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Consumption trends of alpha-lipoic acid: drugs vs. dietary supplements in the Republic of Serbia

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Abstract

On the Serbian market, alpha-lipoic acid (ALA) is available in 7 drug formulations and over 50 dietary supplements (DS). This study aimed to analyze and compare the consumption of ALA drugs and DS. The data on drug consumption were obtained from the annual reports of the Medicines and Medical Devices Agency of Serbia, while the data for DS were sourced from IMS Health's monthly audit reports. The consumption of ALA drugs significantly increased during 2010-2016 ($R^2 = 0.753$, $F(1, 5) = 15.219$, $p = 0.011$), with a notable drop observed in 2017. The consumption of ALA DS surged by 156.67% from 2018 to 2020, reaching 0.77 DDD/1000 inhabitants/day, with a notable increase observed at the end of 2020. From January to October 2021, the consumption doubled compared to the same period in 2020, reaching 1 DDD/1000 inhabitants/day. The increase in ALA drug consumption during 2010-2016 paralleled the registration and clinical adoption of ALA drugs. A significant drop in 2017 might have resulted from registering new ALA DS. However, during 2018-2020, ALA drugs were more commonly

consumed compared to ALA DS. The increased consumption of ALA DS at the end of 2020 was associated with the COVID-19 epidemic. While both drugs and DS offer 600 mg ALA doses, only drug regulations ensure quality and efficacy, highlighting the need for stricter regulations on DS to enhance consumer safety and information.

Key words: alpha-lipoic acid, dietary supplements, consumption trends, regulation, antioxidants

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Introduction

Alpha-lipoic acid (ALA, syn. thioctic acid) is an antioxidant found in all human cells. As its endogenous synthesis might not be sufficient to cover our bodies' needs, ALA is often consumed via dietary products, namely dietary supplements (DS). In addition, ALA is indicated as a drug in relieving the symptoms of diabetes-related peripheral neuropathy.

On the Serbian market, ALA is available in 7 drug formulations (4 oral, 3 parenteral) and more than 50 DS. The dose of ALA in all registered drugs is 600 mg per dosage unit. ALA drugs are not on the approved list of medicines prescribed and dispensed under the compulsory health insurance scheme in Serbia, meaning that patients pay the total price for them (1).

ALA DS are freely available on the Serbian market. The content of ALA in single-ingredient supplements varies from 100 to 600 mg, while the doses of ALA range from 50 to 600 mg in DS with multiple active ingredients. To date, no health claims pertaining to ALA have been approved by the European Union (EU). Several attempts at health claims' authorization have been made, mainly relating ALA to glycemic control, cholesterol levels, and protection from oxidative stress, but failed to meet the EU regulation requirements (2). In Serbia, the Rulebook on Nutrition and Health Claims Listed on Food Labels ("Official Gazette of the Republic of Serbia", No. 51/18, 103/18, 110/23) (3) prescribes the conditions that health claims regarding food, including DS, must meet. DS mostly comply with the Regulation regarding labeling. However, the Regulation governs health claims made in commercial communication, not only during labeling, but also advertising and presenting DS. The potential discrepancy between the health claims made by manufacturers and the regulatory approval process is reflected in a number of health claims found on the official websites of DS manufacturers that are not approved by Annex 2 or Annex 2a of the Regulation (4, 5).

Although unsubstantiated, such claims contribute to the growing interest in ALA DS. The coronavirus pandemic sparked even more interest in ALA due to the potential effects of ALA on the course of infection, as it acts as a free radical scavenger and an anti-inflammatory molecule (6, 7). Moreover, preliminary evidence suggests that ALA could be one of the nutrients that may be an important part of a rehabilitation program for people with long-term COVID (8).

The aim of the study was to analyze the consumption trends of ALA drugs (ATC code: A16AX01) in the Republic of Serbia from 2010 to 2020 and the consumption of ALA DS in the Republic of Serbia from 2018 to 2021. It also aimed to compare the consumption of ALA drugs and DS. Moreover, we aimed to consider how the consumption of ALA drugs and DS can be linked to clinical practice and highlight implications for patients, healthcare professionals, and health policies.

Material and Methods

The data on the consumption of drugs containing ALA (ATC Code: A16AX01) in the Republic of Serbia were obtained from the Medicines and Medical Devices Agency of Serbia (ALIMS) annual reports for the period between 2010 and 2020 (9–19). ALIMS acquires these data from drug producers or their marketing authorization holders.

