REVIEW ARTICLE

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Sales and marketing of foodstuffs for special nutritional purposes and dietary supplements

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Abstract

Nutritional specifics such as foodstuffs for special nutritional purposes and dietary supplements are regulated by the provisions of the *Act of August 25, 2006 on Food and Nutrition Safety*, promulgated in its consolidated text in May 2023 (*Journal of Laws 2023,* item 1448). The provisions of this act refer, among others, to described and defined foodstuffs for special nutritional purposes and dietary supplements, which are offered in pharmacies open to the public and pharmacy outlets for sale (to the general public and by prescription). Foodstuffs for special nutritional purposes and dietary supplements are increasingly popular among consumers. However, through incompetent or irrational consumption, cases of abuse of these products, mainly dietary supplements, or replacing food with them, are recorded. The composition of dietary supplements, the effects described, can sometimes differ from those declared, which carries specific health risks for their recipients. In addition, dietary supplements, which are mostly used without the supervision of a physician or pharmacist in conjunction with medications, may carry the risk of undesirable effects. Foodstuffs for special nutritional purposes, on the other hand, are products that, due to their special preparation or composition, differ from common foodstuffs and are intended to meet the nutritional needs of specific recipient groups. These foods are intended to nourish certain groups of consumers with specific health needs/problems, usually under the supervision and prescription of a physician. The indication for the use of such products is to provide the body with all the necessary nutrients in the right proportions, to improve health, or to treat an existing disease. Both foodstuffs for special nutritional purposes and dietary supplements are categorized as nutritional products, not pharmaceuticals.

Key words

dietary supplements, foodstuffs for special nutritional purposes, food law, pharmacies

INTRODUCTION

The *Act on Food and Nutrition Safety* includes issues concerning foodstuffs for special nutritional purposes (Chapter 6) and dietary supplements (Chapter 7). These products are offered in pharmacies open to the public and at pharmacy outlets. It should be mentioned here that the December 2022 draft amendment to the *Act on Food and Nutrition Safety*, which was still on the legislative path in the second quarter of 2023, was not considered and introduced. Described in the paper 7a, the content was to deal with a number of major restrictions and prohibitions on the sale of dietary supplements, such as restrictions on how and where to conduct presentations or advertisements of these supplements, prohibition of advertising supplements in pharmacies (outside the designated place) and the use of images of a medical professional such as a pharmacist in advertising, the conduct of advertisements targeting children (under 12 years of age), etc. [1]. In its current version, the *Act on Food and Nutrition Safety* describes and categorizes foodstuffs for special nutritional purposes and dietary supplements as nutritional products, the use of which is governed by a specific rationale. This includes modification, enrichment, or recommendation of a special diet that is indicated by a physician, nutritionist, or for voluntary use such as a dietary supplement.

Means of special nutritional use. A foodstuff for special nutritional use, according to the definition in the cited Act (Chapter 6), is a product that, due to its special composition or preparation method, is significantly different from traditional food and, according to the information on the packaging, is marketed to meet the special nutritional needs of specific groups of recipients (e.g., patients) [2]. Foodstuffs for special nutritional purposes are products that must meet both the requirements for commonly used foodstuffs, as well as special requirements as to composition and production method [2]. The rationale for their use is often medical. Therefore,

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this category of food is very important for certain groups of consumers and is used in certain conditions/diseases as a partial or exclusive source of nutrition [3, 4, 5, 6, 7, 8].

Foodstuffs for special nutritional use include, in particular: foodstuffs dedicated to infants, foodstuffs dedicated to young children, foodstuffs for people on a diet, foodstuffs for physically active people (athletes), as well as foodstuffs used for certain diseases [9, 10]. Foodstuffs for special nutritional purposes, described in the act, include in particular:

1) infant formulae (infant milk), and follow-on formulae (follow-on milk);
2) supplementary foodstuffs, including processed cereal products and other foodstuffs for infants and young children aged one to three years;
3) foods used in energy-restricted diets for weight reduction;
4) dietary foods for special medical purposes;
5) foodstuffs to meet the needs of the body during intense physical activity, especially athletes;
6) foodstuffs for people with disorders of carbohydrate metabolism (diabetes);
7) low-sodium foods, including low-sodium or sodium-free dietary salts;
8) gluten-free foods [2].

