



Organizational and Legal Aspects of the Use of Marketing Analysis of Multivitamin Complexes for Pharmaceutical Provision of Health Diseases Among Combatants

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Abstract

The article presents the results of the study of the multivitamin complexes for the pharmaceutical provision of health disorders among combatants in Ukraine. In the conditions of military conflict, combatants experience various health problems and require complex pharmacotherapy and pharmaceutical provision. In that medicines of various clinical and pharmacological groups, including vitamins are widely used. The goal of the study was to conduct analysis on the organizational and legal aspects of multivitamin complexes for the pharmaceutical provision of combatants on the example of the pharmaceutical market of Ukraine in the period of 2015-2020. The organizational and legal study conducted was based on using of normative and legal, documentary, regulatory, forensic and pharmaceutical, and marketing analysis methods. Discussed the range of multivitamin complexes by trade names, composition of active substances, manufacturers, pharmaceutical forms, registration data, and parameters of the control regime. In conclusion, proved that the multivitamin complexes are highly available for pharmacotherapy and pharmaceutical provision of combatants.

Keywords: Pharmaceutical Provision; Combatants; Pharmaceutical Market; Marketing Analysis; Multivitamin Complexes; Control Regime

Introduction

Military operations have a direct impact on combatants who receive traumas of different genesis that may occur during or after the war and require appropriate pharmacotherapy. Indicated in publications on the war in Iraq and Afghanistan [1,2], Columbia [3], Burundi [4], the Persian strait [5], in the east of Ukraine [6]. The formation of health diseases among combatants occurs in the zone of military conflict [7,8].

The study of the experience of doctors of military hospitals shows the importance of timely pharmaceutical provision for com-

batants with their subsequent long-term rehabilitation at the place of residence [9]. Studies by medical center for the study of traumatic brain injury (USA, Texas) show that combatants when using explosives [10] receive more than 50% of all injuries.

In the conditions of psycho-traumatic actions of combat stress servicemen experience anxiety (57%), phobias (35%), depression (48%) and social dezaptiation (75%) in the form of conflict, alienation and abuse of psychoactive substances (alcohol, nicotine, etc.), as a way to overcome a stressful situation against a background of various chronic (psycho-) somatic diseases [11-14]. During the

complex pharmacotherapy of acquired, chronic and comorbid health disorders among the US combatants are widely used medicines of various clinical and pharmacological groups, including vitamins [5,16-18].

Vitamin pharmacotherapy helps to restore physical and mental activity among combatants, reduce the risk of colds, improve liver function, normalize memory, sleep, digestion, fat metabolism, and strengthen the immune system. According to the data obtained by Allott K., McGorry P., Yuen H., Firth J., Proffitt T., Berger G., Maruff P., O'Regan M., Papas A., Stephens T., O'Donnell C. [19] 12-week administration of B vitamins has a specific neuroprotective effect on attention, alertness, especially in patients with affective psychosis.

For the pharmaceutical provision of such states at combatants, vitamins are widely used in symptomatic pharmacotherapy of mental, neurological, traumatological, narcological, cardiological, endocrinological disorders, as well as alcohol-dependent comorbidities of hepatitis, pancreatitis, tuberculosis, tobacco smoking, and others. In our previous studies we analyzed an assortment of medicines containing ethyl alcohol (ethanol) based on forensic pharmacy; assortment of medicines for pharmaceutical correction of alcoholic tremor in the structure of withdrawal syndrome of alcohol dependence; the structure of the pharmaceutical market of OTC medicines, as well as the particularities of circulation, availability and pharmaceutical provision of medicines for different contingents of the population [20-25].

