or altering physiological functions by causing pharmacological, immunological

¹³ M. Ożóg, *System handlu produktem leczniczym i produktami pokrewnymi. Problematyka prawna*, Warszawa 2010, p.42.

¹⁴ Directive 2001/83/EC of the European Parliament and of the Council of November 6, 2001 on the Community code relating to medicinal products for human use (OJ EU. L. 2001, No. 311, p. 67, as amended).

¹⁵ Ż. Pacud, *Ochrona patentowa produktów leczniczych*, Warszawa 2013, p.26.

¹⁶ D.E. Harasimiuk, *Zakazy reklamy towarów w prawie europejskim i polskim*. Oficyna, 2011, p. 320.

¹⁷ M. Kondrat, *Prawo farmaceutyczne. Komentarz*, wyd. II. Wolters Kluwer, 2016, p. 83.

or metabolic effects or for the purpose of making a diagnosis.

The first part of the above article indicates that the very fact of the presentation of a product causes it to qualify as a medicinal product. The intention of the legislator was to protect consumers from using products that do not have medicinal properties that can positively affect their health. There have been cases where consumers have given up tested medicinal products with proven effects in favor of products advertised as medicinal products with specific properties. As a result, their treatment, or treatment support did not proceed as it should.

It seems that it was even more important to protect against products that could harm the consumer through their toxicity or improper and excessive use, as well as through the merely apparent effects of such products. The jurisprudence of the CJEU concerning the characteristics of a medicinal product is extremely rich, and the step-by-step theses contained therein make it possible to understand why the legislator decided to define the product in question so broadly. It is important that the restrictions imposed by legislators, which concern public health, do not hamper the conduct of free economic activity. Nevertheless, it is also important that the measures taken do not impede the development of the sector and the marketing of medicinal products within the European Union.

One of the most important rulings treating a medicinal product is 227/82 Leendert Van Bennekom Case¹⁸. Although this ruling concerns the definition already contained in the Directive 65/65/EEC, nothing has changed to this day in terms of the approach to the presentation of a medicinal product and the interpretation of its definition. The above case involved criminal proceedings against Mr. Leendert van Bennekom, a Dutch citizen. He was accused of possessing large quantities of vitamin and multivitamin preparations without the proper authorization. The products were intended for sale. The accused van Bennekom argued that the products in his possession were not recognized as medicinal products by Directive 65/65/EEC, which was in effect at the time, and the Dutch law regulating the pharmaceutical industry.

In ruling on such a broad definition of a medicinal product, the Court pointed out that "it should be noted that the directive, basing the first Community definition of a medicinal product on the criterion of presentation of the product, is intended to include within its scope not only medicinal products with a genuine therapeutic or curative effect, but also those that are not sufficiently effective, or that do not have the effect that the consumer would be entitled to expect in view of their presentation. Thus, the directive is intended to protect consumers not only from harmful or toxic medicinal products as such, but also from a variety of products used in place of appropriate remedies. For this reason, the concept of product presentation should be interpreted broadly."

Detailing the concept of presentation, the CJEU indicated that a medicinal product is considered a product shown in such a way that the average informed consumer can get the impression that the product in question is a medicinal product. The impression gained, however, must be clear. Such a consumer is defined in Article 18 of the preamble to the Unfair Commercial Practices Directive, where it is indicated that he or she is a consumer who is "reasonably well informed and reasonably observant and circumspect, taking into account social, cultural and linguistic factors, as interpreted by the Court of Justice." The creation of a model of such a consumer has its *ratio legis* in their protection against unfair commercial practices, especially in the context of advertising aimed at the general public. The above definition has been transposed into the Polish law. It is contained in Article 2(8) of the Act on Counteracting Unfair Market Practices. Such an interpretation was also emphasized by the Regional Administrative Court in Warsaw, indicating, that such a consumer is "a reasonably well-informed, reasonably attentive and cautious person. At the same time, it should be emphasized that the level of perceptiveness of the average consumer may vary depending on the type of goods or services¹⁹."

The concept of presentation of a medicinal product has been developed in subsequent years of the CJEU's work. The Court, in its judgment in Case C-369/88 Delattre, pointed out that "a product may be classified as a medicinal product according to its mode of presentation if, by its form and packaging, it is sufficiently similar to a medicinal product, in particular, when its packaging and the accompanying leaflet contain information pointing to pharmaceutical laboratory tests, methods developed by doctors, substances or specific medical testimony

¹⁸ Judgment of November 30, 1983, *van Bennekom*, 227/82, ECR 1983, p. 3883.

