38. Thomson E. M. Air pollution, stress, and allostatic load: linking systemic and central nervous system impacts. *Journal of Alzheimer's Disease*. 2019. Vol. 69, No. 3. P. 597-614. DOI: https://doi.org/10.3233/JAD-190015

39. Trace element fractionation between PM10 and PM2.5 in coal mine dust: Implications for occupational respiratory health / Teresa Moreno et al. *Inter. Journal of Coal Geology*. 2019. Vol. 203. P. 52-59. DOI: https://doi.org/10.1016/j.coal.2019.01.006

40. Winter chemical partitioning of metals bound to atmospheric fine particles in Dongguan, China, and its health risk assessment / Lin Huang et al. *Environmental Science and Pollution Research*. 2019. Vol. 26. P. 664-675. DOI: https://doi.org/10.1007/s11356-019-05001-8

41. Wood Dust and Nanoparticle Exposure among Workers during a New Building Construction / Atin Adhikari et al. *Inter. Journal of Medical and Health Sciences.* 2018. Vol. 12, No. 3.

URL: //digitalcommons.georgiasouthern.edu/bee-facpres/6

42. Yang Gao, Hongbing Ji. Microscopic morphology and seasonal variation of health effect arising from heavy metals in PM2.5 and PM10: One-year measurement in a densely populated area of urban Beijing. *Atmospheric Research*. 2018. Vol. 212. P. 213-226. DOI: https://doi.org/10.1016/j.atmosres.2018.04.027

43. Zapor L. Effects of silver nanoparticles of different sizes on cytotoxicity and oxygen metabolism disorders in both reproductive and respiratory system cells. *Archives of Environmental Protection*. 2016. Vol. 42, No. 4. P. 32-47. DOI: https://doi.org/10.1515/aep-2016-0038

44. Zebrafish behavioral phenomics employed for characterizing behavioral neurotoxicity caused by silica nanoparticles/Li X. et al. *Chemosphere*. 2020.Vol. 240. P. 124937.

DOI: https://doi.org/10.1016/j.chemosphere.2019.124937

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STUDY AND ANALYSIS OF THE SITUATION REGARDING THE CONSUMPTION OF DIETARY SUPPLEMENTS BY THE POPULATION OF UKRAINE

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Key words: dietary supplements, questionnaire survey, statistical analysis, volumes of DS sales, pharmaceutical facilities, laboratory research, risks, safety

Ключові слова: дієтичні добавки, анкетування, статистичний аналіз, об'єм продажів ДД, аптечні заклади, лабораторні дослідження, ризик, безпека

Ключевые слова: диетические добавки, анкетирование, статистический анализ, объем продаж ДД, аптечные учреждения, лабораторные исследования, риск, безопасность.

Abstract. Study and analysis of the situation regarding the consumption of dietary supplements by the population of Ukraine. Kuznetsova O.M., Ostanina N.V. This article shows a study of different aspects of dietary supplement (DS) consumption by the population of Ukraine, the probability of using poor-quality DS is determined. As a part of this project, a questionnaire-based survey on the issue of DS consumption was conducted among residents of the following Ukrainian cities: Kyiv, Poltava, Kharkiv and Vyshneve (Kyiv region). The following data were analyzed: statistical data of the Ukrainian population, presence of pharmaceutical facilities in regions of Ukraine, DS sale volumes and laboratory data concerning correspondence of DS with the claimed content of active ingredients. Statistical analysis was carried out with use of the standard software Microsoft Excel 2007 and STATISTICA 8.0 portable The survey allowed to evaluate health level of respondents who take DS, obtain information concerning purposes or recommendations for DS taking, detect channels of purchase of such products, identify the risks of taking poor-quality DS. According to the survey results, about 72% of respondents are taking DS. The survey results indicate that 39% of respondents that take DS consider themselves healthy, almost half of respondents have insignificant health problems and about 12% of respondents have serious health problems. 79% of respondents purchase DS in pharmacies, which allows to conclude that about 59.7 million packaging of DS were consumed in Ukraine in 2019. It was confirmed that the presence of pharmaceutical facilities is even in all regions of Ukraine and, therefore, residents have access to necessary DS through pharmacies. Taking into account the results of laboratory tests of DS quality, the risks of poor-quality DS consumption in Ukraine in 2019 may be estimated as 9.5%. The research results of test purchases demonstrate that the aforementioned risks may increase significantly.

