

I. O. VLASENKO (<https://orcid.org/0000-0002-5530-4189>),

L. L. DAVTIAN (<https://orcid.org/0000-0001-7827-2418>)

Shupyk National Medical Academy of Post-Graduate Education, Kyiv

ACTIVE PHARMACEUTICAL INGREDIENTS IN DERMATOLOGICAL MEDICINES OF UKRAINIAN PHARMACEUTICAL MARKET

Key words: active pharmaceutical ingredients, dermatological drugs, drug-analogues, competition at release, tensile strength

I. O. ВЛАСЕНКО (<https://orcid.org/0000-0002-5530-4189>), кан. фарм. наук, доцент,

Л. Л. ДАВТЯН (<https://orcid.org/0000-0001-7827-2418>), д-р фарм. наук, проф.

Національна медична академія післядипломної освіти імені П. Л. Шупика, Київ

АКТИВНІ ФАРМАЦЕВТИЧНІ ІНГРЕДІЄНТИ У СКЛАДІ ДЕРМАТОЛОГІЧНИХ ЛІКАРСЬКИХ ЗАСОБІВ НА ФАРМАЦЕВТИЧНОМУ РИНКУ УКРАЇНИ

Ключові слова: активні фармацевтичні інгредієнти, дерматологічні лікарські засоби, препарати-аналоги, конкуренція при випуску, коефіцієнт напруженості

The problem of the diabetic foot is one of the most serious complications of diabetes mellitus. The disease of the limbs affects almost 6% of people with diabetes mellitus, and includes infection, ulcers or destruction of foot tissues [1]. This worsens the quality of life of patients and affects labor and social activity of a person and causes a significant financial burden not only on the patient but also on health care and society as a whole [2]. There is still an active search for medicines (drugs) that could be used in the complex treatment of trophic lesions in diabetic foot. There are a number of objective prerequisites for the creation of new medicines: social, medical, scientific and economic [3]. Therefore, it is important to develop new drugs for the treatment of this pathology.

The period before the development and launch of the drug into the pharmaceutical market is characterized by a large volume of marketing research aimed at ensuring that the future drug is competitive. In this case, the study includes an assessment of the feasibility of a drug, the evaluation of the competitiveness of the drug; market research from the standpoint of a competitive structure [4].

Effective marketing actions should be based on information on the current market conditions, the range of real supply of goods. Obviously, such information in a particular spatial-temporal range in the finished form for the most part does not exist. Market research is absolutely necessary for its obtaining [5]. Another feature of marketing in the pharmaceutical industry is the presence of a large number of competitors in national markets [6].

Therefore, **the purpose** of the work was to analyze the market of dermatological drugs for the treatment of trophic ulcers in order to determine the marketing opportunities for domestic producers.

Materials & methods

The research objects were active pharmaceutical ingredients (APIs), which are part of the dermatological registered drugs in Ukraine. The analysis determined the number and structure of producers, the variety of forms of release, API and their combinations, which were part of the drugs of this group. Materials for research were electronic and paper-based official sources of information on registered in Ukraine drugs [7]. The work is done using statistical, logical and graphical methods, as well as methods of marketing analysis. To

determine the level of tension between manufacturers and the same product, the coefficient of tension K_{vi} was calculated according to the formula 1 [8]:

$$K_{vi} = (n - 1) / n, \quad (1)$$

where n – the number of all competitive analogues of drugs.

Results & discussion

Analysis of the API segment of the dermatological drug was performed according to the groups of the Anatomical Therapeutic Chemical Classification System (ATC) classification, the pharmaceutical form, the manufacturer of the drug, the API and the number of times contained in the drug and combinations thereof.

The authors had pre-established the number of D preparations registered in Ukraine – 452 trade names (January 2018), while Ukrainian preparations of Ukrainian origin are slightly higher (55.3%) [9].

The number of API, which it is in the drugs of the group D , including combinations of API has shown in Fig. 1