Unlike dietary supplements, which are intended to supplement a well-balanced diet rather than replace it, foods for special nutritional purposes can be used as an exclusive nutrition source under the control and prescription of a physician. It should be noted that the issue of the correct classification of a product as a food for special nutritional use was addressed by the Court of Justice of the European Union (CJEU) in a judgment published on 27 October 2022, which stated that: '*for the purposes of such classification, it is not sufficient that the patient, by consuming that food, derives a general benefit from it, as the substances contained in it counteract the disorder or alleviate its symptoms*.' Therefore, it is necessary, based on clearly defined criteria that such foods must meet in order to be classified, as food for special nutritional use [11]. According to Article 24 of the Act in question, foodstuffs for special nutritional use must meet the requirements specified for foodstuffs in general use, as well as certain specific requirements: in terms of composition and method of production. It needs to be emphasized that foods for special nutritional use are fundamentally different from both ordinary/traditional foods, dietary supplements, as well as typical medicinal products.

All of the above-mentioned products, due to their different purposes and specific characteristics, are subject to separate regulations. A foodstuff for special nutritional use, dedicated to the most demanding group of consumers, i.e. infants and young children, significantly affects their growth, maturation and development. It is often a product that is the child's sole source of nutrition, and in this regard must meet very strict safety standards and nutritional needs consistent with the child's age and state of health. Such a product must not contain in its composition any substances in amounts that endanger the health and life of consumers, and their labels must reliably and unambiguously inform about the composition and purpose of these products [6, 13]. At the same time, the label must be legible and not mislead the consumer [7]. Similarly, products dedicated to people with health problems, whose metabolic processes are disturbed, must have a well-defined composition, and their nutritional properties should be confirmed by scientific studies and adapted to the health needs of these people. In the case of consumers burdened with health problems and malnourished, foods for special nutritional purposes are used, as a partial or even exclusive source of nutrition, and therefore must also fully meet the specific nutritional needs of these people. The presentation of food for special nutritional purposes, as well as its advertising, should allow the safe use of such food without attributing to it the property of preventing or treating diseases [10]. The provisions of the Act specify the possibility of advertising such means in a very limited scope, which, it should be pointed out, prohibits:

1) advertisement of infant formula in places where it is sold (e.g., in a pharmacy);
2) conducting promotional activities, e.g., in a pharmacy, such as giving out samples, special promotional displays, discount coupons, premiums, special sales, bundled sales, encouraging the purchase of infant formula and infant feeding items;
3) offering or providing infant formula and infant feeding items by manufacturers or distributors, samples of infant formula and infant feeding items (other promotional items) to consumers, especially pregnant women, parents of infants or their family members, directly or through health care providers, free of charge or at a reduced price [2].

Correct and legible labeling of food products, including special dietary foods, is very important. A product's label should have a primarily informative function, with only an additional promotional function. The label is a very important source of data about the food product for the consumer, and above that it can play an educational and warning role [13]. The label of a product must clearly indicate its characteristics and must not mislead the consumer about the properties and purpose of this product. In the EU market, food product certification systems are used. For example, proper labeling of an organic product should include the EU logo of organic production, the number of the certification body, as well as the place of production of such a product [14]. It is worth noting that the multiplicity of food products on the market hinders their unambiguous classification into the correct group not only by consumers, but also by pharmacists or physicians. Often the exclusive source of information on a product is the leaflet and label. However, the form of food product, packaging, advertising, or information about it can be confusing and even misleading to the consumer. As a result, the consumers are not aware of what they are in fact taking: a drug, a dietary supplement or a foodstuff for special nutritional purposes, and what the differences between these three groups of products are [10]. Therefore, it is important to define the different food products in a precise and understandable way to ensure their transparency and safety of use. Foodstuffs for special nutritional purposes must meet both the requirements for traditional foodstuffs, as well as specific criteria as to their composition and method of production [10]. Such agents are used for specific conditions/diseases, as a partial or exclusive source of nutrition, which is why their composition and health properties must meet quality standards [7, 8]. For example, formulas dedicated to infant nutrition must meet very strict requirements for their manufacture, quality and safety. In their composition, they must not contain any substances in an amount that can

harm the health of infants and young children, and must comply with the requirements for their composition and labeling. Information and recommendations on foodstuffs for special nutritional purposes may be addressed only to persons qualified in medicine, pharmacy or nutrition (nutritionists). This requirement is of particular importance for those who offer this type of remedy, namely pharmacists. Then the pharmacist, as a person who is qualified and has specialized knowledge, informs those interested about their action, specifics, purpose and safety of use. Then, by virtue of the fact that these remedies (or parts thereof) are covered by reimbursement, the pharmacist must verify the details related to the dispensing of a remedy subject to such reimbursement. In addition, information about such products can only be published in popular science or scientific studies, and its purpose is to promote medical knowledge only. The content provided must be supported by scientific studies and must not suggest that, e.g., artificial feeding is equivalent to or more beneficial than breastfeeding.