Реферат. Изучение и анализ ситуации касательно потребления дистических добавок населением Украины. Кузнецова Е.М., Останина Н.В. В данной статье показано исследование различных аспектов потребления диетических добавок (ДД) населением Украины и определена вероятность употребления некачественных ДД. В рамках выполнения работы был проведен анкетный опрос среди жителей городов Киев, Полтава, Харьков и Вишневое (Киевская область) касательно применения ДД. Анализировали статистические данные численности населения Украины, наличие по регионам аптечных учреждений, объемы продаж ДД и данные лабораторных исследований на соответствие ДД заявленному составу активных ингредиентов. Статистический анализ был выполнен с использованием стандартного программного обеспечения Microsoft Excel 2007 и STATISTICA 8.0 portable. Анкетирование позволило оценить состояние здоровья респондентов, принимающих ДД, выяснить информацию относительно рекомендаций для применения ДД, выявить пути приобретения данной продукции, установить риск приема некачественных ДД. По данным анкетирования установлено, что ДД принимают около 72% населения. Результаты опроса свидетельствуют, что ДД принимают 39% здоровых людей, почти половина опрошенных имеет небольшие проблемы со здоровьем и 12% опрошенных имеют серьезные проблемы со здоровьем. 79% анкетируемых покупают ДД в аптеках, и это позволяет предположить, что всего в 2019 году в Украине было использовано около 59,7 млн упаковок ДД. Доказано, что обеспеченность населения Украины аптечными учреждениями равномерная для всех регионов Украины и, соответственно, у населения имеется возможность приобретения в аптеках необходимых ДД. Учитывая результаты лабораторных исследований качества ДД, риск употребления некачественных ДД в Украине в 2019 году может составить около 9,5%. Результаты исследований контрольных закупок показывают, что данный риск может значительно увеличиться.

Maintaining health for the full-quality life of citizens is one of the most important tasks of modern medicine. The desire to maintain the optimal functional state of the human body by improving the quality of food has led to the widespread popularity of special foods such as dietary supplements (DS), which makes the problem of ensuring their quality and safety relevant [7].

In Ukraine, as in the European Union (EU) [9, 11, 12] and the United States [10], DS is a type of food and their circulation is regulated by food legislation. The main feature of DS is their consumption in small quantities in addition to the usual diet.

The growth rates of revenues from their sale in different territorial segments of the world range from 5 to 15%. The markets of the USA, the EU, China, India and Japan are developing most dynamically. The increasing use of DS in the world and in

Ukraine leads to new problems in controlling their production, circulation and use in order to prevent harm to public health [6].

Today, the issue of nutrition and food safety is of concern to experts from different countries and continents. Discussing the problem of the place and role of dietary supplements in the life of a modern person, it should be emphasized once again that the widespread use of DS in everyday practice of nutrition is the only quick, effective way to return humanity to symbiosis with nature, in which the human body is able to fully use its natural potential for adaptation, protection, self-renewal. This is a direct way to improve health, reduce morbidity, prolong human life.

The situation in the field of circulation of DS in Ukraine is quite complex, the Law of Ukraine N 1602-VII of September 20, 2015 abolished the

state registration of food products, including DS [5]. Today, there are no requirements for mandatory quality control and safety for dietary supplements, which, in turn, opens our market for substandard products. The analysis of the circulation of dietary supplements in terms of the possibility of containing prohibited components in them showed that the results of the study of the DS market allow to develop a classification of the main types of risks faced by its subjects. Most of them arise as a result of nontransparent competition and unfair business activities, as well as constant changes in the political and economic situation in the country. The DS market in Ukraine is characterized by specific types of risks: regulatory and legal, the risk of spreading counterfeit goods, the risk of competition with drugs, the risk of distrust on the part of doctors and the public [3]. That is why there is a need to clarify the real situation in order to assess the level of consumption of DS in Ukraine and identify the risks that arise in their application.

