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ANALYSIS OF THE UKRAINIAN MARKET OF PARAPHARMACEUTICALS FOR PREVENTION OF KELOID SCARS

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Аналіз ринку парафармацевтиків антикелоїдної дії (ПФАД), для профілактики утворення келоїдних рубців (КР) та забезпечення населення доступними засобами є актуальним питанням на цей час. Причини утворення КР медиками досі не виявлено. Схильність до келоїдоутворення було відзначено у таких випадках, як: після хірургічних втручань, спадковість, етнічні фактори, імунні патології та ін.

Мета дослідження полягала у проведенні аналізу українського ринку парафармацевтиків (ПФ), що застосовуються для профілактики утворення келоїдів.

Матеріали та методи. Матеріалами дослідження було обрано асортимент ПФАД для лікування КР, який був присутній на вітчизняному ринку протягом 2015–2017 рр. за статистичними, аналітичними та економіко-математичними методами аналізу.

Результати дослідження свідчать, що ПФ застосовують у профілактичних, фізіотерапевтичних, фармакотерапевтичних та фармацевтичних методах лікування КР та косметологічних процедурах. Український ринок ПФАД представляють виключно вітчизняні виробники («Євро плюс», ПП «Екобіз», ТОВ НВО «ФітоБіотехнології», група компаній «Ельфа» та ін.). До складу ПФ найчастіше входять гепарин, екстракт цибулі, Д-пантенол. Відзначається присутність однакових за складом засобів, але одні знаходяться в обігу як ЛЗ, а інші – як ПФ. Для споживачів у анотаціях на ПФАД доцільно чітко рекомендувати застосовувати їх тільки з метою першої долікарської допомоги та профілактики утворення келоїду.

Висновки свідчать, що найбільша частка ПФАД (42,9 %) представлена у формі гелю. При аналізі цінових показників ПФАД за 2015–2017 рр., встановлено, що показник коефіцієнту ліквідності знаходиться у межах 0,133–0,433. Всі вітчизняні ПФАД мають високий коефіцієнт адекватності платоспроможності у 2015–2017 рр. Протягом 2015–2016 рр всі розраховані значення показника доступності аналізованих товарів дорівнюють одиниці або більше одиниці ($D \geq 1$). Але у 2017 р. значення аналізованого показника менше одиниці, що є наслідком нестабільної ситуації на фармацевтичному ринку країни

Ключові слова: келоїди, парафармацевтика, аналіз парафармацевтичного ринку, профілактика утворення келоїдів, цінова доступність парафармацевтиків

1. Introduction

Keloid – has a Greek origin and translated kele – a tumor and éidos – a species. KS is a special type of scarring that grows into normal tissues and is formed after operations, burns, wounds, bites, injections (rarely KS arise without obvious reasons). According to statistics, about 10 % of the planet's population suffers from the formation of KS. Patients from 10 to 40 years of age are at a risk group. Young children and elderly people almost never suffer from the appearance of keloid-type scars [1, 2]. Most often, girls and young women are gotten at a risk group. To date, the average age of patients complaining to the KS is 25.8 years [3].

2. Formulation of the problem in a general way, the relevance of the theme and its connection with important scientific and practical issues

According to medical statistics, about 10–20 % of all patients with scar tissue changes after surgery are the "owners" of the KS. Among them 85 % of women, due to the presence of many factors (puncture of ears, piercing, frequent plastic surgery, skin polishing, etc.). Quite often the predisposition to the emergence of the KS is transmitted hereditary. In people with darker colour of the skin, the KS arise ten times more often. The tendency to keloid formation can be noted in such cases as: immune pathologies, heredity, ethnic factors, disturbance of regulatory functions of the central nervous system [4].

3. Analysis of recent studies and publications in which a solution of the problem are described and to which the author refers

For the first time the term "primary keloids" that arose without injury was initiated by the outstanding scientist of the twentieth century – M. M. Zheltakov (1957). A. A. Studnicyn introduced such concept as "spontaneous keloids" (1968). Analysis of the literature on the chosen topic allowed establishing that many domestic scientists worked on the problem of the prevention of the formation of pathological scars [4].

