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Monika Dąbrowska, Małgorzata Starek

Talking about dietary supplements

Introduction

A dietary supplement, known also as nutritional product or food supplement, is intended to provide nutrients, that may be missing or may not be consumed in sufficient quantities in a person's diet. They are defined as foods in some countries, while in others – as natural health products or even drugs (http://healthywellbeing.info). Dietary Supplement Health and Education Act (DSHEA) defines dietary supplements as: a dietary substance to supplement the diet by increasing the total dietary intake (e.g. tissues, enzymes secreted by organs or glands), a vitamin or mineral, an herb or other phytochemical, an amino acid, or a concentrate, metabolite, or extract. Summarizing, dietary supplements are not meal or food substitutes in occurring in natural form. The DSHEA permits only sorts of statements on tags of dietary supplements such as: nutrient content (e.g. "rich in magnesium"), "structure-acting" or nutrition assistance, e.g. "vitamin C (ascorbic acid) averts scurvy" or "zinc strengthens nails", and diseases claims. Food and Drug Administration (FDA) authorizes only that last, based on a scientific research. Furthermore, the statement: "This statement has not been evaluated by the FDA. This product is not intended to diagnose, treat, cure, mitigate, or prevent any disease" must be placed on the dietary supplements label (Mechanick 2003).

The proper diet of healthy people provides properly balanced nutritional components of daily intake of foods. Only in the event of occurrence of some disorders, hyponutrition or malnutrition there is a need to correct the physiological or metabolic imbalance to re-establish homeostasis. Nutritional deficiency that could come into during illness, malnutrition resulting from eating disorders or hyponutrition from excessive physical effort may be corrected through the intake of dietary supplements. People who are malnourished as a result of for example cancer may benefit from some supplements to complement deficiency in essential biomolecules, e.g. people suffering from incorrect stool composition may increase their intake of fiber through supplements rather than eating volume quantities of meal. Sportspeople who exposed their organisms to intensive physical training and effect injure, benefit from supplements containing mainly protein to rebuild damaged muscle, mineral and vitamin to optimize restorative processes and align

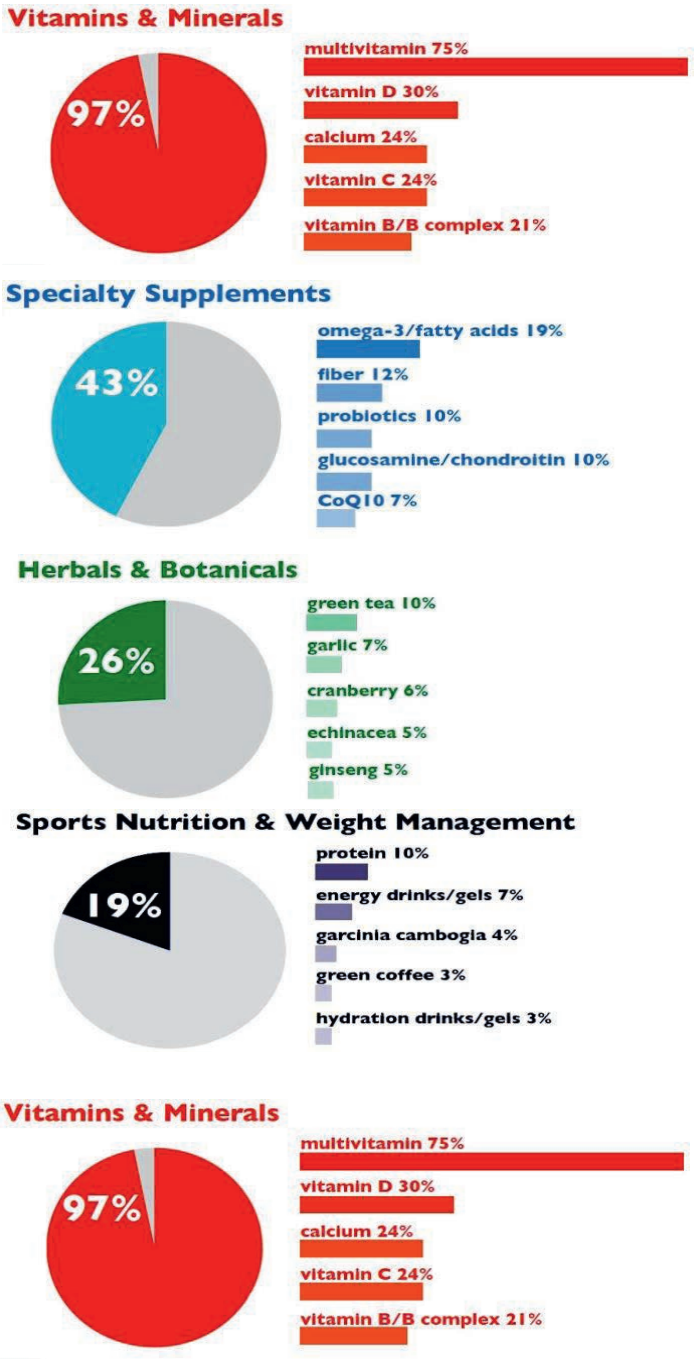
for the decline of minerals via excretory pathways (i.e. sweat or urine). Thus, under special conditions, dietary supplements can be an alternative to ingesting sometimes intolerable quantities of food (www.mwdicalwellnessassociation.com).