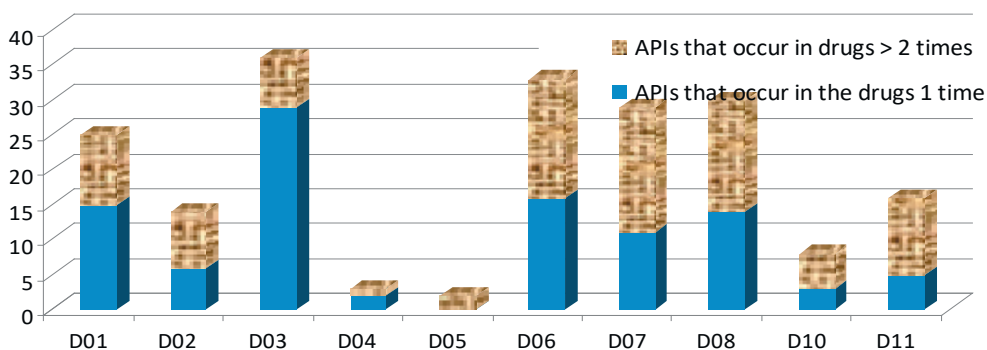


Fig. 1. Number of API occurring in drug therapy groups

As a result of the analysis it can be seen that the most numerous API are in groups $D01$, $D03$, $D06$, $D07$ and $D08$, in which the number of APIs is 25, 36, 33, 29 and 30, respectively. Moreover, in group $D03$, the highest number of API, which contains occur in the drugs only one time. And in the $D07$ group, the largest number of APIs, which are part of many drugs (from 2 to 30 drugs).

In table 1 the APIs, which most often included in the dermatological drug, has shown (regarding to component, dosage form and manufacturer).

Table 1

APIs, which are most often included in dermatological drugs

Group	Active Pharmaceutical Ingredients	Number of medicines, pcs			Number of manufacturers, pcs		Pharmaceutical form, pcs				
		In all	Mono-component	Combination	domestic	foreign	gel	cream	ointment	solution	others
D01	<i>Terbinafine</i>	14	13	1	4	10	4	6		1	3 ¹
	<i>Clotrimazole</i>	13	11	2	5	8		5	5	2	1 ²
	<i>Salicylic acid</i>	9	8	1	9				1	8	
	<i>Naphthofine</i>	5	5		1	4		2		2	1 ¹
	<i>Ketoconazol</i>	4	4		2	2			4		
D02	<i>Urea</i>	7	5		1	4		1	2		1 ³
	<i>Zinc oxide</i>	6	3	3	5	1		1	3		2 ⁹
	<i>Glycerin</i>	6	5	1	6				1	6	
	<i>Salicylic acid</i>	5	1	4		5			2	1	2 ⁹
	<i>Vaseline</i>	4	4		4				4		

Group	Active Pharmaceutical Ingredients	Number of medicines, pcs			Number of manufacturers, pcs		Pharmaceutical form, pcs				
		In all	Mono-component	Combination	domestic	foreign	gel	cream	ointment	solution	others
D03	<i>Dexpanthenol</i>	10	7	3	4	6	1	4	4		1 ⁴
	<i>Laevomycesin</i>	5		5		5			5		
	<i>Methyluracil</i>	6		6		6			6		
	<i>Tincture of Calendula</i>	16	16		16				6		1 ⁷
D04	<i>Dimentinden</i>	2	2			2	1				1 ³
D05	<i>Calcipotriol</i>	3	3			3	1		2		
D06	<i>Acyclovir</i>	11	10	1	4	7		9	2		
	<i>Streptocide</i>	5	5		5				4		1 ⁸
	<i>Fusidic acid</i>	5	5			5	1	2	2		
	<i>Laevomycesin</i>	4	1	3	3	1			3	1	
	<i>Synthomycin</i>	4	3	1	4				1		3 ⁸
	<i>Lidocaine</i>	3		3	3					3	
	<i>Silver sulfadiazine</i>	3	3			3		2	1		
	<i>Supirocin</i>	3	3			3		1	2		
	<i>Metronidazole</i>	3	2	1	1	2	1	1	1		
	<i>Penciclovir</i>	3	3		1	2		3			
D07	<i>Betamethasone</i>	30	15	15	9	21		15	10	2	1 ¹ ;1 ³ ;1 ⁵
	<i>Hydrocortisone</i>	12	6	3	2	8		4	5		1 ³
	<i>Clobetasol</i>	12	12		1	11		6	5	1	
	<i>Mometasone</i>	12	5	3	3	5		2	6		
	<i>Gentamycin</i>	12		11	5	6		7	4		
	<i>Salicylic acid</i>	9		10	1	9		1	7	1	1 ⁵
	<i>Methylprednisolone</i>	6	6		2	4		3	2		1 ³
	<i>Fluocinolone</i>	8	6	2	4	4	1	1	6		
	<i>Clotrimazole</i>	8		6	2	4		5	1		
D08	<i>Hydrogen peroxide</i>	18	18		17	1				18	
	<i>Brilliant green</i>	9	9		9					9	
	<i>Iodine</i>	9	10		10					10	
	<i>Xeroform</i>	7	1	6	7						1 ² ; 6 ⁸
	<i>Povidone-iodine</i>	5	5		3	2			2	2	1 ⁸
	<i>Chlorhexidine</i>	7	4	3	5	2		2		5	
	<i>Boric acid</i>	7	7	2	9				1	8	
	<i>Birch tar</i>	6		6	6						6 ⁸
		<i>Ethanol 70%</i>	15	15		15					15
	<i>Ethanol 96%</i>	14	14		14					14	
D10	<i>Azelain acid</i>	4	4		2	2	2	2			
	<i>Clindamycin</i>	4	2	2		4	3			1	
	<i>Adapalene</i>	4	3	1		4	4				
	<i>Sulfur</i>	4	4		4				4		
D11	<i>Formaldehyde</i>	6	4	2	6						
	<i>Zinc pyrithioneate</i>	4	4		1	3		4			
	<i>Salicylic acid</i>	3	1	2	2	1					1 ⁶ ; 2 ⁹