ALIMS follows the World Health Organization (WHO) guidelines for drug utilization research, calculating the quantity of drugs consumed using the defined daily dose (DDD) methodology. The DDD is the assumed average maintenance dose per day for a drug used for its main indication in adults, and in the case of ALA, it is 600 mg. Sales data presented in DDD per 1000 inhabitants per day (DDD/1000 inhabitants/day) may provide a rough estimate of the proportion of the study population treated daily with a particular drug or group of drugs. The use of DDD/1000 inhabitants/day allows the aggregation of data across drug groups and comparisons between countries, regions, and health facilities (20).

The data on the quantity of ALA DS consumed in the period between January 2018 and October 2021 were obtained from the IMS Health monthly audit reports by contacting Romanca Pekurari (Country Commercial Lead Serbia, Montenegro, Bosnia and Herzegovina at IQVIA). Although it would have been significant to have data on ALA DS consumption for the same period as for the ALA drugs, we were only able to obtain data for a portion of that period.

IMS Health or IQVIA measures unit sales for pharmaceutical products across multiple distribution channels, including retail, mail, and non-retail. The data is being collected from a panel of wholesalers, distributors, and pharmaceutical manufacturers representing 90% of the pharmaceutical market, and is projected to reach a national total (21).

Based on the doses per dosage unit, the number of dosage units per package, the number of days in the year, and Serbian population data, the quantity of consumed DS was expressed in DDD/1000 inhabitants/day. The data on the population at the beginning of the observed period (1st of January) was taken from the official publications of the Statistical Office of the Republic of Serbia for 2018, 2019, 2020, and 2021 (22).

Statistical analysis was performed using SPSS Statistics, version 23 (IBM Corporation), and linear regression analysis was employed to investigate the drug consumption trends from 2010 to 2020. A p value of < 0.05 was considered statistically significant.

Results

The analyzed ALA drugs included formulations for oral and parenteral administration. The predominant way of administration during 2012-2020 was oral administration, with $98.66 \pm 0.54\%$ on average (Table I). The percentage of parenterally used ALA drugs during this period varied from 0.38% to 2.11%.

Table I Share of orally and parenterally consumed DDDs (600mg of ALA) presented as the percentage (%) of total consumption, in the period from 2012 to 2020

Tabela I Udeo oralno i parenteralno potrošenih DDD (600mg ALA) predstavljen kao procenat (%) ukupne potrošnje, u periodu od 2012. do 2020. godine

Year	Oral administration (%)	Parenteral administration (%)	Year	Oral administration (%)	Parenteral administration (%)
2012[1]	97.89	2.11	**2017**	98.94	1.06
2013	98.17	1.83	**2018**	98.98	1.02
2014	98.04	1.96	**2019**	99.13	0.87
2015	98.44	1.56	**2020**	99.62	0.38
2016	98.74	1.26			

[1]Data on parenterally administered ALA during 2010 and 2011 were not available.

To explore the consumption trend of ALA drugs, a scatter plot of the data was made. It revealed an overall increasing trend over the entire period, with a noticeable sharp drop observed in 2017, followed by a subsequent increase until 2020 (Figure 1). Three separate simple linear regression analyses were conducted to further assess the consumption trends.

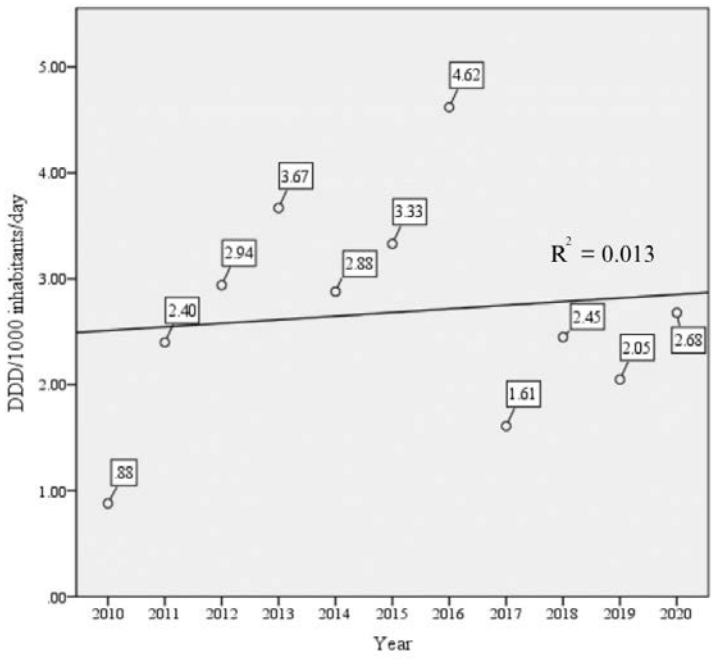

Figure 1. Linear regression of ALA drugs consumption for the period 2010-2020, source: ALIMS