Clinical and pharmacological groups of vitamins is included to the State Medicinal Products Formulary of Ukraine, clinical protocols for the provision of medical care to patients with mental and behavioral disorders due to alcohol use, cancer, diabetic neuropathy, tuberculosis, alcoholic hepatitis, etc. According to the anatomical, therapeutic and chemical classification system of the WHO (Anatomical Therapeutic Chemical (ATC) classification system, WHO, 2016), vitamins belong to the clinical and pharmacological group "A – medications, affecting the digestive system and metabolism". Pharmaceutical market of Ukraine represented by an extremely wide spectrum of vitamins in the form of multivitamin complexes for the non-prescription release. However, the uncontrolled use multivitamin complexes with high doses of vitamins can lead to overdose, the development of hypervitaminosis, hypermicroelementosis, imbalance of vitamins and even toxic effects [26].

Aim

The goal of the study was to conduct marketing analysis in the organizational and legal aspects and to determine the parameters of the control regime of multivitamin complexes according to the ATC code A11BA, which are in circulation on the pharmaceutical market of Ukraine in the period of 2016-2020 for the pharmaceutical provision of health disorders among combatants.

Material and Methods

The organizational and legal study was conducted on the example of the pharmaceutical market of Ukraine. The methodology and design of the organizational and legal research were built on the solution of eight problems: The circulation and the range of multivitamin complexes on the pharmaceutical market; Characteristics of multivitamin complexes by the composition of active substances; Distribution of manufacturers' countries of multivitamin complexes on the pharmaceutical market; Distribution of domestic manufacturers of multivitamin complexes on the pharmaceutical market; The study of the range of multivitamin complexes by medicinal forms; Distribution of multivitamin complexes by medicinal form; Distribution of multivitamin complexes by quantity of medicinal forms and manufacturers; Registration certificates validity periods of multivitamin complexes.

The organizational and legal study was conducted on basic using normative and legal, documentary, regulatory, forensic and pharmaceutical, marketing analysis methods. The normative and legal analysis was carried out based on the legal framework in force in Ukraine (laws, orders, orders, and recommendations). Regulatory and documentary analysis was based on the study of documents regulating the circulation of medicines (clinical protocols, treatment standards, instructions for medical use, medical history, prescriptions, and literature). Forensic and pharmaceutical analysis consisted in determining the clinical and pharmacological, classification and legal, nomenclature and legal groups of drugs.

The marketing analysis conducted using current legal documents, namely: the Order of the Ministry of Healthcare of Ukraine of September 21, 2009 No. 681 "On Approval of Clinical Protocols for the Provision of Medical Aid in the Specialty "Narcology"; the Order of the Ministry of Healthcare of Ukraine of September 17,

2007 No. 554 “On approval of medical treatment protocols on the specialty “Oncology”; the Order of the Ministry of Healthcare of Ukraine dated May 22, 2009 No. 356 “On approval of medical treatment protocols on the specialty “Endocrinology”; the Order of the Ministry of Healthcare of Ukraine dated September 04, 2014 No. 620 “Unified clinical protocol of primary, secondary (specialized) and tertiary (highly specialized) medical care to adults. Tuberculosis”; the Order of the Ministry of Healthcare of Ukraine dated November 6, 2014, No. 826 “Unified clinical protocol of primary, secondary (specialized) medical aid. Alcoholic Hepatitis”; the Order of the Ministry of Healthcare of Ukraine of April 03, 2017 No. 363 “On approval of the ninth issue of the State Formulary of Medicines and ensuring its availability”, etc. The definition of control regime of multivitamin complexes carried out in accordance with the current legislation of Ukraine according to the method [27,28].

Results and Discussion

Organizational and legal researches included the marketing, comparative, forensic and pharmaceutical analysis of multivitamin complexes according to the ATC code A11BA, conducted in the following areas: the study of the range of multivitamin complexes with trade names; the characteristic of multivitamin complexes in the composition of active substances; distribution of multivitamin complexes by manufacturers on the pharmaceutical market; analysis of the range of multivitamin complexes in pharmaceutical forms; a comparative analysis of multivitamin complexes by the number of dosage forms and manufacturers; studying of the terms of validity of the registration certificates of multivitamin complexes; determination of parameters of the control regime for multivitamin complexes.