¹⁹ Judgment of the Provincial Administrative Court in Warsaw from October 10, 2005.VI SA/Wa 882/05.

supporting the occurrence of the relevant properties of the product"²⁰. In the ruling in question, the panel of judges had to consider whether the products shipped from Belgian territory, which according to the defendant were cosmetics and foodstuffs, were medicinal products illegally introduced into France.

This interpretation was confirmed by the ruling in case number C-219/91 *Ter Voort*. The case concerned a leaflet describing the therapeutic and prophylactic effects of an herbal tea imported from South America. The above leaflet was sent by the seller at the request of the customer. Criminal proceedings were pending against the defendant *Ter Voort* on the grounds that he did not have a license to sell the aforementioned tea, which was treated as a medicinal product by the competent Dutch authority. In response to a preliminary question, the Court indicated that "a product expressly indicated or recommended as having therapeutic or prophylactic properties should be considered a medicinal product by virtue of its presentation, even if it has no known therapeutic effect"²¹. The information leaflet added to the order thus met the criteria of a medicinal product in the directive at the time regarding its presentation.

The second part of the definition of a medicinal product refers to the actual effect of a specific medicinal product, i.e. the active substances contained in its composition on the health of the consumer. This impact can therefore be the improvement, recovery or change of human physiological functions. Pharmacological, immunological and metabolic actions are not precisely defined in EU legislation, and their use is necessary to distinguish medicinal products from other means, called borderline products, such as medical devices, dietary supplements, cosmetics and food. Their precise definition is not possible at the legal level, because these are scientific concepts, and the differences between them, as well as the exact specifics or how certain properties are measured, are almost impossible to grasp and carry out by a layperson. In this case, by lawyers. Thus, it seems that due to the helplessness of the legislature in this regard, disputes over medicinal products and products similar to them will always occur. The main objective guiding the legislator was to introduce uniform rules for the classification of medicinal products and products similar to them within the European Union, so that the free movement of goods in the community could be preserved.

In *Hecht-Pharma GmbH v. Staatliches Gewerbeaufsichtsamt Lüneburg*, the CJEU indicated that "in order to determine whether a product falls within the definition of a medicinal product according to its function within the meaning of Directive 2001/83, the national authorities, acting under judicial review must decide on a case-by-case basis having regard to the totality of the product's characteristics and, in particular, its composition, its pharmacological properties which can be established on the basis of current scientific knowledge, its mode of use, the extent of its distribution, knowledge of it among consumers and the risks associated with its use"²². Given the above, it can be concluded that competent national authorities should qualify a particular product as a medicinal product only if current scientific research clearly indicates that the product has the defining properties and actually affects human health. There must therefore be certainty, based on scientific research, about the properties and effects of a medicinal product.

In the *Hecht-Pharma* case (the so-called *Red Rice* case), the Court had to decide whether capsules that contained a substance called *monoclin K* derived from fermented red rice could be considered a medicinal product. The aforementioned component is an active substance with an effect such as *lowastine* (an inhibitor of cholesterol synthesis), which is included in prescription preparations and can cause adverse reactions. According to Article 2(2) of Directive 83/2001/EC, a product that does not have scientifically established medicinal functions cannot be considered a medicinal product. Moreover, for a product to be considered a medicinal product, it is necessary to examine all the circumstances, so "the criteria of how the product is used, the extent of its distribution, knowledge of it among consumers and the risks associated with its use are still relevant in determining whether a product falls within the definition of medicinal product by function." According to the theses of the *Hecht-Pharma (Red Rice)* ruling, a medicinal product is considered to be a product that meets three conditions, i.e., the

²⁰ Judgment of March 21, 1991 in Case C 369/88 *Delattre* [1991] ECR I 1487, para. 4.

²¹ *Ibid.*

²² Opinion of Ombudsman General *Trstenjak* submitted on June 19, 2008. *Hecht-Pharma GmbH v. Staatliches Gewerbeaufsichtsamt Lüneburg*, Case C-140/07.

therapeutic effect of the product must be scientifically proven, the physiological effect of the product must be significant and the therapeutic effect is achieved with the recommended dosage.

4. Definition of borderline products and summary

Despite attempts to define all types of medicinal products in detail, practice shows that in some cases it is not possible to clearly determine whether a product can be included in the category of medicinal products or other product categories. Thus, the problem of borderline products arises. The term borderline products is used to describe a variety of products that are traded in pharmacies, but do not fall within the definition of a medicinal product under the Pharmaceutical Law. In addition to medicinal products, pharmacies and pharmaceutical wholesalers may offer products such as medical devices, foodstuffs for special nutritional purposes or dietary supplements.