Slika 1. Linearna regresija potrošnje lekova ALA, za period 2010-2020. godine, izvor: ALIMS

For the entire period of 2010-2020, the regression analysis yielded a non-significant positive relationship between the year and ALA consumption, with an R^2 = 0.013 (F(1, 9) = 0.114, p = 0.743). The regression equation was: y = -66.010 + 0.034 * x.

In contrast, for the period of 2010-2016, a significant positive relationship was found between the year and ALA consumption, indicating an increasing trend during this period (R^2 = 0.753, F(1, 5) = 15.219, p = 0.011). The regression equation was: y = -933.085 + 0.465 * x (Figure 2).

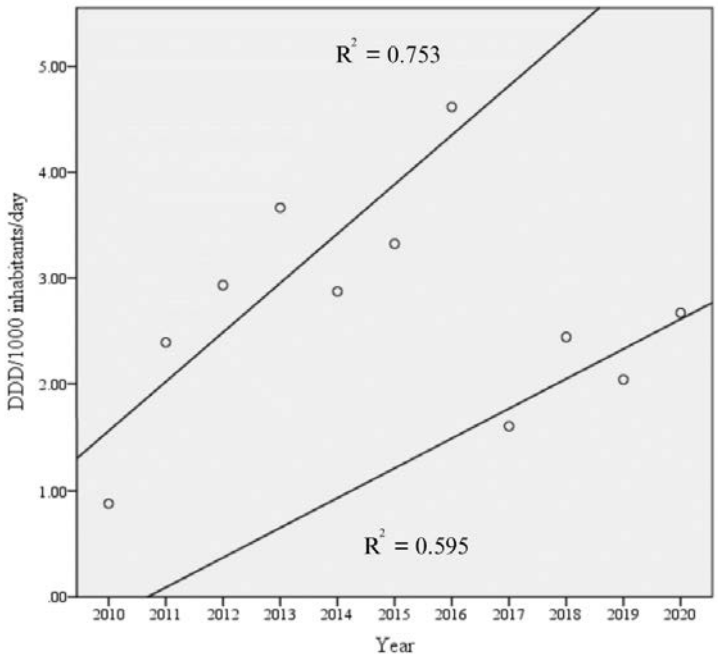

Figure 2. Linear regression of ALA drugs consumption during 2010-2016 and 2017-2020, source: ALIMS

Slika 2. Linearna regresija potrošnje lekova ALA za periode od 2010. do 2016. godine i od 2017. do 2020. godine, izvor: ALIMS

However, for the period of 2017-2020, the regression analysis did not reveal a significant relationship between the year and ALA consumption (R^2 = 0.595, F(1, 2) = 2.939, p = 0.229). The regression equation was: y = -565.001 + 0.281 * x (Figure 2).

Figure 3 shows DS consumption in 2018, 2019, and 2020. It also shows consumption in 2020 and 2021 from January 1 to October 31 (source: IMS Health). Regarding annual consumption trends, DS consumption remained relatively stable between 2018 and 2019, slightly decreasing from 0.30 to 0.26 DDD/1000 inhabitants/day. However, a significant increase in consumption was observed in 2020, when it rose from 0.26 to 0.77 DDD per 1000 inhabitants per day. This increase occurred at the end of 2020, since in November and December 2020 the total consumption of ALA DS amounted to 0.33, which is higher than for the entire year 2019. From January to the end of October

2020, consumption amounted to 0.44 DDD/1000 inhabitants/day. In the same period of 2021, consumption more than doubled, reaching 1 DDD/1000 inhabitants/day.

For the years where the data on consumption were obtained for both ALA drugs and DS, drug consumption was higher in each year (2018: 2.45 vs. 0.30, 2019: 2.05 vs. 0.26, 2020: 2.68 vs. 0.77 DDD/1000 inhabitants/day).