Research was conducted on the use of parapharmaceuticals (PF) in clinical practice to prevent the onset of KS [5, 6]. The number of studies is limited, but the use of "Dermatiks" and "Fermencol" drugs were experimentally analyzed in the treatment of scarring and prevent their development [7, 8].

4. The field of research considering the general problem, which is described in the article

At the same time, individual researches were devoted to organizational and economic problems in improving the PF turnover in the pharmaceutical market of Ukraine [9]. Thus, the problem of avoiding the formation of pathological scars with the use of AKPF is relevant to today.

5. Formulation of goals (tasks) of article

The aim of the work is to analyze the Ukrainian market of PFs, which are used to prevent the formation of KS.

6. Presentation of the main research material (methods and objects) with the justification of the results

The following analytical methods were used in the work: statistical, analytical and economical-mathematical. The subject of the research was the selection of AKPF assortment, which is being implemented in pharmacies of Ukraine for the prevention and treatment of CS. The subjects of the study were price and other indicators that characterize AKPF.

To date, Ukraine has faced a difficult situation: the simplicity of registration of PF and their out-of-order release led to a significant increase in the consumption of these goods. PF can include the same ingredients as in the composition of medicines. Therefore, when applying PF in larger doses than recommended in the annotations to their application, they can either act as a drug. In conditions of high competition on the world and domestic market of anti-keloid drugs, in circulation there is domination by foreign-made drugs, which have a price several times higher than AKPF. Quite often, the components of the active substances of drug and AKPF are the same. Therefore, the analysis of the AKPF market in order to prevent the creation of the CS and to provide the population with affordable medicines is a topical issue of the day.

Unfortunately, in Ukraine there is no statistical record of the pathology of the formation of the CS. In accordance with the international classification of diseases of the tenth revision (ICD-10), the CS belongs to class XII – Diseases of the skin and subcutaneous tissue. Scar conditions and fibrosis of the skin (L90.5) [9]. According to the "International guidelines for the management of patients with pathological scarring" there are such methods of treatment: surgical excision, radiation therapy, compression, laser treatment, cryotherapy, ointment therapy.

According to literary sources, it is customary to classify the keloid as true (spontaneous) and false [10, 11]. CS of small and medium size can be practically completely removed with the help of medicines that contain corticosteroids.

In CS of large size use a combination of several methods:

- scar removal and the use of occlusion bandages with the drug and AKPF;
- providing increased pressure on damaged fabrics;
- introduction of corticosteroids and immunomodulators.

But none of the methods of treatment of the CS guarantee the absence of relapse of the keloid. For the prevention of relapses after the operation, both drug and AKPF are used (the latter are usually more affordable). According to the order of the Ministry of Health of Ukraine No. 691 dated November 7, 2007 "On approval of clinical protocols for the provision of medical aid to patients with burns and their consequences" regarding the further provision of ambulatory care recommended to provide a prevention of scar formation by conservative dissolving therapy using "Contractubex" gel, 20 g. (Merz Pharmaceuticals GmbH, Germany) [12].

It should be noted that many aspects of the use of PF cause controversy and are ambiguously treated by experts. The main risks with prolonged and uncontrolled use of PF are: overdose; the emergence of allergic skin reactions and tumours, especially in pregnant women, children with other diseases (diabetes mellitus, hypertension, etc.); absence of clear recommendations of official medicine regarding the application of PF. Sometimes consumers think that if PF are sold through a pharmacy network, they also belong to the drug store. Therefore, it is worthwhile in annotations on AKPF, in order to increase the effectiveness of use and awareness of the population about PF, it is strongly recommended to use them only as the first pre-care and prevention of the establishment of the KS. Also, in the annotations on the medical device, clearly indicate at which stages of the disease in the KS they need to use them. In the conditions of ex-

tremely limited budget financing of health facilities and the absence of a system of social health insurance, in particular the effective reimbursement of the cost of drugs, consumers need to obtain accessible, truthful and competent information about the means of treatment of the KS. In our opinion, limiting the access of patients to information on AKPF for self-treatment in these conditions is inappropriate.