Based on the conducted researches it was determined that multivitamin complexes according to the ATC belong to the subgroup A11BA – Multivitamin complexes without additives. The range of multivitamin complexes (A11VA), which are in circulation on the pharmaceutical market of Ukraine, given in the table 1.

Discussion of the research results of the circulation and the range of multivitamin complexes on the pharmaceutical market of Ukraine (Table 1) shows that they contains up 16 active substance. The multivitamin complexes are in one clinical and pharmacological group: Multivitamin complexes without additions. The multivitamin complexes have the same ATC code - A11BA.

Characteristics of multivitamin complexes by the composition of active substances presented in table 2.

Discussion of the results after researches of the characteristics of multivitamin complexes by the composition of active substances

No	Active substance	Clinical and pharmacological group	ATC code
	Alpha-tocopherol acetate(Vitamin E)	Multivitamin complexes without additions	A11BA
	Ascorbic acid (Vitamin C)		
	Dexpanthenol (D-panthenol)		
	Calcium		
	D-calcium-pantothenate		
	Folic acid		
	Methionine		
	Nicotinamide		
	Pyridoxine (vit B6)		
	Retinol(Vitamin A)		
	Riboflavin (Vitamin B2)		
	Rutoside		
	Thiamine(Vitamin B1)		
	Phosphor		
	Colecalciferol (Vitamin D3)		
	Cyanocobalamin (Vitamin B12)		

Table 1: The range of multivitamin complexes in circulation on the pharmaceutical market of Ukraine.

(Table 2) showed that the composition of all multivitamin complexes consist from Ascorbic acid and Riboflavin in various amounts. However, the composition of some multivitamin complexes differs from other available active ingredients: Dexpanthenol (Pikovit), Methionine (Decamevit), Calcium and Phosphor (Pikovit, Pikovit D).

Discussion of the results of the analysis of the distribution of manufacturers’ countries of multivitamin complexes on the pharmaceutical market manufacturers showed that on the pharmaceutical market of Ukraine four multivitamin complexes are foreign (Pikovit, Syrup, Pikovit, Pikovit D, Pikovit forte) and twelve multivitamin complexes produced in Ukraine (in particular, Hexavit, Decamevit, Complevit, Revit, Undevit , Undetab), which is 75%. Regarding the foreign multivitamin complexes, found that they shipped to Ukraine from Slovenia; their number in this segment of the market is 25% (Figure 1).

Discussion of the results of the distribution of domestic manufacturers of multivitamin complexes on the pharmaceutical market showed that established three pharmaceutical manufacturers

Active substance	Trade names							
	Hexavit	Decamevit	Complevit	Pikovit	Pikovit, Pikovit D	Pikovit forte	Revit	Undevit, Undetab
	Quantity of active substances in 1 dragee, pill, capsule, 5 ml of syrup							
Alpha-tocopherol acetate(Vitamin E)	-	10 mg	-	-	-	15 mg	-	10 mg
Ascorbic acid (Vitamin C)	70 mg	200 mg	100 mg	50 mg	10 mg	60 mg	35 mg	75 mg
Dexpanthenol (D-panthenol)	-	-	-	2 mg	-	-	-	-
Calcium	-	-	-	-	12,5 mg	-	-	-
D-calcium-pantothenate	-	-	25 mg	-	1,2 mg	10 mg	-	3 mg
Folic acid	-	2 mg	0,25 mg	-	0,04 mg	0,40 mg	-	0,07 mg
Methionine	-	200 mg	-	-	-	-	-	-
Nicotinamide	15 mg	50 mg	50 mg	5 mg	3,0 mg	20 mg	-	20 mg
Pyridoxine (vit B6)	2 mg	20 mg	10 mg	0,6 mg	0,3 mg	2 mg	-	3 mg
Retinol (Vitamin A)	1,72 mg or 2,75 mg	6600 IU	-	900 IU	600 IU	5000 IU	0,86 mg or 1,38 mg	1,135 mg
Riboflavin (Vitamin B2)	2 mg	10 mg	15 mg	1 mg	0,3 mg	1,70 mg	1 mg	2 mg
Rutoside	-	20 mg	-	-	-	-	-	10 mg
Thiamine (Vitamin B1)	2 mg	20 mg	15 mg	1 mg	0,25 mg	1,50 mg	1 mg	2 mg
Phosphor	-	-	-	-	10,0 mg	-	-	-
Colecalciferol (Vitamin D3)	-	-	-	100 IU	80 IU	400 IU	-	-
Cyanocobalamin (Vitamin B12)	-	0,1 mg	0,002 mg	1 mcg	0,2 mcg	6 mcg	-	0,002 mg