With help comes Article 3a of the Pharmaceutical Law, which states that "the provisions of this Law shall apply to a product that simultaneously meets the criteria for a medicinal product and the criteria for another type of product, in particular a dietary supplement, cosmetic or medical device, as defined by separate regulations." The legislator in this provision is thus guided by the higher protection of the consumer²³.

On the basis of Article 7(6) of the Law of 18.03.2011 on the Office for Registration of Medicinal Products, Medical Devices and Biocidal Products, there is a provision for the establishment of a special Commission for Borderline Products at the President of the Office, considering cases of products that meet the criteria for medicinal products as well as other products such as dietary supplements. The tasks of the Commission for Borderline Products include issuing opinions on the classification of products (medicinal product, device or biocidal product) and carrying out tasks commissioned by the President of the above Office, and concerning a borderline product (Article 6 point 7)²⁴. The opinions of this Authority in disputed cases take precedence over private opinions.

If a product, according to the regulation in question, meets the criteria for qualifying as a medicinal product and another type of product, the regulations for a medicinal product must be applied. In such a situation, a higher standard of consumer protection is applicable. If a product classified as a dietary supplement or cosmetic meets the criteria for qualification as a medicinal product, the pharmaceutical inspection authorities are obliged to qualify it as a medicinal product admitted to the market without the corresponding authorization (Article 3a of the Pharmaceutical Law). In this situation, the responsible entity will have to withdraw the specific product from the market and stop the release of subsequent batches to the market. Moreover, the initiated proceedings will be conducted on the basis of the Pharmaceutical Law, and not, for example, on the basis of the Food and Nutrition Safety Act, if the case involved a dietary supplement. In such a situation, the relevant authority, in the case of a medicinal product it is the Chief Pharmaceutical Inspector, is obliged to notify law enforcement authorities. Prosecution will also be initiated (Article 124 of the Pharmaceutical Law).

In a judgment dated October 28, 1992, the Court of Justice of the European Union in criminal proceedings against Johannes Stephanus Wilhelmus Ter Voort stated that "a product prescribed or described as having prophylactic or therapeutic properties is a medicinal product by virtue of the way it is presented within the meaning of the first paragraph of Article 1(2) of Directive 65/65 on ready-made medicines, even when it is essentially regarded as a foodstuff and when, given the current state of scientific knowledge, it has no known therapeutic effect"²⁵. In the above ruling, the CJEU indicated that even if the medicinal properties of a particular product are indicated only in a publication in the form of a brochure sent to the purchaser at his or her request or as a result of a sale, it may be classified as a medicinal product within the meaning of the above-mentioned regulations. The concept of product presentation is interpreted in an expansive manner. Directive 2001/83/EC

²³ M. Kondrat, *Prawo farmaceutyczne. Komentarz, wyd. II.*, Wolters Kluwer, 2016.

²⁴ Act of March 18, 2011 on the Office for Registration of Medicinal Products, Medical Devices and Biocidal Products. (i.e., OJ of 2016, item 1718).

²⁵ Judgment of the Court of Justice of the EU on October 28, 1992, Criminal proceedings against Johannes Stephanus Wilhelmus Ter Voort, case C-219/91.

covers not only medicinal products that have an actual therapeutic or medical effect, but also those for which the consumer would have a right to expect the aforementioned effects, based on their presentation.

This conclusion was also reached by the CJEU in its judgment of June 9, 2005

in Joined Cases C-211/03, C-299/03, C-316 to C-318/03 *HLH Warenvertriebs GmbH and Orthica BV v. Germany*²⁶. It stresses that in case of doubt in the classification of a given product, which may fall within the definition of a drug or a product subject to the provisions of another act, the provisions of the pharmaceutical law apply. Products that meet the criteria of two or more categories at the same time are referred to by the doctrine as borderline products, but this name is not defined in any legislation. Borderline products refer to pharmaceutical products that are traded in pharmacies, but do not fall within the definition of a medicinal product in the Pharmaceutical Law. In the current state of the law, it is not possible to obtain a binding opinion from the Office for Registration of Medicinal Products as to whether a product is a medicinal product²⁷.

According to the thesis of the CJEU judgment of 15.1.2009 "the criterion of suitability to recover, improve or change physiological functions should not lead to qualify as a medicinal product by function of those types of products that although affect the human body but do not have significant physiological effects and therefore do not actually modify the conditions of functioning of the body"²⁸. According to well-established CJEU case law, a product presenting properties of treatment and disease prevention, used to restore, correct or modify physiological functions in humans, must be considered a medicinal product. In this case, the more restrictive rules that govern a medicinal product apply even if the product falls within the scope of another Community regulation²⁹.