In the analysis of the Ukrainian parapharmaceutical market of AKPF we found that it was dominated by soft drugs, namely: in the form of gel – 43 %, creams and balsams occupy about the same values – 22 % and 21 % respectively, in the form of oils for external use – 14 % (Fig. 1).

The AKPF market is represented exclusively by means of domestic production ("Euro plus", PP "Ekobiz", TOV NVO "PhytoBiotechnology", a group of companies "Elfa", etc.)

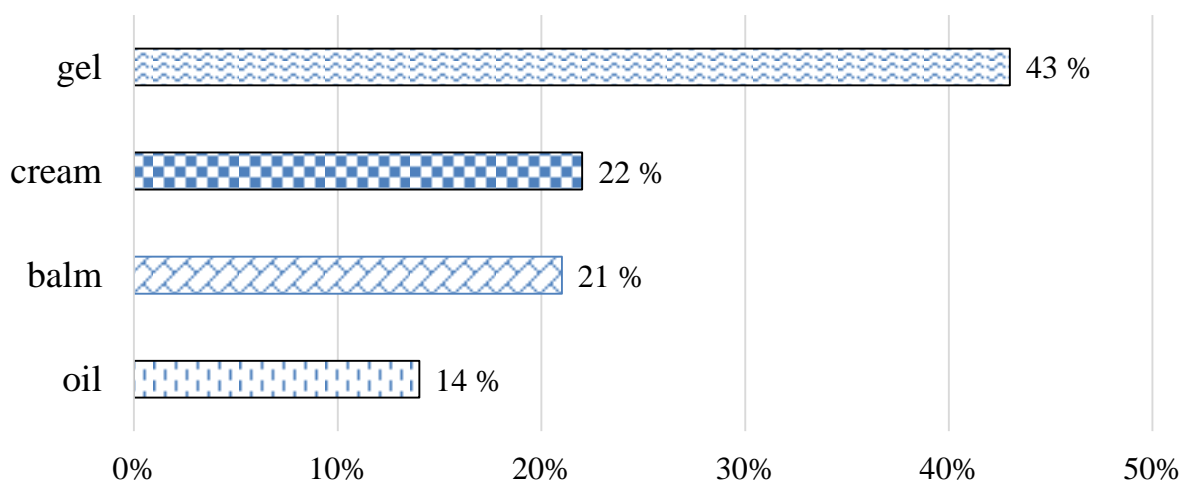


Fig. 1. Ranking of AKPF for dosage forms

It is known that the same substances, such as vitamins, trace elements, essential fatty acids, biologically active compounds, are both included into PFs and drugs. It was established that 28.5 % of AKPF are the main active substances: heparin – acid sulfur-containing glycosaminoglycane; onion extract (extr. Cepae) – flavon of onion obtained with low temperature extraction; D-panthenol (Dexpanthenol) is a vitamin of group B, a derivative of pantothenic acid. Other biologically active compounds, such as hydrocortisone acetate, methyluratsil, silicone gel, urea, D-camphor, that are part of AKPF, occupy 71.5 %.

Simplified procedure for registration of PF promotes the appearance on the pharmaceutical market of Ukraine of the same composition of funds: one is in circulation as a drug, and the other – as a PF. For example, "Contractubex" gel 20 g (Merz Pharmaceuticals GmbH, Germany), which according to the ATC-classification belongs to dermatological preparations

(code ATC-D03AX50). The composition of the gel includes: extract of onion, allantoin, and sodium heparin. And in the composition of such AKPF (similar to the effect of drugs) in the form of a gel as: "Rubtsov.Net" 20 ml "Zhuvin" series (PP "Charley", Ukraine); "Anti-rubets Mg⁺⁺", 20 ml (PE "Ekobiz", Ukraine); "Contrarubets" 40 ml ("Cortes", Ukraine), also includes onion extract, heparin sodium and D-panthenol. At the same time, the prices for the specified goods differ several times. For example, the average retail price of "Contractubex" gel as of January 1, 2018 amounted to 365.00 UAH, and "Rubtsov.Net" gel was 40.00 UAH. Therefore, the availability of PF is much higher than one of a similar drug.