Dietary supplements. Dietary supplements are classified as foodstuffs and can also be offered in pharmacies, drug stores, and online sales in commercial form. Unlike medicinal products, they are not tested for persistence, interaction or pharmacovigilance [16]. In the European Union and Poland, dietary supplements are treated as foodstuffs, and their use is not intended to treat or prevent diseases among humans or to modify physiological functions [17]. In the US, a dietary supplement is defined as a product intended to supplement the diet. A dietary supplement contains one or more dietary ingredients (including vitamins, minerals, herbs or other plant constituents, amino acids and other substances) or their components, is intended to be taken orally in the form of a pill, capsule, tablet or liquid, and is specified on the front label of the product as a dietary supplement [21]. This definition emphasizes the typically dietary supplementary nature of such products, which is also to be reflected in the relevant description on the product label. Supplements are a form of food and are not medicinal products, and therefore do not contain information on potential health risks and other relevant information on the packaging [9]. However, it is worth noting the safety of their use and reactions with other medications taken [24]. For example, St. John's wort may reduce the effect of some anticancer and antiviral drugs due to an increase in glycoprotein activity [20, 21]. Since 2007, when the first such agent was presented, the sales growth rate and the value of dietary supplements market have increased manifold [28]. It is estimated that more than 80% of the world's population uses dietary supplements, or herbal medicinal products [19]. The 2017–2018 National Health and Nutrition Examination Survey found that the prevalence of supplement use among 3,683 children and adolescents in the US increased by 34.0%. It was observed that the use of supplements was higher among girls than boys, and the prevalence of supplement intake was age-dependent, with the highest among children aged 2–5 years (43.3%), followed by those aged 6–11 years (37.5%) [31].

In Poland, this phenomenon was studied in 2018, and the results of a study conducted in Lesser Poland among 332 children show that one-third (33.8%) took dietary supplements, most often containing vitamin D and C, followed by multivitamin supplements and omega-3 fatty acids [21]. In another study (conducted on caregivers of 743 children), 40% of children aged 6–12 had taken dietary supplements in the year prior to the survey [27]. It was confirmed that parents pass on their own health behaviour patterns to their children. Parents who have taken/are taking dietary supplements themselves give these products to their children [28]. In a study of preschool children in Kraków, 21.7% of parents 'supplemented' their children daily [29]. A 2015 study reported that taking dietary supplements is common among children, especially those of school age (32.4%) [30].

Dietary supplements represent a large market that also benefits from marketing solutions. Through various types of advertising, e.g. marketing, promotions, participation of athletes and celebrities, Internet personalities, sales and popularity of dietary supplements are increasing. The effect of such specifics indicates that they should be a supplement to the diet, and are almost becoming a separate category of means and substances that affect the fitness or vitality of the body. Dietary supplements are designed to meet the specific requirements of different groups of consumers. Differences and similarities in the context of promotion and perception of drugs and dietary supplements can be important in the social context [32].The composition, appearance and purpose of such preparations make them confusingly similar to drugs [32, 33]. Supplements are popular, but at the same time there are risks associated with their irresponsible intake, such as overdosing, combining different types, and combining with drugs. A separate category of risk has to do with their composition, which may be contaminated, for example, with heavy metals or other harmful substances. The presence of hazardous substances, questionable or restricted compounds in a product is undoubtedly dangerous to human health [33, 34, 35]. There may also be adulterated dietary supplements on the market, the actual composition of which differs from that presented on the packaging. It is also important to keep in mind the real danger of taking too many supplements (such as vitamins and minerals).

An audit conducted in Poland by the Supreme Chamber of Audit showed that the system of supervision over the introduction of dietary supplements to the market did not provide adequate protection for consumers [34]. The audit identified 20 dietary supplements offered on the Internet containing ingredients that are not permitted in food and may endanger health. Unauthorized ingredients were found in the composition of 36 products, the use of which is not permitted in dietary supplements [34]. The market for supplements continues to grow dynamically, which is related to the prevalence of this category of products in the mass media, the relatively hassle-free procedure for entering the Polish market, and their widespread availability (they can be purchased at pharmacies, herbal and grocery stores, as well as online) [36]. The dynamics of the market value in dietary supplements should also be compared with the number of notifications to the Chief Sanitary Inspector, which are notifications about the introduction of a product for the first time to the market in the territory of Poland. Between 2017 and 2020, the Chief Sanitary Inspector received 62,808 notifications about the introduction or intention to introduce dietary supplements to the market for the first time [34]. In Europe, Regulation (EC) No. 1924/2006 of the European Parliament and of the Council of 20 December 2006 on Nutrition and Health Claims Made on Foods and Directive 2002/46/EC of the European Parliament and of the Council

of 10 June 2002 on the approximation of the laws of the Member States relating to food supplements describes dietary supplements as: 'foodstuffs intended to supplement the normal diet and which are concentrated sources of nutrients or other substances having a nutritional or physiological effect, whether single or combined, sold in dosage form (capsules, lozenges, tablets, pills and other similar forms, as well as sachets of powder, ampoules of liquid, dropper bottles and similar forms of liquids or powders) intended to be absorbed in small measured unit quantities' [39,40].