Such action by the authorities was indicated by the CJEU in its judgment of January 15, 2009. in Case C 140/07 *Hecht-Pharma*, stating that "in order to determine whether a product falls within the definition of a medicinal product by function within the meaning of Directive 2001/83, the national authorities, acting under judicial review, must decide on a case-by-case basis, taking into account the totality of the product's characteristics, and in particular its composition, its pharmacological, immunological or metabolic properties, which can be established on the basis of the current state of scientific knowledge, its mode of use, the extent of its distribution, knowledge of it among consumers and the risks associated with its use"³⁰. On the basis of pharmacological, immunological or metabolic properties, an assessment is made as to whether the action of a particular product can help recover, improve or change physiological functions in humans within the meaning of Article 1 pt. 2(b) of Directive 2001/83/EC³¹. The decision as to the category into which a particular product should be classified should be made on a case-by-case basis, after analyzing the accumulated material. It is necessary in this case to rely on both European and national case law, as well as the body of doctrine.

The qualification of a particular product as a medicinal product in one European Union member state does not guarantee that in another country the product will have the same status. The lack of harmonization and qualification uncertainties arising from scientific research still in progress allow competent authorities in member states to decide on the level of protection for the health and lives of consumers. Nevertheless, these authorities, within the discretion granted to them, must respect the principle of proportionality³². National authorities are required to demonstrate in each case, with reference to national dietary habits and international scientific research, that the regulations they enact are necessary to effectively protect the interests indicated in Article 36 of the Treaty. Most important is the demonstration of a real threat to public health³³. The authorities with the competence to determine the legal status of specific products are the Chief Pharmaceutical Inspector in the case of medicinal

²⁶ Judgment of June 9, 2005 in *Joined Cases C-211/03, C-299/03, C-316 to C-318/03*, ECR 2005 s. I-5141.

²⁷ M. Krekora, *Prawo farmaceutyczne*, wydanie 2, Warszawa 2012, p.62.

²⁸ CJEU Judgment no. C-140/07, *Hecht-Pharma GmbH v. Staatliches Gewerbeaufsichtsamt Lüneburg*.

²⁹ *Ibid.*, pt. 53.

³⁰ Judgment of January 15, 2009 in Case C-140/07 *Hecht-Pharma*, not yet published in the collection, paragraph 39).

³¹ Judgment of the Court of Justice of the EU of April 30, 2009 in case C-27/08.

³² M. Kondrat, *Prawo farmaceutyczne. Komentarz, wyd. II.*, Wolters Kluwer, 2016, p.110.

³³ C-24/00, *Commission of the European Communities v. French Republic* - Judgment of the Court of Justice.

products (Art. of the Pharmaceutical Law) and the Chief Sanitary Inspector in the case of dietary supplements (Art. of the Food and Nutrition Law). The only evidence that resolves doubts about the nature of a particular product should be an expert opinion from a competent scientific institute.

In the case of *BIOS Naturprodukte v. Saarland*³⁴, the Court had to decide whether a preparation containing boswellia extract registered in Austria as a dietary supplement failed to meet the criteria for classification as a medicinal product. The company appealing the decision argued that the packaging clearly indicated that it was a dietary supplement and provided no indication of therapeutic or disease-preventing properties (method of presentation). Moreover, the recommended daily dose, 400 mg, available in one capsule, does not have a pharmacological effect (function), and according to the traditional use of boswellia, as an aroma and spice, it serves a food purpose. The national court concluded that, according to the manner of presentation, the product in question is not a medicinal product. However, taking into account the latest scientific findings, it is a medicinal product according to function. The court cited a study stating that the use of the product in question in low doses can promote inflammatory processes, the opposite of what happens with higher doses.

Accordingly, it concluded that from the point of view of the purpose of health protection, the negative effects caused by using the product in too low doses are a pharmacological activity. However, the Court did not share the view of the national court and ruled that "a product that includes a substance that has physiological effects when used in a certain dose does not constitute a medicinal product according to function when, having regard to the dose of the active substances under normal conditions of use, it presents a risk to health, but is not capable of leading to the recovery, improvement or alteration of physiological functions in humans." The product in question therefore did not meet the criteria for presentation and function of a medicinal product.

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³⁴ Judgment of the Court of Justice of the EU of April 30, 2009, Case C-27/08.

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