Taking into account the need for long-term use of AKPF after treatment, we analyzed the economic availability of AKPF in 2017, and the coefficient of variation was calculated, which shows how large the difference is between the AKPF names having the highest (C_{min}) and the lowest value of the price (C_{max}) (Fig. 2).

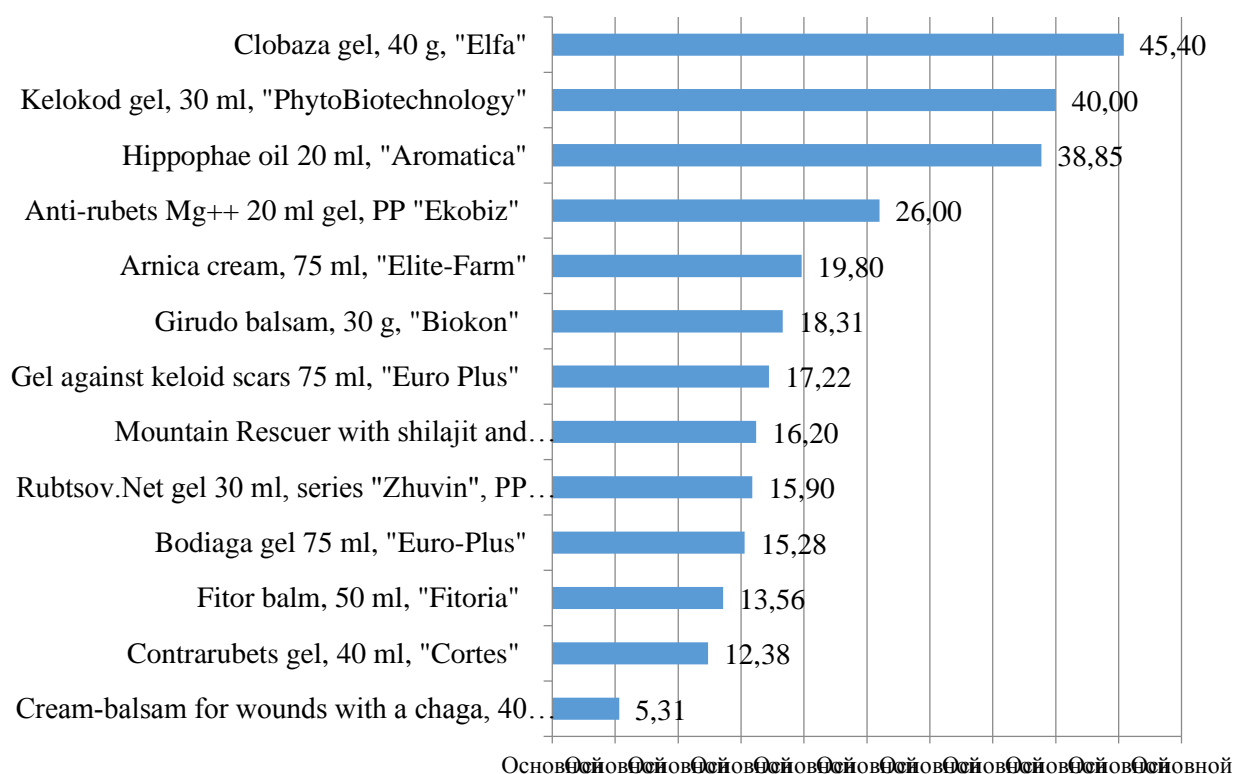


Fig. 2. Analysis of the coefficients range of variability by the AKPF name

In the course of the study, we analyzed the value of the price liquidity ratios (C_{liq}) for AKPF for 2015–2017. The price liquidity ratio reflects the degree of competition in the market and to a certain degree characterizes the availability of AKPF. It is generally known that the smaller the value of the liquidity ratio (usually 0 to 0.5), the stronger is the level of competition in the parafarmaceutical market, and the more affordable the analyzed goods. Calculation of this indicator was carried out according to the formula:

$$C_{liq} = \frac{C_{max} - C_{min}}{C_{min}},$$

where

C_{max} – the highest price of AKPF; C_{min} – the lowest price of AKPF [13].