Supplements are intended to supplement the diet, i.e., they are intended to supplement human nutrition, naturally, if there is a need, thus supplements are categorized as food. It is Directive 2002/46/EC of the EP that implies a distinction between dietary supplements and medicinal products (a product that has the properties of a medicinal product does not constitute a dietary supplement). Supplements cannot have a medicinal effect, such as typical drugs (a substance introduced into the body in pharmaceutical form to achieve a desired therapeutic or curative effect). EU Regulation No. 1169/2011 of 25 October 2011 on the provision of food information to consumers, amending Regulations (EC) No. 1924/2006 and (EC) No. 1925/2006 of the European Parliament and of the Council, and repealing Commission Directive 87/250/EEC, Council Directive 90/496/EEC, Commission Directive 1999/10/EC, Directive 2000/13/EC of the European Parliament and of the Council, Commission Directives 2002/67/EC and 2008/5/EC, and Commission Regulation (EC) No. 608/2004, sets out the principles, requirements and scope of information on so-called 'food labeling', i.e. general information placed with food offered (including dietary supplements) [41].

In Poland, the Regulation of the Minister of Health on the composition and labeling of dietary supplements, specifies requirements for the labeling of dietary supplements, the level of vitamins and minerals present in dietary supplements, in the manufacturer's recommended daily portion of the dietary supplement consumed, as well as the minimum amount of vitamins and minerals present in dietary supplements in the recommended portion to be consumed during the day [42]. Dietary supplements released to the market must be labeled with the following information on the package: 'dietary supplement', the name of the category of nutrients or substances characterizing the product, an indication of the nature of such substances, and the dose of product recommended for consumption during the day. The following information must also be displayed:

1. warning: not to exceed the stated recommended daily dose;
2. statement: that dietary supplements should not replace a balanced diet;
3. statement: that the product should be kept out of the reach of young children [42].

The *Act on Food and Nutrition Safety* specifies in Chapter 7 that dietary supplements may contain in their composition vitamins and minerals that naturally occur in food and are consumed, as a part of food, and other substances that show a nutritional or other physiological effect. Ingredients of dietary supplements can be: vitamins, minerals, other ingredients, e.g. fatty acids, dietary fiber, lutein, probiotics and prebiotics, plant ingredients and preparations. The content of minerals and vitamin present in a dietary supplement is declared in the labeling in graphical or numerical form per daily declared by the manufacturer and as a percentage of meeting the reference intake values [2].

Data from the financial turnover of the analyzed wholesale and retail entities (wholesalers, pharmacies) from the Lublin Province show a noticeable dynamics of sales of the products in question over 3 years (2021–2023) (Tab. 1). Naturally, in the context of interpreting the present results, the analysis concerned special dietary agents and dietary supplements, sales of which tend to increase. The percentage of special foodstuffs and dietary supplements has, also from the point of view of pharmaceutical wholesalers, a measurable financial significance. The data presented below prove the growing interest of buyers (pharmacies), in these products due to the demand for these products reported by patients and consumers. In the data presented, it is possible to note the scale of turnover and sales of foodstuffs for special nutritional purposes and dietary supplements in wholesalers and pharmacies from the Lublin region. The growing role of dietary supplements can be seen in the sales of these products, but mainly in pharmacy sales, less in wholesale. Nevertheless, it should be recognized at the same time that dietary supplements account for a significant part of turnover and wholesale sales, and the percentage of these products in the turnover of pharmacies is significant and growing. At the same time, the exact scale of the purchase of dietary supplements by interested parties would be more difficult to estimate, as some of them remain outside the main distribution chains (due to sales on the Internet, directly from the manufacturer, or according to other forms of sales).