The main method of collecting sociological information is a survey. Among the common methods of interviewing respondents, the questionnaire method occupies an important place [4]. In order to identify the real situation regarding the use of DS by the population of Ukraine, a survey was conducted which allows to assess the health of respondents receiving DS, to identify ways to purchase such products, to determine the risk of low-quality DS consumption.

The aim of the work was to study and analyze the actual consumption of DS by the population of Ukraine.

MATERIALS AND METHODS OF RESEARCH

As a part of the work, a survey of the population on the use of DS was conducted, the task of which was to assess the level of consumption of DS in Ukraine and identify the risks that arise when using them. The sample size was determined as indicated in the monograph by M.Yu. Antomonova [1], taking into account that the number of people who can buy DS (age over 18 years) is 34,607,469 people [8], i.e. about 350 million. Therefore, having the volume of the general population, according to [10]:

$$n_{\min} = \frac{t_{a,v}^2 \sigma^2 N}{N \Delta^2 + t_{a,v}^2 \sigma^2} ,$$

where t=2.58 is the limit value of the Student's coefficient at the level of insignificance.

To increase the accuracy of the calculation, a higher level of significance alpha = 0.01 was used.

We obtain that $n_{min}=166.4$.

In order to take into account the possibility of the presence of spoiled questionnaires, it was decided to conduct a survey of at least 200 people.

The survey was conducted among residents of Kyiv, Poltava, Kharkiv and Vyshneve (Kyiv-Sviatoshynskyi district of Kyiv region). Both knowledgeable respondents (doctors, pharmacy workers, employees of controlling organizations) and uninformed respondents were involved in the survey. Statistical analysis was performed using standard software Microsoft Excel 2007 and STATISTICA 8.0. portable.

RESULTS AND DISCUSSION

It was found that respondents aged 18 to 70 took part in the survey. There was no significant statistical difference in the answers of informed and uninformed respondents.

According to the survey, 72% of respondents use dietary supplements. The obtained data unequivocally indicate that DS is very popular in Ukraine and is used by the vast majority of the population, which is confirmed by the literature data. First of all, this can be explained by the fact that today many over-the-counter drugs are converted into the category of dietary supplements, these are almost all vitamin preparations, probiotics, herbal preparations, etc. In addition, the lack of a DS registration procedure allows for price competition with medicines. The results presented in Figure 1 show that most often the choice of DS is guided by "doctor's administration" (35%) and "own experience" (34%).

One of the tasks of the survey was to find out which contingent of the population uses DS. The survey showed that almost half of the respondents (49%) have minor health problems, respectively, we can assume that DS were used to correct the condition of the body. 39% of respondents do not have health problems, and this certainly shows that the citizens of our country care about their health and prevent its deterioration by correcting the diet and consuming DS. 12% of respondents have serious health problems and use DS, probably in combination therapy with drugs.

Thus, it can be concluded that most people who take DS expect some improvement in their health from their use. Therefore, if you use DS that do not meet the stated requirements (do not contain the declared components or contain undeclared or inappropriate amounts of active ingredients), and, accordingly, the expected effect from their taking will not be obtained. And if a person consumes DS that contains undeclared prohibited components (pharmaceutical ingredients), it can cause significant damage to the health, and especially if they already have certain problems.

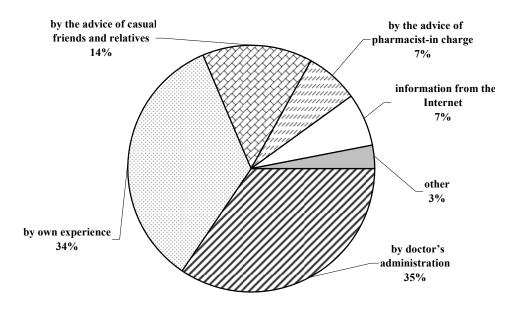


Fig. 1. Distribution of the surveyed in dependence on being guided in their choice of DS

It is noted that almost 4/5 of the population buy DS in pharmacies, but it should be noted that a fairly large percentage of DS is sold through network marketing and online stores (6% respectively). These sales channels are difficult to track, they are poorly controlled. It was revealed that DS which are sold via the Internet are counterfeited most of all. Therefore, special attention should be paid to such cases. The results are presented in Figure 2.