It should be noted that during 2015–2017 the value of the liquidity ratio of the AKPF price does not exceed 0.5, which indicates a high level of competition in the parafarmaceutical market. At the same time, relatively low values of the liquidity ratio positively characterize the availability of AKPF for the population.

It should be noted that during the years 2015–2017, many AKPF names were not readily available to the end user, for example, in 2015 Hippophae oil 20 ml, "Aromatica" ($C_{liq}=0.533$); gel against keloid scars 75 ml, "Euro Plus" ($C_{liq}=0.499$). The most accessible in 2015 were the following AKPFs: Rubtsov.Net 30 ml, series "Zhuvin", PP "Charley" ($C_{liq}=0.113$) and Cream-balsam for wounds with a chaga, 40 g, "Elixir" ($C_{liq}=0.126$).

It was established that in 2016, the least accessible for consumers was the Mountain Rescuer with shilajit and hippophae 75 ml, "Elixir" ($C_{liq}=0.263$), and the most accessible in the same year were AKPFs as: Bodiaga gel 75 ml, "Euro -Plus" ($C_{liq}=0.195$) and Cream-balsam for wounds with a chaga, 40 g, "Elixir", ($C_{liq}=0.169$).

In 2017, the most accessible to the population was Rubtsov gel 30 ml, series "Zhuvin", PP "Charley" ($C_{liq}=0.190$). The low availability of this year had Antiscar Mg⁺⁺ 20 ml gel, PP Ekobiz ($C_{liq}=0.367$) and Hippophae oil 20 ml, "Aromatica" ($C_{liq}=0.365$). In the above-mentioned AKPFs, the C_{liq} is more than 0.30, indicating their low availability in 2017, due to the volatile situation with the exchange rate on the market and the rise in prices of raw materials (Fig. 3).