The dietary supplements are defined as products composed of nutrients, treated as a supplement to usual diet, located on the market in a shape that allows dosing. The form of dietary supplements, and pharmacy – a place of purchase, may insinuate a strong connection with the drug. Meanwhile, according to European Union legislation, dietary supplements were not and are not medicine! In Poland, The Chief Sanitary Inspector, not the Chief Pharmaceutical Inspector and the Office for Registration of Medicines and Biocidal Products in Poland as is the case with medicines, is responsible for the admission of dietary supplements to the market (www.krsio.org.pl/pl).

Currently, supplements can consist of minerals, vitamins, amino and fatty acids, herbals and/or botanicals enzymes, and many other substances. They may be in various dosage forms e.g. capsules, tablets, powders, as well as energy drinks and bars. They are not drugs and are not used to cure, treat or prevent diseases. Dietary supplements are food products intended to complement the diet. If the diet is deficient in certain nutrients, some supplements can help to get appropriate amounts of substantial aliments. However, it should be remembered that supplements cannot replace a balanced diet (http://ods.nih.gov).

Consumption of dietary supplements

In the 1990s, a significant demand for supplements was observed. Nearly 100 percent Between 1992 and 1996, sales of dietary supplements increased by nearly 100% – from 3.7 billion to 6.5 billion $. In 1999, the industry grossed an assessed 15.4 billion $. Over 1,500 manufacturers produce dietary supplements (by the FDA). Nowadays, dietary supplements are commonly available in pharmacies, grocery stores with healthy food, and on the Internet (www.dhhs.gov/oig/oei). In the United States (US) most adults consume one or more various dietary supplements (either occasionally or every day). Roughly 6 in 10 Americans consume some kind of dietary supplement, and approximately 1 in 6 eats herbal remedies systematically. The variety of manufacturers and production processes, as well as quality control matter are tremendous (Gershwin et al. 2010). The consumer reaches for compliments to support or improve health (maybe to lose weight, supplement a vitamin and minerals deficiency, or support organ action) frequently believing them to be quite natural, pure and powerful than food or drugs. Dietary supplements with claiming a broad range of health benefits are widely available, and the consumer may think that they have been proven potent. Their labels do not have to list risks or contraindications, and the consumer may posit that they are safe. Unfortunately, in some case the recipient may be mistaken (www.health.ny.gov/regulations/task_force/docs/dietary_supplement_safety.pdf). Many people select to take supplements, but taking too much or taking them for too long could be harmful (figure 1).