According to the *Act on Pharmaceutical Law,* a pharmacy is a public health care facility in which authorized persons provide, in particular, pharmaceutical services included in the regulations. Foodstuffs for special nutritional purposes and dietary supplements are products that are available for purchase to interested parties or patients, in pharmacies as well as on the Internet (where sales of dietary supplements, e.g., are rapidly growing) [43]. It is worth noting that a pharmacist working in a pharmacy selling these products should provide counselling in patients' pharmacological self-medication based on non-prescription products (Article 86. 2b. item 2) [44]. Accordingly, the pharmacist should inform people wishing to purchase such products (especially dietary supplements) about the properties and use of a particular product, its specific use, or safe dosage. Also, it is necessary to inform about possible dangerous interactions with other products, mainly medicinal products, food, or similar products.

Data from pharmacies in the Lublin Province show that the turnover of dietary supplements is clearly increasing. The percentage of dietary supplements in total pharmacy turnover was 9.71% in 2021, followed by 9.88% in 2022, while in 2023 it was almost 10%. Pharmacy sales of dietary supplements increased from 10.98% in 2021 to 11.67% in 2023. Pharmacy customers are increasingly eager and willing to use dietary supplements available through pharmacy sales. This trend is clearly visible and deserves careful and long-term observation, taking into account detailed variables such as, among others: type of products most frequently purchased, possible variability over time/seasonality, profiles of customers reaching for dietary supplements, their motivations for purchasing the aforementioned products, and whether the use of dietary supplements has been consulted with a physician/recommended by a physician or takes place without any professional control.

The results of the present study are interesting as they indicate a very wide scale of the Polish population reaching for dietary supplements, and likely combining them with other foods, herbs and medicines. The topic of dietary supplements' percentage in overall pharmacy sales is a topical issue and deserves extended analysis, as the results obtained by the authors prove that the value of dietary supplements market in Poland is huge and is growing dynamically. It should be noted that the study included only data from pharmacies located in the Lublin Province, which is one of the less affluent regions of Poland. It can be assumed that similar studies conducted in central or western Poland, may provide results indicating a different dynamics of sales of dietary supplements, as these products are available without a prescription, and their sales certainly correspond also to the material situation of consumers. Already in 2020, nearly 25,000 notifications were submitted to the General Inspection Service (GIS) regarding supplements entering the Polish market. In 2021, the number of dietary supplement manufacturers increased by 4.4%. There are nearly 30,000 entities in the market that sell or are associated with the production of such products [45, 46]. In Poland, the value of dietary supplements market in 2022 increased by nearly 12% in the pharmacy and non-pharmacy market combined [44, 46]. The value of this market amounted to PLN 7.7 billion, and the nominal growth rate was about 14% despite inflation [47]. Margins have left pharmacies with little opportunity to generate revenue from the sale of reimbursed drugs and instead focused efforts on increasing sales of non-prescription drugs and dietary supplements, which are not subject to margin regulations. Nonetheless, taxed products were still a very important source of revenue for pharmacies, and their owners would certainly be interested in increasing their sales in their outlets.

Limitations of the study. This study has several limitations. The analysis was based on data obtained from pharmacies and pharmaceutical wholesalers located only in the Lublin Province, which may have limited the extrapolation of the findings to the entire country. Regional differences in socio-economic status and consumer behaviour may influence the sales dynamics of dietary supplements and foodstuffs for special nutritional purposes. Therefore, further analyses involving multiple regions of Poland are warranted.

CONCLUSIONS

The provisions of the *Act on Food and Nutrition Safety* (Chapters 6 and 7) describe foodstuffs for special nutritional purposes and dietary supplements. They are sold in pharmacies and drugstores, and therefore it is necessary to have knowledge of their purpose and use (either as a typical dietary supplement, or as a special-medication diet prescribed by an authorized person). This group of products also includes remedies for certain health disorders and diseases, thus their purpose is significant. The described types of specifics are clearly separated from medicinal products in European as well as national law, as typical drugs. That is, they are listed in food law, as in the cited Act. In spite of this, their offering and use resemble, and especially in a pharmacy, the marketing of traditional medicines. Therefore, when they are offered, certain information should be provided by the pharmacist, either in written form (leaflets) or verbally, based on specially designed labels and markings. Such information should be reliable, not misleading about their use, and the labeling of such products should be clear, without suggestive references to medicinal products.

The offering and sale in pharmacies of various means, other than typical medicinal products (drugs), is a noticeable change in the specificity of this place and the range of products offered is being expanded to include dietary supplements, or small medical equipment. Naturally, typical medicinal products continue to be the main domain of operation, turnover and profit of pharmacies as public health institutions. It is worth noting that in case of damage caused by such specifics, the liability is borne by its manufacturer under the rules of the Civil Code. This data is important for the presentation of the market for pharmacy products dispensed without a prescription or with special dietary purposes, and thus encourages more in-depth analysis on the scale of several provinces or even the country.

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