Note: 1 – spray; 2 – powder; 3 – emulsion; 4 – foam; 5 – lotion; 6 – plaster; 7 – tincture; 8 – liniment; 9 – paste.

The range of drugs *D01* group «Antifungal drugs for use in dermatology» is significant (64 trade names) and is used in case of detection of a fungal infection in a city suffering from a diabetic foot. The group has 25 APIs, of which 10 are most commonly found in the drug (≥ 2 times). The leader of substances in this group is *terbinafine*, which is contained in 14 mono-drugs and 1 combi-drug. Drugs contains *terbinafine*, are presented in the form of cream, gel, spray and solution. The predominant part is the foreign drug production. In this group, APIs are mainly in the form of mono-drugs, only a small amount of them (*terbinafine*, *clotrimazole*, *salicylic acid*, *isoconazole*, *bifonazole*, *urea*) is in combination with other APIs.

In the group *D02* «Preparations with softening and protective action» identified 14 API, of which 5 most often occur in the drug substance of this group. In addition, some of the identified API (*zinc oxide, glycerol, salicylic acid, menthol, novocaine, anestezin*) are part of the combined drug.

The most numerous are groups *D03* and *D06*, drugs that are often used in the treatment of trophic ulcers.

Analysis of group *D03* – «Wounds and ulcers» has identified 49 trade names. The composition of drugs consists of about 36 API, of which 7 names are most common. In this group, most of the identified APIs (*dexpanthenol, levomitsetin, methyluratsil, miramistin*) are in combination with other APIs.

The etiology and flow of trophic ulcers complicated by diabetes involves the use of a large range of *D06* – «Antibiotics and chemotherapeutic drugs for use in dermatology». This group has 57 trade names, consisting of 36 APIs, including 7 of which, occur ≥ 2 times. Some API (*acyclovir, laevomycesin, synthomycin, lidocaine, metronidazole, methyluratsil, etc.*) are often in the drug in combination with other APIs.

The number of dermatological drugs used for the treatment of trophic ulcers with diabetic foot, belonging to the group *D04* – «Antiemetic drugs» and *D05*, are not numerical as itching is not a characteristic symptom for trophic ulcers. There are 3 API in mono-preparations of group *D04*, and 2 API in *D05*, one of which (*betamethasone*) is a part of the combined preparation.

A significant range (106 trade names) of the group *D07* «Corticosteroids for use in dermatology» is not used frequently, because corticosteroids are not recommended for use in this pathology. But some of the combined drugs of this group may be appropriate in the treatment. In this group, 29 APIs, including 18, were found, which are contained in the SC ≥ 2 times. Most of the APIs (*betamethasone, hydrocortisone, mometasone, gentamicin, salicylic acid, fluocinolone, clotrimazole, prednisone, triamcinolone, oxytetracycline, natamycin, neomycin, flumetasone*) are found in the drug, often in combination with other APIs.

Groups *D08* and *D011* are mainly antiseptic medical drugs, the use of which is not sufficient for adequate therapy for wound lesions.

As a result of the analysis of group *D08* «Antiseptic and Disinfectants», 108 trade names were established. In the structure of dermatological drugs, 30 APIs were detected, 16 of which are found in the drug ≥ 2 times. Part of the APIs (*xeroform, chlorhexidine, boric acid, birch tar, phenol, resorcinol, dexpanthenol*) are part of dermatological preparations in combination with other APIs.

In group *D011* «Other dermatological preparations» 18 trade names have been defined, in which there are a number of APIs – 16, of which 11 are found in preparations ≥ 2 times. The main part of the API (*formaldehyde, salicylic acid and boric acid, sodium tetraborate, zinc oxide, hexamethylenetetramine, lead acetate, peppermint oil*) is included in the combined drug substance.