Vitamins & Minerals
97%
multivitamin 75%
vitamin D 30%
calcium 24%
vitamin C 24%
vitamin B/B complex 21%
Specialty Supplements
43%
omega-3/fatty acids 19%
fiber 12%
probiotics 10%
glucosamine/chondroitin 10%
CoQ10 7%
Herbals & Botanicals
26%
green tea 10%
garlic 7%
cranberry 6%
echinacea 5%
ginseng 5%
Sports Nutrition & Weight Management
19%
protein 10%
energy drinks/gels 7%
garcinia cambogia 4%
green coffee 3%
hydration drinks/gels 3%
Vitamins & Minerals
97%
multivitamin 75%
vitamin D 30%
calcium 24%
vitamin C 24%
vitamin B/B complex 21%

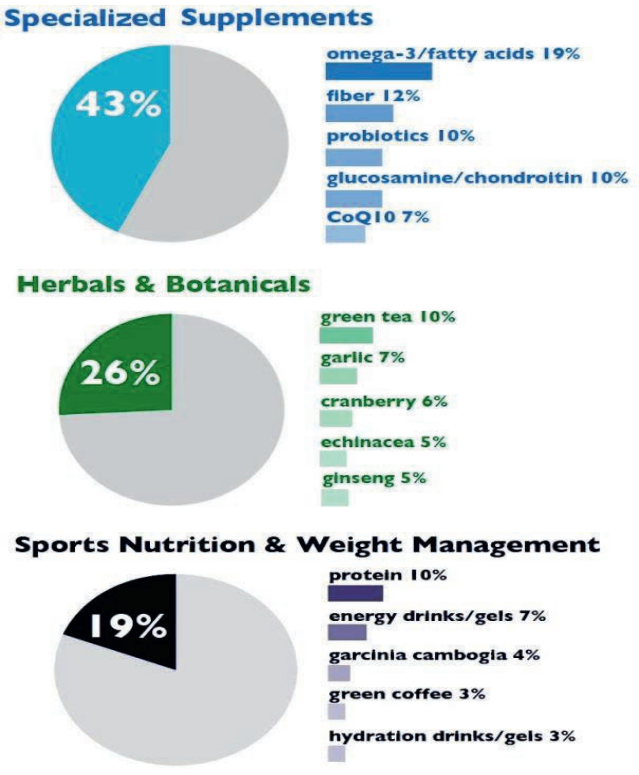


Fig. 1. The percentage of preparations in the most popular categories (www.crnusa.org/CRNconsumersurvey/2014)

Legal regulations

Quality of all prescription drugs are adjusted in the United States by the FDA. As unit of its duty to monitor supplement safety, the FDA look after reports of malady, harm, or side reactions from supplements (www.cancer.org/treatment/treatments-and-side-effects/complementary-and-alternative-medicine/dietary-supplements.html). Supplements are considered more like particular foods. Because supplements are not drugs, they are not subject to the same exact safety and efficacy requirements that medicines are. All the drugs that people can get even without a prescription, must be proven secure and potent, but dietetic supplements do not. When the FDA affirms the drug, it must be manufactured under carefully monitored conditions and packaged with complete information on the best portion, way and schedule. The attached information must also include conditions the drug has been proven to cure, certain incidental effects, contraindications (special conditions under which using

the drug should not be used because it would cause too much risk), and hazardous interplays with other consumed drugs.

The DSHEA, in 1994, designated dietary supplements as a section of food, which puts them under separate regulations than drugs. They cannot claim none of them has "a significant or unreasonable risk of illness or injury" when the supplement is being used as directed on the label, and also with proper use if there are no directions on the tag. Manufacturers are not required to test new matters or supplements in clinical tests, which would help discover hazards and vital interactions with medicines and additional substances. When the FDA demonstrates that a dietary supplement constitutes an important risk to people's health, DSHEA gives the FDA permission to stop a manufacture from making a dietary supplement. This way, they are risky only after they provoke harm. Producers have to inform the FDA (at least 75 days) before marketing products containing new dietary substances, stating that a product containing the new dietary component that will rationally be prospective to be safe. The FDA must prove that a dietary product is unsafe, it can take action to limit, or remove the dietary supplement from the market (The Johns Hopkins University 2006).