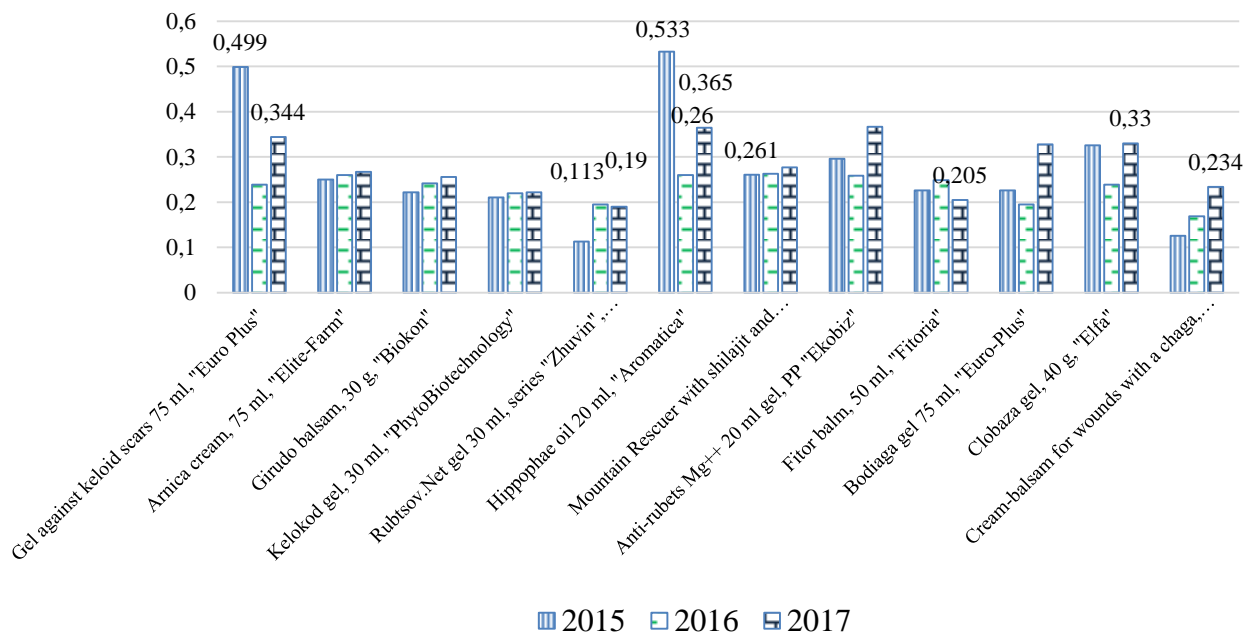


Fig. 3. Dynamics of liquidity ratios for AKPFs in 2015–2017

The next stage of the study was the analysis of the solvency adequacy ratio (Ca.s.), which made it possible to determine the level of AKPFs availability in relation to the income of the population in 2015–2017. It is generally known that the smaller the value of this indicator, the more accessible to the population AKPFs, which are being analyzed. The calculation was carried out according to the following formula:

$$C_{a.s.} = \frac{P}{Wa.w} \times 100\%$$

where *P* – the average weighted retail price of AKPF for a certain period; *Wa.w.* – the average wage for the analogous period [13].

Analyzing the obtained results, it was found that the largest indicator of adequacy of solvency during the analyzed years had AKPF "Clobaza gel", 40 g ("Elfa", Ukraine) – in 2015, Ca.s.=3.81 %; in 2016 Ca.s.=3.01 %; in 2017 Ca.s.=2.61 %, and the lowest – "Cream-balsam for wounds with a chaga", 40 g ("Elixir" Ukraine) – in 2015 Ca.s.=0.73 %; in 2016 Ca.s.=0.54 %; in 2017 Ca.s.=0.45 %. This shows that the highest availability for the population had AKPF "Cream-balsam for wounds with a chaga", 40 g ("Elixir" Ukraine) (Fig. 4).