Drugs of group *D10* – «Acne treatment» are not used in the treatment of trophic ulcers. In this group, there are 8 APIs, of which 3 (*clindamycin, adapalene, benzoyl peroxide*) are found in the drug in combinations.

The next stage of the study was to determine the number of analogues in the groups of dermatological drugs and establish competition on the pharmaceutical market of Ukraine which based on the calculation of the stress factor (K_{vi}).

In table 2 summarizes information on the indicators of tension coefficient between manufacturers of analogues of *D* drugs with the definition of names and the number of analogues has shown.

**Indicators of tension coefficients between manufacturers of analogues
of drugs groups D**

ATC group	Non-proprietary trading name / combination of API / «name of drug»	Number of drug analogues, pcs	Tension Coefficient (Kvi)
D01	<i>Terbinafine</i>	13	0.923
	<i>Clotrimazole</i>	11	0.909
	<i>Sol. Salicylic Acid</i>	8	0.875
	<i>Naphthyphine</i>	5	0.800
	<i>Ketoconazole</i>	4	0.750
	<i>Isoconazole</i>	2	0.500
	<i>Bifonazole</i>	2	0.500
	<i>Miconazole</i>	2	0.500
D02	<i>Econazole</i>	2	0.500
	<i>Vaseline</i>	4	0.750
	<i>Glycerin</i>	5	0.800
	<i>Urea</i>	5	0.800
	<i>Menovazine</i>	2	0.500
	<i>Salicylic-zinc paste</i>	2	0.500
D03	<i>Zinc Ointment</i>	2	0.500
	<i>Dexpanthenol</i>	7	0.857
	<i>Calendula Ointment</i>	6	0.833
	<i>Tincture of Calendula</i>	10	0.900
	<i>Laevomekol</i>	5	0.800
D06	<i>Propolis tincture</i>	2	0.500
	<i>Acyclovir</i>	8	0.875
	<i>Streptocide</i>	5	0.800
	<i>Fusidic acid</i>	5	0.800
	<i>Mupirocin</i>	3	0.667
	<i>Synthomycin</i>	3	0.667
	<i>Silver Salt</i>	3	0.667
	<i>Levosin</i>	2	0.500
D07	<i>Imikvimod</i>	2	0.500
	<i>Metronidazole</i>	2	0.500
	<i>Betamethasone</i>	15	0.933
	<i>Hydrocortisone</i>	6	0.833
	<i>Clobetasol</i>	12	0.917
	<i>Mometasone</i>	5	0.800
	<i>Fluocinolone</i>	6	0.833
	<i>Methylprednisolone</i>	6	0.833
	<i>Prednisolone</i>	2	0.500
	<i>Flutikazone</i>	5	0.800
	<i>Betamethasone + Gentamicin + Clotrimazole</i>	5	0.800
	<i>Betamethasone+Salicylic Acid</i>	3	0.667
<i>Betamethasone + Gentamycin</i>	2	0.500	
<i>Hydrocortisone + Oxytocin</i>	2	0.500	

ATC group	Non-proprietary trading name / combination of API / «name of drug»	Number of drug analogues, pcs	Tension Coefficient (Kvi)
D08	<i>Balsamic Lineament of Vyshnevsky</i>	6	0.833
	<i>Ichtiolov Ointment</i>	3	0.667
	<i>Sol.Boric Acid alcohol</i>	6	0.833
	<i>Sol.Chlorhexidine 0.05%</i>	4	0.750
	<i>Fukortsin</i>	2	0.500
	<i>Povidon-iodine</i>	4	0.750
	<i>5% Sol.Iodine alcohol</i>	9	0.889
	<i>Brilliant Green</i>	9	0.889
	<i>3% Sol.Peroxide hydrogen</i>	17	0.941
		<i>Ethanol 70%</i>	15
	<i>Ethanol 96%</i>	14	0.929
D10	<i>Azelaic acid</i>	4	0.750
	<i>Clindamycin</i>	2	0.500
	<i>Adaptalene + Clindamycin</i>	2	0.500
	<i>Adaptalene</i>	2	0.500
	<i>Sulfur Ointment</i>	4	0.750
D11	<i>Zinc Pyrironate</i>	4	0.750
	<i>Paste of Teimurov</i>	2	0.500
	<i>Formidron</i>	4	0.750

A significant number of analogs are installed in the *D01* group. Significant competition was found in the manufacture of *terbinafine*, in addition, it should be noted that the main competition is between the producers of India and Switzerland, and also the analogues are issued by 5 enterprises of Ukraine and foreign countries (France, Palestine, Turkey, Hungary, Romania). Also, high competition is observed in the production of *clotrimazole* analogues (India, Germany and Ukraine). Only 8 domestic enterprises compete for the production of p-alcoholic *salicylic acid*. *Naftifin* is produced by two Ukrainian producers, which compete with the Austrian enterprise. There is a similar situation in the production of *ketoconazole* – 2 domestic plants compete with the manufacturer from Belgium. Other analogues in this group do not compete slightly.