Dietary products are ordinarily self-prescribed, so there is no controlled network for analyzing side effects and adverse reactions. If a dietary supplement has strange effects or interactions with foods, drugs, or other products of supplement, they are not surely to be discovered as quickly as new medicines (www.cancer.org/treatment/treatments-and-side-effects/complementary-and-alternative-medicine/dietary-supplements.html). Authority to control medicines and foods is divided between the governments (federal and state). In the US the Federal Trade Commission (FTC) and the FDA adjust food supplement labeling, announcement and marketing. The FDA takes primary responsibility for product labeling, both food and supplement, while the FTC aligns its marketing and advertising. For supplements, the most important amendment is DSHEA. In 1994, the Congress adopted DSHEA grounded on the reason that "legislative action that protects the right of access of consumers to safe dietary supplements is necessary to promote wellness" (www.dhhs.gov/oig/oei). The provisions of DSHEA designate and enlarge the sense of dietary supplements and its ingredients, institute a new organization for evaluating safety, draft guidelines for writing displayed where supplements are sold, yield outlines for the use of claims and nutritional assistance statements, demand component and nutrition labeling, and give the FDA the control to establish good manufacturing experience regulations. Furthermore, DSHEA demands the creation of an executive level Commission on Dietary Supplement Labels and an Office of Dietary Supplements (ODS) within the National Institutes of Health (NIH). Deficiency of DSHEA are the impossibility to address the lack of scientifically based reference about safety, observed virtual to causing damage, absence of suitable scientific reason of clinical advantage, DS/N manufacturing process. Patients have to be alert to the eventuality of deceitful products, which are often named by pseudomedical slang as a new discovery, purify, detoxify, energize, or a secret, miracle and cure. The DSHEA does not claim demonstration of efficacy and safety, and also no regulatory

method exists for quality control and that is no procedures inspect that the correct volume or even the proper constituent has been manufactured (Mechanick 2003).

Federal adjustment of food supplements is far away from versatile. Albeit some dietary products are generally more like drugs than foods, they are commonly adjusted as foods. Given the absence of effective federal oversight of the production process, dietary supplements are adjusted less precisely than typical foods. Producers make claims that supplements act or support the functioning and structure of the human body, and can ensure a benefit related to cure of a standard nutrient deficiency illness, and promote global well being, without the need to provide substantiating data to the FDA (www.health.ny.gov/regulations/task_force/docs/dietary_supplement_safety.pdf). According to DSHEA, supplements may affect the structure or/and function of the human body, but not to prevent, treat, cure, mitigate disease, e.g. "retains urinary tract health" is permitted, but "treats urinary tract contagion" is not, and that is why it is often hard to distinguish the two sorts of claims. Major unfriendly reactions with food supplements have been reported. The FDA may issue warnings to consumers and require from the to issue a recall of a product, but producers are not obliged to withdraw a product from the market unless it is shown to be a "near hazard" to consumers (Harris 2000).

The DHHS (Department of Health and Human Services) guidelines require that supplements follow standard procedures named Good Manufacturing Practices (GMPs). It means, that supplements have to be manufactured in a quality manner, not include any impurities and contaminants, be labeled with the substances that are truly in the product.

The US Pharmacopeia (USP) is an independent framework dedicated to quality control for the strength, quality, and purity of pharmaceuticals. In the 1997, USP started publishing patterns for supplements, which focus on the quality, purity, strength, labeling and packaging. Producers of dietary products are not required by law to follow USP standards, but many of them have chosen to do so. Manufacturers are expected to follow FDA recipes, but the USP sign indicates that they choose to follow higher quality norms (www.cancer.org/treatment/treatments-and-side-effects/complementary-and-alternative-medicine/dietary-supplements.html). In European Union (EU) countries, the European Commission is the body responsible for creating the law related to the pharmaceutical sector. European Commission works with the European Medicinal Agency (EMA) and the European Food Safety Authority (EFSA). The EMA is mainly responsible for protecting and promoting human and animal health, evaluating medical products for human use, and for veterinary purposes. On behalf of the EMA, Committee on Herbal Medicinal Products deals with the topics and problems of plant medicines, created as part of the EMA.