Table 2: Characteristics of multivitamin complexes by the composition of active substances.

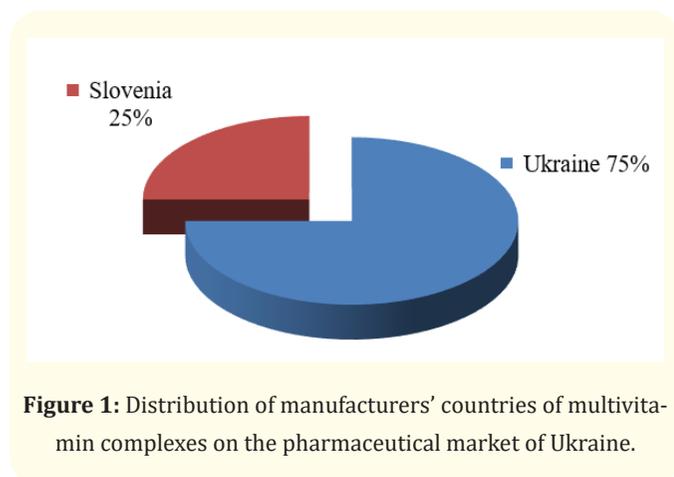


Figure 1: Distribution of manufacturers' countries of multivitamin complexes on the pharmaceutical market of Ukraine.

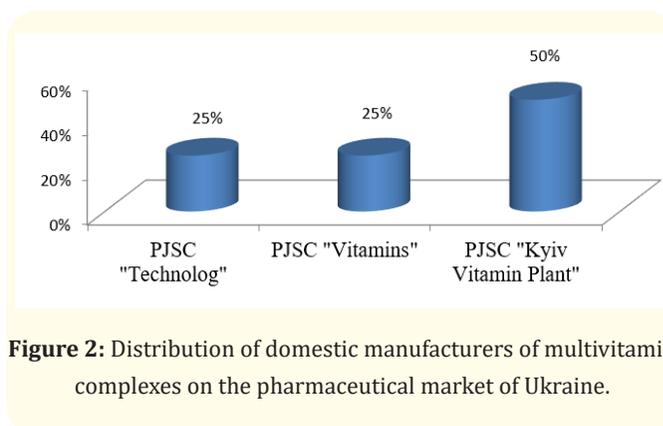


Figure 2: Distribution of domestic manufacturers of multivitamin complexes on the pharmaceutical market of Ukraine.

provide the assortment of domestic multivitamin complexes: PJSC "Vitamins", PJSC "Kyiv Vitamin Plant", PJSC "Technolog" (Figure 2). Among the national producers, the majority of multivitamin complexes (50%) is produced by PJSC "Kiev Vitamin Plant" (Hexavit, Decamevit, Complevit, Revit, Undevit, Undetab).

The next stage of the research was the study of the range of multivitamin complexes by medicinal forms (Table 3).

Discussion of the study of the range of multivitamin complexes by medicinal forms shows the following results. According to the results of the study (Table 3, Figure 3), established that multivitamin complexes represented in the majority on the pharmaceutical market of Ukraine in the form of dragee (56.25%) and pills (31.25%), and in the minority – in the form of syrup and capsules (6.25% equally).