There is a slight competition among Ukrainian producers in the production of *D02* preparations: *menovasin*, *salicylic-zinc paste* and *zinc ointment*. Urea in the topical form is produced by the enterprises of Germany, Ukraine and Switzerland, with the latter offers several medical forms (emulsion of the skin, ointment).

Based on the analysis of the data obtained from the group *D03*, it can be concluded that the greatest competition is observed between the manufacturers of *dexpanthenol*, *calendula ointments*, *calendula tincture* and combined *laevomecol ointment*. It should be noted that the main competition of producers of *ointment calendula*, *calendula tinctures* and *propolis tinctures* unfolded between domestic enterprises, and between manufacturers of analogues of *dexpanthenol* - between foreign producers (Germany, Croatia, Serbia) and two Ukrainian enterprises.

There is no competition in the *D04* group, which consists of 4 names of foreign-made medicines.

Despite the fact that only 3 drugs in the *D05* group, there is little competition in the production of a combined ointment containing *betamethasone* and *calcipotriol*.

Analyzing the results of the *D06* group, it was found that the largest competition among *acyclovir* producers is observed both between foreign enterprises (Germany, Canada, Cro-

atia, Great Britain) and 4 Ukrainians. In the release of soft streptocide-containing *streptocide*, only domestic producers compete with each other, and with the release of *fusidic acid* – enterprises in Germany and Jordan. There is competition between foreign producers (Germany, Poland, Estonia) when producing analogues of *silver salts*. Competitions by foreign producers (Great Britain, Croatia) in the manufacture of *mupirocin*. Analogues of topical forms of *syntomycin* are manufactured only by Ukrainian producers. Insignificant competition in the production of combined ointment *Levosin*.

The most diverse competition is set in the *D07* group. Thus, the highest coefficient of tension in the production of *betamethasone*, carried out along with two of the two domestic producers, also produces from Croatia, the USA and Germany. *Clobetasol* also has a viscous coefficient of intensity, while rival producers from Jordan, Poland, Germany, India and Ukraine. *Hydrocortisone* is supplied from Italy and Poland. In the production of *mometasone* companies from Turkey, Jordan, Poland, India, Spain and Ukraine compete. *Fluocinonide* is produced not only by three domestic enterprises, but also from Russia and Poland. When producing *methylprednisolone* rival domestic and Italian manufacturers. Competition is also observed when producing combinations: *betamethasone*, *gentamycin* and *clotrimazole* between producers in India, USA and Ukraine; a combination of *betamethasone* and *salicylic acid* - between two domestic producers and from Croatia and the USA. Dermatological drugs containing the combination of *betamethasone* and *gentamycin* are supplied by Poland and Croatia. There is little competition between enterprises in Russia and Ukraine in the manufacture of the topical form of *prednisolone*.

In the *D08* group, there is considerable competition from domestic producers. The highest competition in the production of *ethanol 70%* and *ethanol 96%* is the tensile strength. This group often duplicates the long-known formulation: *brilliant green*, *hydrogen peroxide 3%*, *5% alcohol iodine*, *boric acid alcohol*, balsamic lineament of Vishnevsky, *Ichtiolov ointment*. Only in the manufacture of *povidone iodine* in the form of soft lesions in the competition against the two producers of Ukraine enter the producers from Hungary and Macedonia.

In the *D10* group, there was little competition. Thus, in the production of azelaic acid drug, two domestic companies compete with the German manufacturer, while foreign manufacturers of Croatia and the USA compete against the *clindamycin* antibiotic production, while there is a slight competition in the production of a drug containing a combination of *clindomycin* and adapted between Indian and French enterprises. Adaptable are supplied from Croatia and India. 4 Ukrainian producers produce Sulfur Ointment.

According to the analysis of the results, it was found that in the *D11* group, competition was observed only between the three drugs: in the production of *zinc pyrithioneum* - between pharmaceutical companies in Spain and Ukraine. And when produced a long-known formula – Paste of Teimurov and formidron compete only domestic producers.