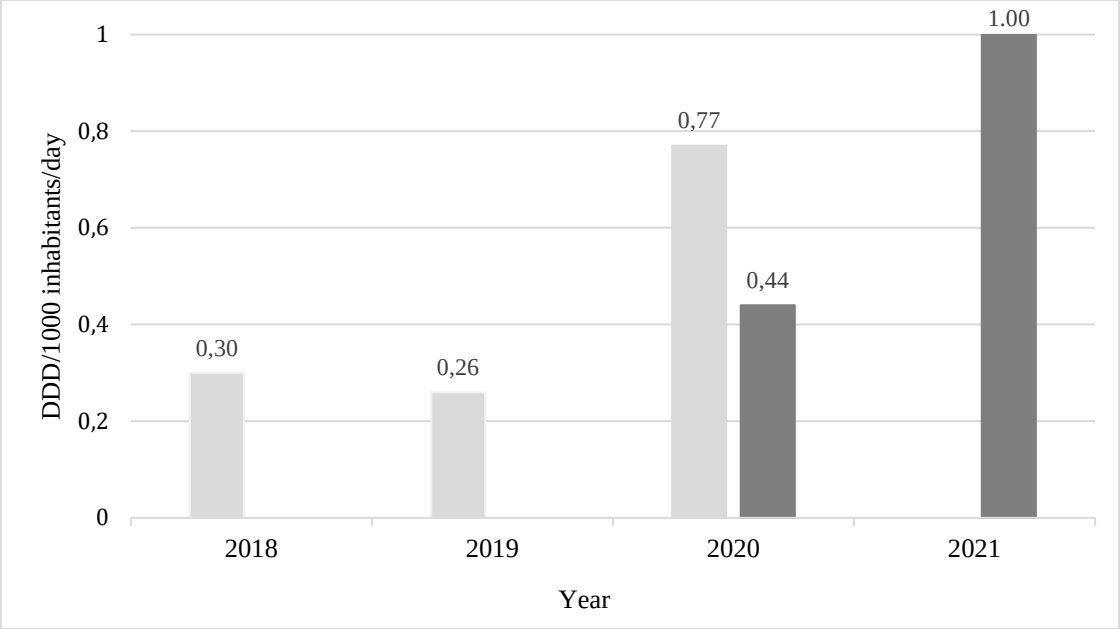

Figure 3. ALA dietary supplements consumption. Jan-Dec (light grey), Jan-Oct (dark grey); source: IMS Health (IQVIA)

Slika 3. Potrošnja dijetetskih suplemenata ALA. Jan-dec (svetlo sivo), jan-okt (tamno sivo); izvor: IMS Health (IQVIA)

Discussion

The number of diabetes patients in Serbia, who are the main users of ALA drugs, is following the global trend of continual growth. It rose by 28.3% in the period of 10 years, from 600,000 patients in 2010 to 770,000 in 2020 (23). A total of 12% of the adult population of Serbia suffers from diabetes, which corresponds to a comparative prevalence of 9%, many of whom are still undiagnosed (24).

ALA is indicated for use in the treatment of symptoms of peripheral (sensomotor) diabetic polyneuropathy. The efficacy of parenterally administered ALA (600 mg/day i.v. over 3 weeks) in the treatment of diabetic polyneuropathy has been confirmed by a meta-analysis (25). The bioavailability of intravenously administered parenteral formulations (100%) favors higher efficiency. Thus, these formulations are intended for patients with more severe symptoms of diabetic polyneuropathy. In contrast, after oral application, ALA is rapidly absorbed, but due to a marked first-pass effect, instability of ALA at

gastric pH, and its low solubility, the absolute bioavailability of orally administered ALA is estimated to be about 30% (26). However, oral administration of ALA has its advantages. It is more convenient for patients and also costs less. As diabetic polyneuropathy is a chronic disease, it requires long-term treatment for which oral formulations are more favorable. Therefore, greater consumption of peroral formulations was expected and confirmed by our results.