No	INN	Trade name	Medicinal form
1	Comb drug	Pikovit	Syrup
2			Coated pills
3		Pikovit D	Coated pills
4		Pikovit forte	Coated pills
5		Decamevit	Coated pills
6		Complevit	Capsules
7		Undevit	Dragee
8			Dragee
9			Dragee
10		Revit	Dragee
11			Dragee
12			Dragee
13		Hexavit	Dragee
14			Dragee
15			Dragee
16		Undetab	Coated pills

Table 3: The range of multivitamin complexes by medicinal forms.

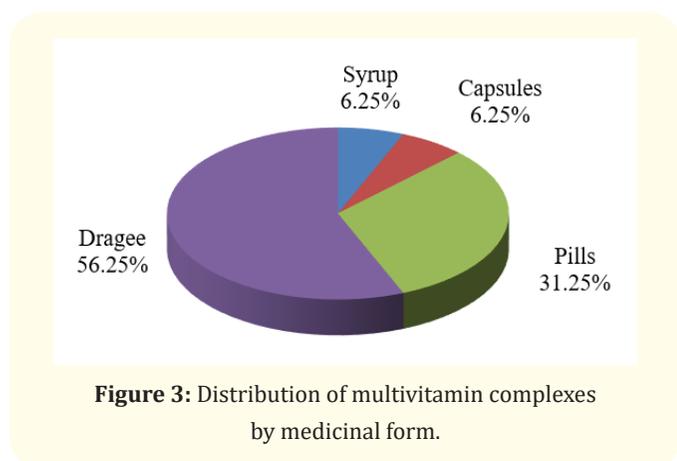


Figure 3: Distribution of multivitamin complexes by medicinal form.

The comparative characteristic of multivitamin complexes by the number of dosage forms and number of manufacturers presented on figure 4.

Discussion of the results of the study about the distribution of multivitamin complexes by quantity of medicinal forms and manufacturers showed that Pikovit presented in two pharmaceutical forms – in the form of syrup and pills, and all other multivitamin complexes – in one form. At the same time, Hexavit, Revit and Undevit multivitamin complexes manufactured by three domestic pharmaceutical companies.

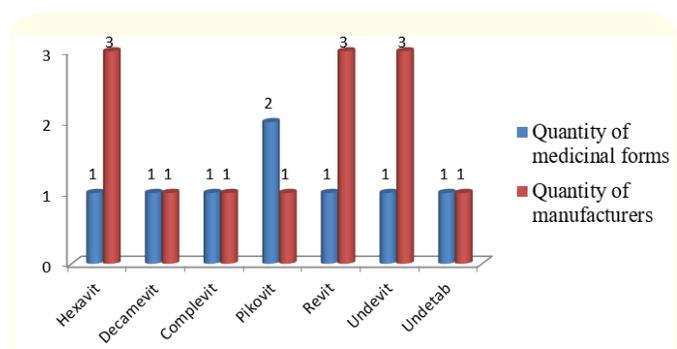


Figure 4: Distribution of multivitamin complexes by quantity of medicinal forms and manufacturers.

During the study if the registration data of multivitamin complexes (Figure 5), established that five of them have unlimited registration certificates on the territory of Ukraine – Pikovit (pills),

Hexavit, Undevit, Pikovit forte, Pikovit D; one of them (Undevit) has the validity period of the registration certificate of 2013-2018; another one (Complevit) – 2014-2019; three of them (Undevit, Hexavit, Revit) – 2015-2020; six of them (Revit, Pikovit (syrup), Revit, Hexavit, Undetab, Decamevit) – 2016-2021.

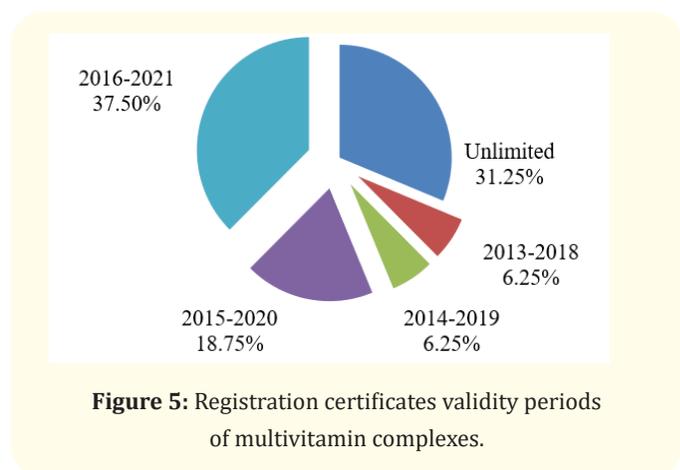


Figure 5: Registration certificates validity periods of multivitamin complexes.