The conducted analysis showed the promise and relevance of the creation of domestic dermatological drugs of a combined effect for the treatment of trophic ulcers. The results of the analysis will be the basis for further studies on the feasibility of the combination of APIs in the pharmaceutical development of combined drugs for the treatment of trophic ulcers with a diabetic foot, taking into account the etiology, pathogenesis and stage of the wound process.

Conclusion

1. A detailed marketing research of the pharmaceutical market of Ukraine, concerning API, which are part of the dermatological drugs, was conducted. In groups *D01*, *D03*, *D06*, *D07* and *D08* the highest number of APIs is determined, which is 25, 36, 33, 29 and 30, respectively.

2. Part API is contained in the drug in combination with other API. In the *D01* group, only a small amount of API – 7 is present in combination with other substances, and in group *D02* – 6, certain APIs are part of the combined drug. In preparations of *D03* 4 API are in combination. In group *D06*, 12 APIs are contained in combination drugs. Most of the established API groups *D07* (13) are found in the drug in combination. In the *D08* group, part of the API (8) is part of a combined drug. There is a combination of APIs antiseptic or antimicrobial activity, anti-inflammatory effect, local anesthetic and wound healing effect.

3. According to the results of the calculation of the tension indices between the manufacturers of analogues of drugs in group *D*, the highest competition ($K_{vi} \geq 0.800$) was observed in the groups *D01* and *D03* (for 4 drugs with $K_{vi} \geq 0.800$), *D06* (3 drugs), *D07* (8 drugs), *D08* (7 drugs). An analysis of the competitiveness of analogue manufacturers has shown that Ukrainian manufacturers are not sufficiently competing in the production of modern analogues of dermatological drugs.

Reference

1. Zhang P. J. Lu, Y. Jing, S. et al. Global epidemiology of diabetic foot ulceration: a systematic review and meta-analysis // *Annals of Medicine*. – 2017. – V. 49. – P. 106–116. <https://doi.org/10.1080/07853890.2016.1231932>

2. Prevention and management of foot problems in diabetes: a Summary Guidance for daily practice 2015, based on the IWGDF Guidance documents [Electronic resource]. – Mode of access: URL: <https://www.ncbi.nlm.nih.gov/pubmed/26335366>. – Title from the screen. <https://doi.org/10.1002/dmrr.2695>

3. Mnushko Z. N., Dihtyareva N. M. Menedzhment i marketing v farmacii. ch. II. marketing v farmacii: ucheb. dlya studentov vuzov. – 2-e izd. / Pod red. Z. N. Mnushko. – Har'kov: izd-vo NFaU: zolotyie stranicy, 2008. – 536 s.

4. Gromovik B. L., Gasyuk G. D., Levic'ka O. R. Farmaceutichnyi marketing: teoretichni ta prikladni zasady. – Vinnicya: Nova kniga, 2004. – 464 s.

5. Daynovs'kiy Yu. A. Rol' doslidzhen' u marketingoviy diyal'nosti // Aktual'ni problemi ekonomiki i torgivli v suchasniy umovah evrointegracii: materialy nauk. konferencii profesors'ko-vkladach'kogo skladu ta aspirantiv L'vivs'kogo torgovel'no-ekonomichnogo universitetu (11–12 travnya 2017 r.). – L'viv, 2017. – S. 47 – 48.

6. Shul'gina L. M. Osoblivosti farmacevtichnogo marketingu: strategichnyi aspekt // *Visnik Berdyans'kogo universitetu menedzhmentu i biznesu*. – 2012. – № 4. – S. 112–114.

7. Normativno-direktivni dokumenti MOZ Ukraïni. Rezhim dostupu: <http://mozdocs.kiev.ua/>.

8. Bodak V. M. Metodichni pidhodi do marketingoviy doslidzhen' rinku likars'kih zasobiv organami vikonavchoi vladi u sferi ohoroni zdorov'ya // *Ukraïna. Zdorov'ya nacii*. – 2010. – № 4. – S. 72–77.

9. Vlasenko I. O., Davtyan L. L. Porivnyal'nyy analiz rinku dermatologichniy likars'kih zasobiv v Ukraïni za 2013 ta 2018 rr. // *Zb. nauk. prac' spivr. NMAPO imeni P. L. Shupika*. – K., 2018. – Vip. 29, – S. 192–204.

Надійшла до редакції 1 грудня 2018 р.

Прийнято до друку 12 грудня 2018 р.