Since 79% of Ukrainians buy DS in pharmacies, the availability of this way of obtaining DS is crucial in their circulation in the Ukrainian market. The analysis of the level of accessibility of pharmacies for the population by regions is carried out.

Data on population base were taken from the website of the State Statistics Service of Ukraine [4], namely: population (estimated) on September 1, 2019 and the average number in January-August 2019 (excluding the temporarily occupied territory of the Autonomous Republic of Crimea and Sevastopol). Calculations (estimates) of the population were made on the basis of available administrative data on the state registration of births and deaths and changes in the registration of residence).

Using the data from the website of the State Service of Ukraine for Medicines and Drug Control on the number of pharmacies, information was obtained on the availability of pharmacies (data obtained in November 2019) and the indicator "Number of pharmacies per 10,000 population" for some regions of Ukraine. The data "Existing population: average population base in January-August 2019" were used in the calculation [2].

The indicator "Number of pharmacies per 10,000 of population" for different regions is in the range from 4.6 to 6.6 and the average in Ukraine is 5.6. The lowest values of the indicator are in Rivne, Volyn and Chernihiv regions, and the highest value is in Cherkasy.

The analysis of the above data shows that the provision of the population of Ukraine with pharmacies is quite the same for different regions, and, accordingly, in all regions there is a sufficient opportunity to buy DS in pharmacies.

It is DS sales through pharmacies that are the most controlled in terms of information on sales volumes. Analysis of pharmaceutical market data presented in [8] shows that one of the trends in the pharmaceutical market of Ukraine in recent years has been an increase in sales, which is expressed in the number of packages. In the last three years, there has been an increase in consumption by 1.7% annually.

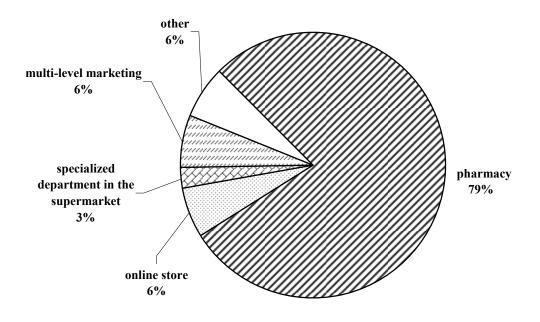


Fig. 2. Ways of buying DS

As noted in [8], following the results of the Ist quarter of the year 2019, the share of dietary supplements in the structure of the pharmacy market in monetary terms was 6.0%, while in the Ist quarter of the year 2015 this figure was 3.4%. In recent years, the growth rate of sales of dietary supplements is much higher than the market average, and it is clear that these data do not reflect the DS which are sold under other sales schemes as well as imported DS which citizens order on foreign sites independently or through intermediaries. Actual sales of various DSs in Ukraine can be much higher.

Using the above data, it can be estimated that in 2019 about 47.2 million packages of DS were sold

through the pharmacy network. If we use the survey data that purchases of DS in pharmacies account for 79% of the total, then in 2019 in Ukraine about 59.7 million packages of DS can be consumed.

The analysis of the results of quality control of DS was carried out in the laboratory of quality control and product safety of SI "IPH NAMSU".

Table 1 shows the data on the number of analyzed samples of DS and their compliance with the stated requirements. It should be noted that samples for research were provided by manufacturers in the framework of sanitaryepidemiological examination.

Table 1

The results of quality control of DS which came to the laboratory for sanitary and epidemiological examination and at the request of manufacturers

Year	Compliance with the stated requirements	Non-compliance with the stated requirements	Samples, total
2017	15	1	16
2018	81	2	83
2019	93	5	98



Analyzing these data, we can estimate that about 4.1% of DS in the Ukrainian market may not meet the stated requirements.