In Poland, the body that evaluates medical products is a Chief Pharmaceutical Inspectorate (GIF) and Office for Registration of Medicinal Products, Medical Devices and Biocidal Products. Whereas, the market for dietary supplements, which belongs to the food category, is supervised by Chief Sanitary Inspectorate (GIS) (Baraniak, Kania 2015). Other organizations were also established, such as The Polish Council for Supplements and Nutritional Foods (KRSiO), which actively cooperates with the Ministry of Health on the shape of planned changes in the market for dietary

supplements. A competent team at the Ministry of Health deals with the amendment of food law in the field of dietary supplements. It proposes to create a transparent administrative procedures for reporting and verification of dietary supplements, which will organize the dietary supplements market in terms of eliminating marketing illegal products (www.krsio.org.pl).

Hazards associated with the consumption of dietary supplements

The dietary supplements should be used mainly by healthy people, the purpose of the products is not to treat illnesses (www.krsio.org.pl). Albeit dietary products have a long history of providing good to extraordinary benefits for health, for people who take them, they provide no health profit at all (Wheatley, Spink 2013). Many supplements contain active components that can give strong effects in the body. The properties of ingredients used in the production of supplements vary widely, some of which may have adverse effects if consumed in too large quantities. It is therefore very important to know the safe doses of each ingredient (www.krsio.org.pl).

People should always be aware of the possibility of sudden side effects, especially when they take a new supplement. Moreover, a lot of interactions can arise between drugs, herbal medicines and daily food leading to serious clinical implications (Baraniak, Kania 2015). Supplements are most probable to cause harm or side effects, especially when people consume them instead of prescribed drugs or when people take many various products in combination. Some of them can increase the risk of bleeding and if someone takes them before or after surgery, they can affect the anesthesia, while vitamin K can reduce the capacity of the blood thinner Coumadin® to prevent blood from coagulating. Eating more than people require is always more costly and can also pick up the risk of experiencing side effects, e.g. taking too much vitamin A can cause liver damage or headaches, birth defects or reduce bone strength (http://ods.nih.gov). Consumers' safety can be at venture due to flaws in the EU and domestic legislations. They are exposed to potentially major side effects, deceptive evidence and to the endangering of wasting money for creations that do not live up to the engagements they make (Passarani 2016).

Most people are capable of getting all the substantial nutrients from a balanced diet. Minerals and vitamins are important nutrients that human body needs in reasonable amounts to work properly. However, if people already choose to take supplements containing mineral and vitamin, they should be conscious that taking them for too long or too much can cause some harmful effects (http://healthywellbeing.info). The use of dietary supplements is common among people doing sports. Athletes should be informed that some dietary supplements can match the excessive performance and health claims, that are frequently posed for them. A few dietary supplements may have something to give in terms of health security or yield increase, but cannot equate an adequate diet. The venture of an unfavorable outcome, in particular, a positive doping test, remains real, and the hazards of dietary supplement use must be put versus the virtual rewards (Maughan 2011).