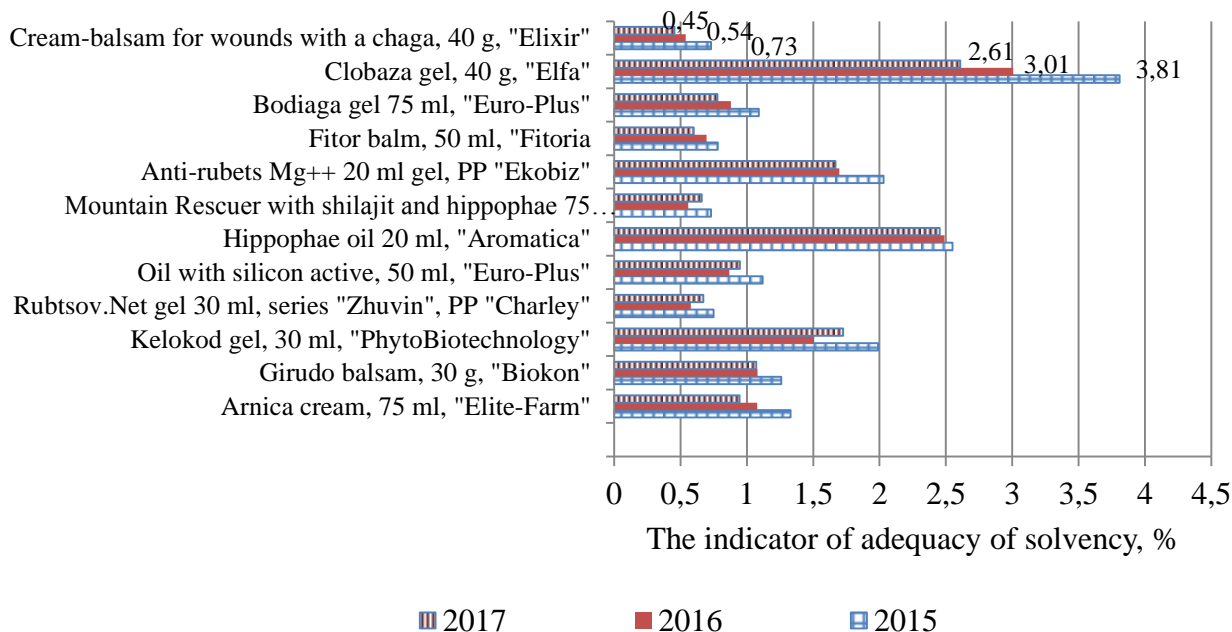


Fig. 4. The indicator of adequacy of solvency of the population considering AKPF in 2015–2017

The next stage of the study was to determine the availability of AKPF for the period 2015–2017 by the formula:

$$D = \frac{I_x \times Z_{min}}{I_s \times V_k}$$

where I_x – index of average wage change for a certain period; Z_{min} – minimal wage in the country; I_s – consolidated price index for AKPF for the same period; V_k – the cost of the consumer basket [13].

It is known that in order to achieve the optimum level of accessibility of the analyzed goods guaranteed

by the state, the value of the accessibility index should correspond to the optimal level ($D \geq 1$).

To perform the relevant calculations of the AKPF availability index for the period 2015–2017, the official statistical data presented in table 1 was used.

According to the results of calculations, it was determined that the values of the AKPF availability index in 2015–2016 correspond to the optimal level ($D \geq 1$). However, in 2017, the decline in the availability rate in most of the analyzed AKPFs – 57 %, which is the result of an unstable situation in the parapharmaceutical market of the country (Fig. 5).

Table 1

Characteristics of socio-economic indicators of the population of Ukraine in 2015–2017*

Year	Minimal wage	Index of average wage change for a period	The cost of the consumer basket
2015	1253.00	1.21	1253.00
2016	1378.00	1.13	1330.00
2017	3200.00	1.67	1544.00

Note: In accordance with the Laws of Ukraine "On the State Budget of Ukraine for 2015, 2016, 2017", respectively