I. O. Vlasenko (<https://orcid.org/0000-0002-5530-4189>),

L. L. Davtian (<https://orcid.org/0000-0001-7827-2418>)

Shupyk National Medical Academy of Post-Graduate Education, Kyiv

ACTIVE PHARMACEUTICAL INGREDIENTS IN DERMATOLOGICAL MEDICINES OF UKRAINIAN PHARMACEUTICAL MARKET

Key words: active pharmaceutical ingredients, dermatological drugs, drug-analogues, competition at release, tensile strength

ABSTRACT

The problem of the diabetic foot is one of the most serious complications of diabetes mellitus. There is still an active search for medicines (drugs) that could be used in the complex treatment of trophic lesions in diabetic foot. The period before the development and launch of the drug into the pharmaceutical market need to make marketing research aimed at ensuring that the future drug is competitive.

The purpose of the work was to analyze the market of dermatological drugs for the treatment of trophic ulcers in order to determine the marketing opportunities for domestic producers.

The research objects were active pharmaceutical ingredients (APIs), which are part of the dermatological registered drugs in Ukraine. Materials for research were official sources of information about drugs registered in Ukraine. Marketing analytical methods were used. To determine the level of tension between manufacturers and the same product, the coefficient of tension.

Number of *D* preparations registered in Ukraine – 452 trade names (January 2018) was established. Medicines wick produced by Ukraine are slightly higher (55.3%). In groups *D01*, *D03*, *D06*, *D07* and *D08* the highest number of APIs is determined, which is 25, 36, 33, 29 and 30, respectively.

Part API is contained in the drug in combination with other API. In the *D01* group, only a small amount of API – 7 is present in combination with other substances, and in group *D02* – 6, certain APIs are part of the combined drug. In preparations of *D03* 4 API are in combination. In group *D06*, 12 APIs are contained in combination drugs. Most of the established API groups *D07* (13) are found in the drug in combination. In the *D08* group, part of the API (8) is part of a combined drug. There is a combination of APIs antiseptic or antimicrobial activity, anti-inflammatory effect, local anesthetic and wound healing effect. According to the results of the calculation of the tension indices between the manufacturers of analogues of drugs in group *D*, the highest competition ($K_{vi} \geq 0.800$) was observed in the groups *D01* and *D03* (for 4 drugs with $K_{vi} \geq 0.800$), *D06* (3 drugs), *D07* (8 drugs), *D08* (7 drugs). An analysis of the competitiveness of analogue manufacturers has shown that Ukrainian manufacturers are not sufficiently competing in the production of modern analogues of dermatological drugs.

І. О. Власенко (<https://orcid.org/0000-0002-5530-4189>),

Л. Л. Давтян (<https://orcid.org/0000-0001-7827-2418>)

Національна медична академія післядипломної освіти імені П. Л. Шупика, м. Київ
АКТИВНІ ФАРМАЦЕВТИЧНІ ІНГРЕДІЄНТИ У СКЛАДІ ДЕРМАТОЛОГІЧНИХ ЛІКАРСЬКИХ ЗАСОБІВ НА ФАРМАЦЕВТИЧНОМУ РИНКУ УКРАЇНИ

Ключові слова: активні фармацевтичні інгредієнти, дерматологічні лікарські засоби, препарати-аналоги, конкуренція при випуску, коефіцієнт напруженості

А Н О Т А Ц І Я

Проблема діабетичної стопи є одним із найсерйозніших ускладнень цукрового діабету. Досі ведеться активний пошук лікарських засобів, які можна було б використовувати в комплексному лікуванні трофічних уражень за діабетичної стопи. Перед розробленням та виведенням препарату на ринок необхідно провести маркетингові дослідження та оцінити доцільність створення препарату та його конкурентоспроможність.

Тому метою роботи став аналіз ринку дерматологічних препаратів для лікування трофічних виразок із метою визначення маркетингових можливостей для вітчизняного виробника.

Об'єктами дослідження стали активні фармацевтичні інгредієнти (АФІ), які входять до складу дерматологічних лікарських засобів, зареєстрованих в Україні. Матеріалами для дослідження слугували електронні джерела інформації про зареєстровані в Україні лікарських засобів. Застосовували методи маркетингового аналізу та розраховували коефіцієнт напруженості.

Встановлено кількість препаратів групи *D*, які зареєстровані в Україні – 452 торговельні назви, при цьому незначно переважають препарати українського виробництва (55,3%). Проведено детальне маркетингове дослідження фармацевтичного ринку України щодо АФІ, які входять до складу дерматологічних лікарських засобів. В групах *D01*, *D03*, *D06*, *D07* та *D08* визначено найбільшу кількість АФІ, яка складає 25, 36, 33, 29 та 30 відповідно.

