THE CURRENT STATE AND THE DEVELOPMENT PROSPECTS OF THE UKRAINIAN MARKET OF ANTIHISTAMINES

Nowadays allergy has become a global problem for all humanity. According to the WHO about 30-40 % of the world’s population suffers from allergic diseases. Environment pollution, as well as everyday use of a large number of synthetic substances, contribute to the rapid increase in incidence of allergic reactions. The therapy of these diseases is based mainly on the antihistamine drugs (AHD), which makes it reasonable to study the Ukrainian market of AHD and to identify its promising directions of development.

Aim. To study the assortment of antihistamine drugs registered in Ukraine.

Materials and methods. The analysis was based on the official sources of information and materials of the previous marketing research using the methods of systematic, graphical and comparative analysis with the subsequent obtaining of explanations and conclusions.

Results. During the analysis of the domestic pharmaceutical market regarding the assortment of antihistamines it has been found that 128 drugs are used in Ukraine for the treatment of allergic diseases. The study of distribution by dosage forms has revealed the prevalence of solid dosage forms – tablets and dragee – their percentage is 71 %. The analysis of AHD by the manufacturing countries has shown the import dependence of the Ukrainian market: the foreign manufacturers represent 61 % of the drugs. Moreover, in recent years there is a downward trend of the share of domestic manufacturers (50 % – in 2014; 39 % – in 2019). India is the largest importer of antihistamines at the market (17.2 %); the total market share of the European Union countries is 39 %. The analysis of the current state of the pharmaceutical market has determined a change in the distribution of AHD by INN in favor of the new-generation drugs. The study has revealed the absence of anti-allergic herbal medicines in Ukraine; it substantiates the development of new drugs for the phytotherapy of allergic diseases.

Conclusions. The absence of plant-based anti-allergic drugs at pharmaceutical market of Ukraine has been found. Taking into account an increasing popularity of herbal medicines and growing demand for drugs with a good safety profile we have concluded that the development of a new plant-based drug for the allergy treatment is a topical direction for further studies.

Key words: allergic diseases; pharmaceutical market; antihistamines.
Выводы. Установлено отсутствие противаллергических растительных препаратов на фармацевтичном рынке Украины. Врачующие зростающей популярностью растительных лекарственных средств в высокий рост попытку изменения лекарств заслуги с хорошим профилем безопасности, мы делились висковую, что разработка нового противаллергического препарата на рослинной основе с актуальным напрямиком подальших до слежений.

Ключевые слова: аллергические захворювання; фармацевтичний ринок; антигістамінні лікарські засоби.

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**Современное состояние и перспективы развития рынка антигистаминных препаратов в Украине**

В наше время аллергия стала глобальной проблемой для всего человечества. По данным ВОЗ, около 30-40 % населения земного шара страдают от аллергических заболеваний. Загрязнение внешней среды вместе с частым использованием в быту большого количества синтетических веществ способствует стремительному распространению аллергических реакций. Терапия этих заболеваний основывается в большей степени на применении антигистаминных препаратов (АГП), что обусловливает целесообразность исследования рынка АГП в Украине и выявления приоритетных направлений его развития.

Цель: исследование ассортимента зарегистрированных в Украине антигистаминных лекарственных средств.

Материалы и методы. Анализ проводился на основании официальных источников информации и материалов предварительных маркетинговых исследований, а также методов системного, графического и сравнительного анализа и последующим получением объяснений и выводов.

Результаты исследования. В ходе анализа отечественного фармацевтического рынка по ассортименту антигистаминных лекарственных средств было установлено, что в Украине зарегистрировано 128 препаратов, применяемых для лечения аллергических заболеваний. Исследование распределения препарата по лекарственным формам выявило преимущество твердых лекарственных форм – таблетки и драже насчитывают 71 %. Анализ АГП по странам-производителям показал импортозависимость рынка – 61 % препаратов представлен импортными производителями. При этом за последние годы наблюдается тенденция к уменьшению доли отечественного производителя (50 % – в 2014 г.; 39 % – в 2019 г.). Крупнейшим импортером антигистаминных лекарственных средств на рынке является Индия (17,2 %); суммарный вклад стран Европейского Союза составляет 39 %. Анализ современного состояния фармацевтического рынка установил изменение распределения АГП по МНН в пользу лекарственных средств нового поколения. В ходе исследования выявлен отсутствие в Украине противоваллергических лекарственных средств растительного происхождения, что обосновывает разработку новых препаратов для фитотерапии аллергических заболеваний.

Выводы. Установлено отсутствие антиаллергических препаратов растительного происхождения на фармацевтическом рынке Украины. Примыкая во внимание растущую популярность растительных лекарственных средств и виский спрос на лекарства с хорошим профилем безопасности, мы пришли к выводу, что разработка нового растительного лекарственного средства для лечения аллергии является актуальным направлением для дальнейших исследований.

Ключевые слова: аллергические заболевания; фармацевтический рынок; антигистаминные лекарственные препараты.

Statement of the problem. Human modern life is inseparably connected with the daily use of a large number of synthetic substances. Environment pollution by industrial waste, use of chemicals in farming and daily life, the frequent use of dyes and preservatives in the food and pharmaceutical industry negatively affect the health and lead to the different types of allergic reactions. The upward trend in the incidence of allergy is also caused by nutrition disorders, uncontrolled medication, various chronic diseases and long-term stress, which are an integral part of the human existence [1, 2].

To date, about 30-40 % of the world’s population suffers from the allergic diseases. In addition, statistics indicate a rapid increase in the incidence of allergic reactions over the last 50 years, especially in countries with the pro-western lifestyle [1]. There are no official data of these diseases in Ukraine, but according to literature sources, the number of patients is about 20-30 %, confirming the relatively high incidence of allergies in our country.