Taking into account the above information on the volume of DS sales and the number of people who consume them, we can assess the risk of using DS that do not meet the stated requirements in 2019. According to the survey, as mentioned above, 72% of respondents use diet supplements.

The probability of using DS that do not meet the stated requirements was estimated as the ratio of the number of people who can use "inappropriate DS" in relation to the total number of people who use DS. The number of people who can use "non-compliant DS" can be estimated as the number of packages of these DS (given that one person can consume several packages of different DS per year, but assuming that they do not receive more than one "inappropriate DS" per year). Thus, it will be a one-sided estimate of the probability of using "inappropriate DS" (i.e. the maximum possible value of the estimate). Data estimates of the probability of using DS which do not meet the stated requirements in 2019 are given in Table 2.

Table 2

The current population of Ukraine in 2019 for the analyzed regions (from Table 1), persons	35 762 599
The estimated volume of consumption of DS on the market of Ukraine in 2019, packaging	59 700 000
The number of people who use DS, persons	25 749 071
Approximate number of DS packages that do not meet the stated requirements, packages	2 447 700
Probability of using DS which do not meet the stated requirements in 2019.	9,5%

Estimation of the probability of using DS that do not meet the stated requirements

Thus, the probability of using DS which do not meet the stated requirements by the population of Ukraine in 2019 may be up to 9.5%. That is, it is possible that up to 9 people out of 100 using DS during the year may take at least one DS that does not meet the standards for quality or safety. However, if we take into account DS which were at will bought in pharmacies, and those groups for which, according to the literature, the largest falsifications are observed, and samples obtained from state authorities (SSU, National Police, etc.), we have completely different, much worse statistics (Table 3).

Table 3

Group of DS	Compliance with stated requirements	Non-compliance with stated requirements	Samples, total
DS containing blueberry extract	5	5	10
DS for weight loss	36	15	51
DS for improving erectile functionï	5	5	10

The results of quality control of DS, purchased for control purposes pharmacy sales and samples obtained from government agencies

In this case, non-compliance with the stated requirements is observed in 30-50% of cases and, accordingly, the probability of using poor quality DS increases significantly and becomes critical, which, of course, indicates the need for changes in quality control and safety of DS in Ukraine.

The obtained results testify to the popularity of DS in Ukraine and, unfortunately, problems with their quality which requires regulating the market for these products by making changes to the quality control system and safety of DS.

CONCLUSIONS

1. It is shown that 72% of Ukrainians surveyed use dietary supplements, while almost 80% of them buy DS in pharmacies.

2. It is proved that the provision of the population of Ukraine with pharmacies is the same for different regions and, accordingly, in all regions there is a possibility of purchasing DS in pharmacies and consumption.

3. It is determined that the probability of using DS by the population of Ukraine which do not meet

the stated requirements in 2019 may be up to 9.5% (among those who use) but when using DS with vegitative components, DS for weight loss or to improve erectile function can increase up to 30-70%, which, of course, indicates the need for changes in the quality control system and safety of DS in Ukraine.

Conflict of interest. The authors declare no conflict of interest.

REFERENCES

1. Antomonov MY. [Mathematical processing and analysis of biomedical data. 2rd edition]. Kyiv: Medinform; 2018. p. 579. Ukrainian.

2. [Pharmacy market of Ukraine following the results of I quarter. 2019: Helicopter View]. [Internet]. Ukrainian. Available from: https://www.apteka.ua/article/498776

3. Brulevich VV. [Security of grubby products for the legislation of Ukraine and the European Union]. Sudova apeliatsiia. 2016;2(43):75-82. Ukrainian.

4. Gotlib AC. [Introduction to a case study. Qualitative and quantitative approaches. Methodology. Research practices. 3rd edition]. Moskva: FLINTA; 2014. p. 382. Russian.