The results indicate that ALA drugs consumption in Serbia exhibited varying trends over the analyzed period. A significant increasing trend was observed from 2010 to 2016, corresponding to the timeline of ALA being registered as a drug in Serbia and being implemented into clinical practice. The growing number of diabetes patients consequently led to a higher incidence of diabetes complications, including diabetic polyneuropathy. Moreover, most probably due to its demonstrated efficacy and safety profile, ALA gained trust among clinicians, with its prescription rate increasing annually. However, the consumption of drugs decreased from 4.62 in 2016 to 1.61 DDD/1000 inhabitants/day in 2017. There were no reported ALA drug shortages or changes to therapeutic protocols using ALA during that timeframe. This suggests that other factors influencing ALA drug consumption caused this evident drop in consumption, and the introduction of four new ALA-containing DS to the Serbian market in 2016 (27) may be one of them. In 2016, there were 7 DS containing ALA as their principal ingredient registered in Serbia (27). In contrast, when ALA DS started entering the local market around 2013, only one ALA DS was registered per year (2013-2015) (27). Today, the number of ALA DS has increased to over 50, with doses ranging from 50 to 600 mg, reflecting a significant variation in dosages observed both in Serbia and in the EU countries. The equivalence of ALA doses in some DS and drugs (600 mg) may lead consumers to perceive them as interchangeable. Unfortunately, because the regulatory requirements for DS are looser than those for drugs, these products should not be viewed as interchangeable, nor should they be considered equally effective. DS, classified as food products, fall under less stringent regulatory oversight compared to pharmaceutical drugs. The health safety of DS is ensured through requirements related to microbiological safety, maximum allowed levels of contaminants and residues, and the purity of substances used in their production (28). However, unlike drugs, DS are not subject to rigorous pre-market evaluation for efficacy. On the other hand, pharmaceutical drugs are subject to stringent regulatory requirements aimed at evaluating their safety, efficacy, and quality before they are approved for marketing and use. This process involves extensive preclinical and clinical trials to gather data on safety, efficacy, adverse effects, and potential drug interactions. Moreover, post-market surveillance systems continuously monitor drugs to detect and assess any adverse events or emerging safety concerns.

After a drop in 2017, ALA drugs consumption was on a small but not statistically significant rise in the 2017-2020 period. On the other hand, DS consumption grew from 0.3 to 1 DDD/1000 inhabitants/day from 2018 to October 2021. There are several possible reasons for this. As the advertising of DS in Serbia is allowed, following the registration of their ALA DS in Serbia, pharmaceutical companies engaged in marketing campaigns

via mass media and their representatives, reaching many and stimulating ALA DS consumption. In addition, ALA DS are competitively priced and easily accessible to users via pharmacies and online purchases. Some of them have specific compositions. Several ALA DS contain isolated R-alpha-lipoic acid, while most other DS and all registered drugs are racemic mixtures of S- and R- enantiomers of ALA. A trial that investigated the pharmacokinetics of ALA enantiomers in healthy volunteers reported that maximum plasma concentrations of R-ALA were about 40-50% higher than those of S-ALA (29). However, S-ALA may prevent the polymerization of R-LA in the racemic mixtures (30). Some ALA DS are being advertised for specific uses in different population groups due to the combination of ingredients they contain, e.g., a combination of ALA, magnesium, and vitamin B6 intended for use in pregnancy for "miscarriage prevention" and "premature birth risk reduction", despite the lack of scientific consensus on the efficacy of ALA for these "indications".

Meanwhile, national regulations (31) prohibit online sales of drugs and advertising of prescription-only drugs to the general public. As ALA drugs are prescription-only, they are less visible and accessible to users than DS.

The global pandemic of COVID-19 was critical for the increase of ALA DS use in November and December 2020, with the increasing trend continuing in 2021. The coronavirus pandemic sparked additional interest in ALA, mainly due to its antioxidative properties (32) and its potential as a symptomatic treatment for anosmia (33). ALA was even included in some of the therapeutic protocols (34–36) for COVID-19 in Serbia, for patients with mild symptoms experiencing loss of smell. This use was based on a 2009 study that stated that ALA might help patients with olfactory function loss after an upper respiratory tract infection (33). However, in 2021, the expert panel of the British Rhinological Society made recommendations against the use of ALA for anosmia in COVID-19 patients (37). Nevertheless, the timeline of the sharp increase in ALA DS consumption (November and December 2020) corresponds to a peak in the number of locally reported coronavirus cases. Between November 17, 2020 and December 17, 2020, the number of new daily cases in Serbia ranged from about 5,000 to nearly 8,000 (38). The even higher consumption of ALA DS during 2021 was probably linked with a high incidence of COVID-19 peaking twice, in Mar/Apr and Sep/Oct 2021, despite the lack of scientific support for ALA use in COVID-19. Patients' and even healthcare professionals' experiences during the first peaks of the pandemic added to the already existing infodemic (39) and were possibly responsible for the continuing rising trend of ALA DS use.