Based on the above and in accordance with the current pharmaceutical legislation of Ukraine, the parameters of the control regime of multivitamin complexes that are in circulation on the pharmaceutical market of Ukraine can be represented schematically: Control regime by code A11BA + General classification and legal group + Non-prescription (OTC) nomenclature and legal group.

Discussion of the results obtained during the study showed the following main aspects. Firstly, all multivitamin complexes contain Ascorbic acid and Riboflavin in different amounts. Among of the multivitamin complexes the Ukrainian manufacturers represent 75%. Only Slovenia supplies multivitamin complexes to Ukraine.

Then, the most significant of the multivitamin complexes presented in the form of pills (56.25%) and tablets (31.25%). Pikovit has the largest honeycomb in the form of two dosage forms (syrup and tablets). Three domestic pharmaceutical producers make multivitamin complexes Hexavit, Revit and Undevit. During studying the registration data of the multivitamin complexes, established that five multivitamin complexes have an unlimited registration period on the territory of Ukraine - Pikovit (tablets), Hexavit, Undevit, Pikovit forte, Pikovit D.

Lastly, determined the parameters of the control regime of multivitamin complexes according to the current legislation of Ukraine. Multivitamin complexes belong to the code A11BA of the ATC system according to the clinical and pharmacological group. They are included to the general group according to the classification and legal group. They released without a doctor's prescription according to the nomenclature and legal group.

These results support the conclusion that the clinical and pharmacological group of vitamins is available for pharmacotherapy and pharmaceutical support of combatants.

These results support the conclusion that the control regime of the multivitamin complexes is available for pharmacotherapy and pharmaceutical provision of combatants.

Conclusion

Within the organizational and legal aspects of pharmaceutical provision of health disorders among combatants, carried out a marketing analysis of multivitamin complexes of ATC code A11BA.

Determined the assortment of multivitamin complexes according to trade names, composition of active substances, manufacturer, dosage forms, registration data, and parameters of control regime. Established that in circulation on the pharmaceutical market of Ukraine there are 16 trade names of multivitamin complexes of ATC code A11BA. When studying the composition of the multivitamin complexes, found that Ascorbic acid (vitamin C) and Riboflavin (vitamin B2) in different quantities are contained in all of the studied multivitamin complexes. However, unlike other multivitamin complexes, Pikovit contains Dexpanthenol, Decamevit – Methionine, Pikovit and Pikovit D – Calcium and Phosphor. The analysis of manufactures of multivitamin complexes showed that 75% of them produced by domestic manufacturers and 25% by foreign (KRKA, Novo mesto, Slovenia). The product range of national production provided by three pharmaceutical manufacturers, among which the majority of multivitamin complexes (50%) produced by PJSC “Kiev Vitamin Plant” (Hexavit, Decamevit, Complevit, Revit, Undevit, Undetab). Revealed that the majority of multivitamin complexes represented on the pharmaceutical market of Ukraine in the form of dragees (56.25%) and pills (31.25%). In the course of studying the registration data of multivitamin complexes, established that five of them have an unlimited registration period on the territory of Ukraine, while six of them expire in various periods 2016-2021. The results of determining the parameters of the multivitamin complexes control regime showed that the clinical and pharmacological group of multivitamin complexes refer to ATC code A11VA; classification and legal group – general; nomenclature and legal group – non-prescription (OTC). Proved that the multivitamin complexes are highly available for pharmacotherapy and pharmaceutical provision of combatants.

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