Advantages and Disadvantages

Various studies on dietary supplements are designed to provide beneficial effects and thus do not assess complete safety information. Albeit there is agreement that dietary supplements should be estimated in light of present knowledge of medical and pharmaceutical chemistry, there is a common lack of interest in herb and drug interactions within both pharmaceutical and herbal industries. The deficiency of research can also be ascribed to narrow funding for clinical tests. For consumers that do not eat diverse meals, selected food supplements, including minerals and/or vitamins, can be taken to guarantee adequate consumption of needed nutrients. It is substantial to note, that not all dietary supplement use correlates to incomplete dietary consumption. Data on the profits and hazards of dietary supplements is frequently unavailable and inconclusive. The lack of proof of injury does not necessarily indicate that a food supplement is safe but rather that there is no data to the contrary. The FDA does not assess the quality, efficacy and safety of food supplement products and its constituents. Consequently, consumers, who frequently think that natural is synonymous with safe should be taking food supplements at their own risk. Excessive consumption, delaying conventional medical cure, the concomitant use of supplements and pharmaceuticals, and contraindicated use are potential dangers associated with common dietary supplements. Therefore, because the preparations are not subject to standardized quality monitor measures, contamination, falsification and dosage inconsistency. Although the curative effect of supplements hinges on their potency, there are no federal standards for dosage and purity, and the dose studies that are mandatory for pharmaceuticals are seldom, if whenever, done. For many dietary supplements, active substances have not been identified and the quantity required to have an impact has not been checked. Inferior processing training can lead to inaccuracies in product labeling; products may include lesser or greater amounts of constituents given on their label, and the concentrations of active substances can vary among and within brands. Consumers may not know how much of any individual ingredient they consume (www.health.ny.gov/regulations/task_force/docs/dietary_supplement_safety.pdf).

Botanicals is a division of dietary supplements which is often in question because many botanical supplement ingredients are not derived from plants commonly used for meal, and safety and efficiency often have not been set with randomized, and controlled with using placebo clinical experiments (Camire, Kantor 1999). Botanicals, as well as herbals, have been used medically for thousands of years. Once it was considered “traditional medicine” used by aboriginal and ancient cultures, herbal medicine has become a popular alternative, complementary and supplement of modern medicine. Despite the natural descent, these substances should be taken with wariness, as their intake may have side effects (www.ext.colostate.edu). The accumulation and schedule of phytochemicals in medicinal vascular plants varies in the fruits, roots, flowers, stems, leaves and also vary during the cycle of growth or season. Moreover, plants or connected species similar in appearance may have greatly miscellaneous chemical compositions, e.g., the composition of ginseng grown in Korea (Panax ginseng C.A. Mey) is separate from that of the native American plant (Panax

quinquefolius L.). This may form difficulties in formulating botanical supplements with consistent ingredients and potencies and presents challenges for untrained plant pickers (Camire, Kantor 1999). The impurity of raw plant tools and completed products with pesticides, bacteria, molds, fungi, and mycotoxins constitutes another question with potentially heavy health consequences (Gershwin et al. 2010). Many people trust that any food and food supplement in its present occurring, unprocessed condition is safer and better than those that is manufactured. This is not necessarily accurate. Some of the most hazardous substances in the world exist naturally, e.g. toxic mushrooms and poison oak or ivy are extraordinarily poisonous to people but are totally natural (www.breastcancer.org/tips/nutrition/supplements). The huge majority of botanical supplements mark only slight promises such as healthy hair, nail, joints etc.

Whatever the gradation of the popularized improvement it is essential to warrant that clients can trust the claims on dietary supplements. They should not spend their money on manufactures bearing false promises. Accordingly, botanical claims exactly like other claims on foods should yield a rigorous research assessment according to the highest eventual standards (Passarani 2016).

Summary

Consumers take dietary supplements for various reasons, commonly connected to their health. They expect these will improve vitality, limit the signs of ageing, prolong life, treat particular complaints and reduce the risk of a chronic illness (e.g. cancer). The main cause is, for general, health and well-being (www.nhs.uk). Particular factors contribute to the progressive intake of dietary supplements. People are drawn to supplements because of their nonprescription availability, publicity straight to consumer, and the perception that natural products are practically safe. Furthermore, prevalent media attention to dietary supplements forwards the open message, that they may self medicate for in a number of cases. Unluckily, most consumers are mistaken about the low regulation of supplements, trusting that they must be accepted by a government office, that producers can make claims about effectiveness and safety only if there is reliable scientific proof to back it up, and that warnings about potential side effects or hazards are required (www.health.ny.gov/regulations/task_force/docs/dietary_supplement_safety.pdf). Before purchasing a dietary supplement consumers should be informed by a competent person (doctor or other health care providers) about how to buy a safe and healthy product.