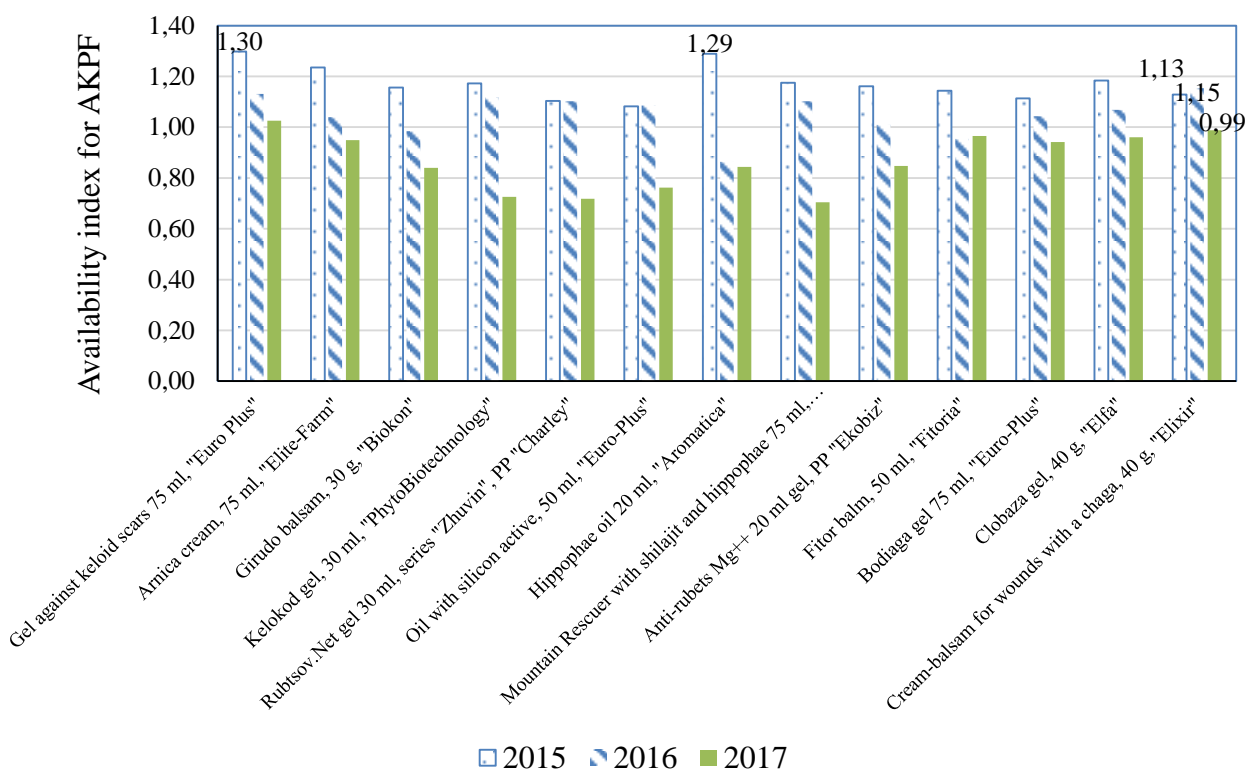


Fig. 5. Availability index for AKPF in 2015–2017

It was found that the most accessible for the population during the analyzed period was – Cream-balsam for wounds with a chaga 40 g, "Elixir" – in 2015, $D=1.30$, in 2016 $D=1.13$, in 2017 $D=1.03$.

7. Conclusions from the conducted research and prospects for further development of this field

1. According to the literature, it is found that about 10 % of the world's population suffers from the

KS. The greatest tendency to the appearance of keloid scars has been observed in patients from 10 to 40 years, among them 85 % – women. There are such methods of treatment of CS: preventive, physiotherapeutic, pharmacotherapeutic, pharmaceutical and cosmetic procedures. In all methods, as a rule, AKPF applied. A simplified procedure for registration of PF in Ukraine has led to a widespread situation where there are identical means in stock in the pharmaceutical market of Ukraine, but one is

in circulation as a drug (for example, Contractubex gel, 20 g (Merz Pharmaceuticals GmbH (Germany), and others – as AKPF (for example, gel "Contrarubets", 40 ml (Cortes, Ukraine).

2. It was established that the Ukrainian market of AKPF is represented exclusively by domestic producers, namely ("Euro plus", PP "Ekobiz", TOV NVO "Phyto-Biotechnology", a group of companies "Elfa", PP "Charley", which mainly produce soft dosage forms in the form of a gel – 42.9 %.

3. The coefficient of the price variation for AKPF is calculated, the price fluctuation is set to more than 50 %. The prices and liquidity ratios of AKPF in 2015–2017 were calculated. The most affordable to the population were: in 2015, Rubtsov.Net gel 30 ml, series "Zhuvin", PP "Charley" ($C_{liq}=0.113$), in 2016 – "Cream-balsam for wounds with a chaga" 40 g, "Elixir", ($C_{liq}=0.169$), in 2017 gel "Rubtsov.Net" ($C_{liq}=0.190$). The coefficients of the adequacy of the solvency of the PF

"Cream-balsam for wounds with a chaga", 40 g ("Elixir" "Ukraine) (2015 (Ca.s.=0.73 %), 2016 (Ca.s.=0.54 %), 2017 (Ca.s.=0.45 %)) were the highest among the studied AKPF, indicating their availability to the population.

4. It has been established that the value of the AKPF availability index for 2015–2016 is equal to or greater than one. In 2017, the decrease of the availability rate in most of the analyzed AKPF (57 %) was determined, which is the result of the unstable situation on the parafarmaceutical market of the country, and as a result the achievement of the guaranteed level of affordability for the Ukrainian population of the analyzed goods in 2017 is unsatisfactory.

But the most accessible for the population during the analyzed period was – "Cream-balsam for wounds with a chaga", 40 g "Elixir", the accessibility index of which during the analyzed years was equal to more than one unit – in 2015 $D=1.30$, in 2016 $p D=1.13$, in 2017 $D=1.03$.

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