Частина АФІ містяться в лікарських засобів у комбінації з іншими АФІ. В групі *D01* лише незначна кількість АФІ – 7 – знаходиться в комбінації з іншими субстанціями, а в групі *D02* – 6 визначених АФІ входять до складу комбінованих лікарських засобів. В препаратах групи *D03* 4 АФІ знаходяться у комбінації. В групі *D06* 12 АФІ містяться у комбінованих препаратах. Більша частина встановлених АФІ групи *D07* (13) зустрічаються в лікарських засобах в комбінації. В групі *D08* частина АФІ (8) входять до складу комбінованих лікарських засобів. Спостерігається поєднання АФІ антисептичної чи антимікробної активності, протизапального ефекту, місцево анестезуючої та ранозагоювальної дії. За результатами розрахунку показників напруженості між виробниками аналогів лікарських засобів у групі *D* встановлено, що найбільша конкуренція спостерігається в групах *D01* та *D03*, *D06*, *D07*, *D08*. Аналіз конкурентоспроможності виробників аналогів свідчить, що українські виробники недостатньо конкурують у виробництві сучасних аналогів дерматологічних препаратів.

И. А. Власенко(<https://orcid.org/0000-0002-5530-4189>),

Л. Л. Давтян (<https://orcid.org/0000-0001-7827-2418>)

*Национальная медицинская академия последипломного образования
имени П. Л. Шупика, г. Киев*

АКТИВНЫЕ ФАРМАЦЕВТИЧЕСКИЕ ИНГРЕДИЕНТЫ В СОСТАВЕ ДЕРМАТОЛОГИЧЕСКИХ ЛЕКАРСТВЕННЫХ СРЕДСТВ НА ФАРМАЦЕВТИЧЕСКОМ РЫНКЕ УКРАИНЫ

Ключевые слова: активные фармацевтические ингредиенты, дерматологические лекарственные средства, препараты-аналоги, конкуренция при выпуске, коэффициент напряженности

А Н Н О Т А Ц И Я

Проблема диабетической стопы является одним из самых серьезных осложнений сахарного диабета. До сих пор ведется активный поиск лекарственных средств, которые можно было бы использовать в комплексном лечении трофических поражений при диабетической стопе. Перед разработкой и выводом препарата на рынок необходимо провести маркетинговые исследования и оценить целесообразность создания препарата и его конкурентоспособность.

Поэтому, целью работы стал анализ рынка дерматологических препаратов для лечения трофических язв с целью определения маркетинговых возможностей для отечественного производителя.

Объектами исследования стали активные фармацевтические ингредиенты (АФИ), которые входят в состав дерматологических лекарственных средств, зарегистрированных в Украине. Материалами для исследования стали электронные источники информации о зарегистрированных в Украине лекарственных средствах. Применяли методы маркетингового анализа и рассчитывали коэффициент напряженности.

Установлено количество препаратов группы *D*, которые зарегистрированы в Украине – 452 торговых названия, при этом незначительно преобладают препараты украинского производства (55,3%). Проведено детальное маркетинговое исследование фармацевтического рынка Украины по АФИ, которые входят в состав дерматологических лекарственных средств. В группах *D01*, *D03*, *D06*, *D07* и *D08* определено наибольшее количество АФИ, которые составляют 25, 36, 33, 29 и 30 соответственно.

Часть АФИ содержатся в лекарственных средствах в комбинации с другими АФИ. В группе *D01* лишь незначительное количество АФИ (7) находится в комбинации с другими субстанция, а в группе *D02* 6 АФИ входят в состав комбинированных лекарственных средств. В препаратах группы *D03* 4 АФИ находятся в комбинации. В группе *D06* 12 АФИ содержатся в комбинированных препаратах. Большая часть установленных АФИ группы *D07* (13) встречаются в лекарственных средствах в комбинации. В группе *D08* часть АФИ (8) входят в состав комбинированных лекарственных средств. Наблюдается сочетание АФИ с антисептической или антимикробной активностью, противовоспалительным эффектом, местноанестезирующим и ранозаживляющим действием. По результатам расчета показателей напряженности между производителями аналогов лекарственных средств в группе *D* установлено, что наибольшая конкуренция наблюдается в группах *D01* и *D03*, *D06*, *D07*, *D08*. Анализ конкурентоспособности производителей аналогов показал, что украинские производители недостаточно конкурируют в производстве современных аналогов дерматологических препаратов.

Электронна адреса для листування з авторами: vlasenkoiryna5@gmail.com

(Власенко І. О.)