Some data suggest ALA might have multiple benefits in the fight against COVID-19 in patients with diabetes (40, 41), but further studies are needed to confirm this. Besides its antioxidant and anti-inflammatory effects, ALA might help control blood sugar (41). Using ALA with insulin in patients with diabetes can also show a synergistic effect against COVID-19 (40).

Conclusion

In summary, the consumption trends of ALA drugs and DS in Serbia reflect a complex interplay between healthcare practices, regulatory frameworks, marketing influences, and public perceptions. Understanding these dynamics is crucial for ensuring informed decision-making and optimizing patient care in the management of diabetic polyneuropathy.

The 600 mg of ALA in the DS formulations is available for purchase on the market, while a prescription is required for the drug formulations. This is a paradoxical situation because the same dose of ALA in DS and drugs should show the same effects, side effects, and interactions, whether registered as a drug or a DS. In clinical practice, prescribing ALA preparations can be challenging. Although DS may have specific formulations and contain multiple active ingredients, the quality and efficacy of preparations are guaranteed only for registered drugs. In addition, greater and more precise sources of information about the method of use, side effects, interactions, use during pregnancy and breastfeeding, as well as the information about the risk of driving motor vehicles and using machines, are provided only for ALA drugs.

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Declaration of Competing Interest

The authors declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

Author contributions

Conceptualization, Milana Vuković and Jelena Jovičić Bata; Data curation, Nemanja Todorović, Dunja Vesković and Jelena Čanji Panić; Formal analysis, Milana Vuković and Jelena Jovičić Bata; Methodology, Milana Vuković and Jelena Jovičić Bata; Supervision, Mladena Lalić-Popović; Visualization, Jelena Jovičić Bata, Jelena Čanji Panić and Dunja Vesković; Roles/Writing - original draft, Milana Vuković, Jelena Jovičić Bata and Mladena Lalić Popović; Writing - review & editing, Milana Vuković, Jelena Jovičić Bata, Nemanja Todorović and Mladena Lalić Popović.

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Trendovi potrošnje alfa lipoinske kiseline: lekovi naspram dijetetskih suplemenata u Republici Srbiji

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Kratak sadržaj

Na tržištu Republike Srbije, alfa lipoinska kiselina (ALK) je dostupna u 7 formulacija lekova i preko 50 dijetetskih suplemenata (DS). Cilj studije bio je da se analiziraju i uporede potrošnje lekova i DS ALK. Podaci o potrošnji lekova su dobijeni iz godišnjih izveštaja Agencije za lekove i medicinska sredstva Republike Srbije, dok su podaci za DS dobijeni iz mesečnih izveštaja IMS Health-a. Potrošnja lekova ALK je značajno rasla tokom perioda od 2010. do 2016. godine ($R^2 = 0,753$, $F(1, 5) = 15,219$, $p = 0,011$), sa primetnim padom u 2017. godini. Potrošnja DS ALK je porasla za 156,67% od 2018. do 2020. godine, dostigavši 0,77 DDD/1000 stanovnika/dan, sa značajnim povećanjem krajem 2020. Od januara do oktobra 2021. godine, nastavio se rastući trend potrošnje, odnosno ona je udvostručena u poređenju sa istim periodom u 2020. godini, dostižući 1 DDD/1000 stanovnika/dan. Potrošnja lekova ALK tokom perioda od 2010. do 2016. godine je rasla je paralelno sa registracijom i kliničkim usvajanjem lekova ALK. Značajan pad u 2017. godini može biti rezultat registracije novih DS. Ipak, tokom perioda od 2018. do 2020. godine, lekovi ALK su bili češće korišćeni u poređenju sa DS. Rastući trend potrošnje DS ALK koji krajem 2020. godine je povezan sa epidemijom COVID-19. Dok se doze od 600 mg ALK mogu pronaći i u lekovima i u DS, zakonski propisi obezbeđuju kvalitet i efikasnost samo za lekove, što ukazuje na potrebu za strožom zakonskom regulativom za DS kako bi se unapredila bezbednost i informisanost potrošača.

Ključne reči: alfa lipoinska kiselina, dijetetski suplementi, trendovi potrošnje, regulativa, antioksidansi