5. [The Law of Ukraine No 1602-VII "On introducing amendments to the relevant legislative acts of Ukraine on the basis of products"]. Ukrainian. Available from: http://https://zakon.rada.gov.ua/laws/show/771/97-%D0%B2%D1%80

6. Timchenko OV. [Overview of legislative changes in the field of quality assurance of dietary supplements in Ukraine]. Pharmacom. 2018;3:19-29. Ukrainian.

7. Timchenko OV. [Overview of legislative changes in the field of quality assurance of dietary supplements in Ukraine]. Pharmacom. 2018;4:15-24, Ukrainian.

8. [Population (estimated) as of September 1, 2019, and the average population in January-August 2019]. [Internet]. Ukrainian. Available from:

http://www.ukrstat.gov.ua/operativ/operativ2019/ds/kn/kn _u/kn0819_u.html

9. Baraniak B, Kujawski R, Ozarowski M. [Law regulations concerning food supplements, dietetic food and novel food containing herbal substances]. Herba Pol. 2016;62:97-106. Polish. doi: https://doi.org/10.1515/hepo-2016-0025

10. Brown A. An overview of herb and dietary supplement efficacy, safety and government regulations in the United States with suggested improvements. Part 1 of 5 series. Food and Chemical Toxicology. 2017;107:449-71. doi: https://doi.org/10.1016/j.fct.2016.11.001

11. 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, sappl.). 2002;L183:51-57. Available from: https://www.fsai.ie/uploadedFiles/Consol2002_46.pdf, EU

12. Regulation (EU) No 1169/2011 of the European Parliament and of the Council 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. doi: https://doi.org/10.1007/978-1-137-54482-7_44

СПИСОК ЛІТЕРАТУРИ

1. Антомонов М. Ю. Математическая обработка и анализ медико-биологических данных: Монография. 2 изд. Киев: Мединформ, 2018. 579 с.

2. Аптечный рынок Украины по итогам I кв. 2019 г.: Helicopter View.

URL: https://www.apteka.ua/article/498776

3. Брулевич В. В. Безпечність харчових продуктів за законодавством України та Європейського Союзу. *Судова апеляція*. 2016. Т. 43, № 2. С. 75-82.

4. Готлиб А.С. Введение в социологическое исследование. Качественный и количественный под-

ходы. *Методология. Исследовательские практики.* 3-е изд. Москва: ФЛИНТА, 2014. 382 с.

5. Про внесення змін до деяких законодавчих актів України щодо харчових продуктів: Закон України № 1602-VII.

URL: https://zakon.rada.gov.ua/laws/show/771/97-%D0%B2%D1%80

6. Тимченко О. В., Котов А. Г. Вопросы законодательного обеспечения качества диетических добавок в Европейском союзе. *Фармаком*. 2018. № 3. С. 19-29.



7. Тимченко О. В., Котов А. Г. Огляд законодавчих змін у сфері забезпечення якості дістичних добавок в Україні. *Фармаком*. 2018. № 4. С. 15-24.

 Чисельність населення (за оцінкою) на 1 вересня 2019 року та середня чисельність у січні-серпні 2019. URL: http://www.ukrstat.gov.ua/operativ/operativ2019/ds /kn/kn_u/kn0819_u.html

9. Baraniak B., Kujawski R., Ozarowski M. Law regulations concerning food supplements, dietetic food and novel food containing herbal substances. *Herba Pol.* 2016. Vol. 62, No. 4. P. 97-106.

DOI: https://doi.org/10.1515/hepo-2016-0025

10. Brown A. An overview of herb and dietary supplements efficacy, safety and government regulations in the United States with suggested improvements. Part 1 of 5 series. *Food and Chemical Toxicology*. 2017. Vol. 107. P. 449-471. DOI: https://doi.org/10.1016/j.fct.2016.11.001

11. 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 (12.07.2002): Official Journal of the European Communities. L183. P. 51-57. URL: https://www.fsai.ie/uploadedFiles/Consol2002_46.pdf

12. Regulation (EU) No 1169/2011 of the European Parliament and of the Council 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. DOI: https://doi.org/10.1007/978-1-137-54482-7_44

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