Recommendations for consumers interested in purchase and the safe use of dietary supplements:

- investigate before you buy or use;
- if you are shopping for a botanical (herb or other plant-based supplement), find a product that uses only the part of the plant that is thought to be helpful;
- avoid products that claim to be “miracle cures,” “breakthroughs,” or “new discoveries,” as well as those that claim to have benefits but no side effects, or are based on a “secret ingredient” or method;

- try to avoid mixtures of many different supplements. The more ingredients, the greater the chances of harmful effects;
- if you have any surgery or procedure planned, including dental surgery, talk with a surgeon about when you should stop taking supplements;
- during pregnancy or if you are breastfeeding, take only dietary supplements prescribed or approved by a doctor;
- do not take any self-prescribed remedy instead of the medicine prescribed by doctor without talking about it with him;
- do not depend on any non-prescription product to cure cancer or any other serious disease,
- follow the dosage limits on the label. Overdoses can be deadly;
- never give a supplement to a baby or a child under the age of 18 without talking to the child's doctor;
- avoid products that claim to treat a wide variety of unrelated illnesses (www.cancer.org/treatment/treatments-and-side-effects/complementary-and-alternative-medicine/dietary-supplements.html).

You must remember:

I. Dietary supplements do not cure!

II. Consult your doctor or pharmacist on the selection of dietary supplements. Find out if the purchased preparation is a dietary supplement or a drug!

III. Dietary supplements are food!

IV. If the deficiency of important health components caused the disease, then you need a drug, not a supplement!

V. Supplements can come in drug interactions hazardous to health and life!

VIII. Dietary supplements can be overdosed!

IX. Dietary supplements are not subject to strict supervision! (www.izba-lekarska.org.pl).

No matter what type of cure you are choosing, it is always safest to ask your doctor about the kind and constituents of each dietary supplement you want to test. Do this before you buy it or begin taking anything new (www.cancer.org/treatment/treatments-and-side-effects/complementary-and-alternative-medicine/dietary-supplements.html).

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Talking about dietary supplements

Abstract

Nutritional deficiency that could occur during illness, eating disorders or hyponutrition from excessive physical training (in athletes) may be corrected through the intake of dietary supplements. The proper diet of healthy people provides correctly balanced nutritional

components of daily intake of foods. Only in the event of some disorders or malnutrition there is a need to correct the physiological or metabolic imbalance. Under special conditions, dietary supplements can be sometimes an alternative to ingesting intolerable quantities of food. In many countries a dietary supplements are define as foods, which complements a diet with a healthy ingredients e.g. vitamins, minerals, amino and fatty acids, herbals and/or botanicals enzymes, and many other substances. These are defined as products composed of nutrients, treated as a supplement to usual diet, located on the market in a shape that allows dosing. The form of dietary supplements, and pharmacy as a place of purchase, may insinuate a strong connection with a drug. Nevertheless, they are not drugs and are not used to treat or prevent diseases. These are food products intended to complement the diet. For this reason supplements are not subject to the same exact safety and effectiveness requirements that medicines are. When the controlling organizations (such as FDA) affirms the drug, it must be manufactured under carefully monitored conditions and packaged with complete information on the best portion, way and schedule. The attached information must also include conditions the drug has been proven to cure, certain incidental effects, contraindications (special conditions under which using the drug should not be used because it would cause too much risk), and hazardous interplays with other consumed drugs. Such information is not required in the case of supplements. However, it is very important that the consumers, before buying dietary supplement, are informed by a competent person (doctor or other health care providers) in order to buy a safe and healthy product. Especially since consumers take dietary supplements for a variety of reasons, commonly associated with their health and improving the condition of the body.

Key words: dietary supplements; nutritional deficiency; application safety; consumer awareness

Monika Dąbrowska, dr hab.
Department of Inorganic and Analytical Chemistry, Jagiellonian University Medical College, Krakow, Poland
email: monika.1.dabrowska@uj.edu.pl

Małgorzata Starek, dr hab.
Department of Inorganic and Analytical Chemistry, Jagiellonian University Medical College, Krakow, Poland
email: m.starek@uj.edu.pl