This problem is especially acute in pediatric practice. In recent years, there has been a steady increase in the incidence of allergic reactions in children and adolescents. The risk of allergy sensitization of the young immune system is much higher; therefore, it is sometimes very difficult to predict the risk of allergy in children. That is why doctors often recommend the prophylactic therapy, which has specific requirements for efficacy and safety [3-7].

[70] Соціальний маркетинг та фармакоекономічні дослідження
In the modern therapeutic practice, the allergic reactions are mainly treated due to the effect on histamine receptors and the metabolism of histamine. There are two main approaches: 1) reducing free histamine; 2) blockade of histamine receptors. By the first approach the activity of the group of drugs called “stabilizers of mast cells membranes” (ketotifen, cromoglycic acid, nedocromil, etc.) is effective. They are widely used in medical practice, but their moderate and long-lasting effect allows using them for prophylactic purposes only. The group of antihistamine drugs (AHD) has faster and stronger anti-allergic activity. Thus, this group is the first line therapy in the treatment of most allergic diseases [8].

The modern AHD classification includes 3 generations. The first-generation drugs (diphenhydramine, demestane, chlorpheniramine, mehydrolin, etc.) have been used in clinical practice for many years; it gives them an advantage in terms of the wide experience of their application. A major disadvantage is their ability to easily dissolve in lipids, pass through the blood – brain barrier (BBB), and bind to histamine, serotonin, dopamine, and n-acetycholine receptors of the brain, affecting the central nervous system (CNS). 40-80 % of patients subjectively notice various types of cognitive impairment: drowsiness, anxiety, nervousness, dizziness, vestibular disorders, hypotension, impaired learning ability, memory impairment, etc. In addition, the first AHD generation also has a short-term effect and provides development of tachyphylaxis.

The 2nd generation of AHD (loratadine, dimethyndene, ceterizine) do not pass through the BBB and have a long and sustainable effect. But pharmacokinetic peculiarities cause the accumulation of their metabolites in the tissues of the heart and provide the cardiotoxic effect (except loratadine) [8-11].

The 3rd AHD generation includes active metabolites and stereoisomers of drugs of the previous generation (desloratadine, levocetirizine, fexofenadine), which are characterized by the best safety profile among other AHD groups [8, 10, 11].

Therefore, the wide range of applications and the peculiar pharmacological actions of each generation of this group of drugs allow us to state that AHD are indispensable for the treatment of allergic reactions of different complexity and etiology.

**Analysis of recent research and publications.** The studies of the domestic pharmaceutical market of AHD in different periods were carried out by L. V. Yakovleva, M. O. Syzenko, O. G. Berdnik, A. O. Gurtyakova etc. [12-14].

**Identification of aspects of the problem unsolved previously.** In 2019, at the Department of Industrial Technology of Drugs of the National University of Pharmacy the research on developing of a new anti-allergic medicine based on a complex plant extract began. The new drug is planned to be created in the form of tablets containing dry extracts of the following plants: *Bidens tripartita*, *Calendula officinalis* and *Cretaegus sanguinea* in the established ratio. Since the development of a new drug always requires the identification of its potential importance for the consumer, conducting the market research in order to identify the state and the potential directions of the AHD market development is an expedient and relevant task.

**Objective statement of the article.** The aim of our work was to analyze the assortment of antihistamines available at the pharmaceutical market of Ukraine.

**Materials and methods.** The analysis was based on the official sources of information, such as the State Register of Medicines of Ukraine, the directory “Compendium 2018 – medicines” and materials of the previous marketing research [12, 13]. The methods of systematic, graphical and comparative analysis were used to obtain explanations and conclusions.

In addition, the AHD affordability for the population of Ukraine was determined. The number of dosage units for the calculation of the indicator was chosen based on the average duration of the treatment of chronic allergic diseases, i.e. 5 weeks [12, 15]. The solvency index (Ca.s., %) was calculated using the formula (1):

\[
\text{Ca.s.} = \frac{P}{\text{Wa.w.}} \times 100\% \quad (1)
\]

where \(P\) – is the average cost of the treatment course as of November 2019; \(\text{Wa.w.}\) – is the average salary as of November 2019.

The average salary was determined according to official statistics [16].

The solvency index Ca.s. was interpreted due to distribution of trade names into 3 groups:
highly affordable if the value of the index Ca.s. was less than 5 %; medium affordable if Ca. s. was in the range of 5-15 % and unaffordable where Ca.s. was above 15 % [17].

**Presentation of the main material of the research.** As of November 2019, the R06A group – “Antihistamine drugs” (according to the ATC-classification) accounted for 128 drugs, which are used to treat allergic diseases, at the pharmaceutical market in Ukraine (Table) [18, 19].

By the results presented in Table the study of the variability of dosage forms (DF), in which AHD were prepared, was performed. According to these results the largest share was solid DF – tablets and dragée (71 %) due to their convenience for the population; syrups and oral solutions mainly used in pediatric practice were 10.2 % and 6.3 %, respectively; solutions for injection had the smallest part of the domestic pharmaceutical market (4.7 %), but their importance should not be underestimated in cases of immediate type allergic reactions (shock, collapse, Quincke’s edema) [10, 11, 18]. The results are presented in Fig. 1.

### Table

| INN | Name of the medicinal product | Pharmaceutical form | Manufacturer | Retail price (UAH) | Ca.s. (%) |
|-----|-------------------------------|----------------------|--------------|-------------------|----------|
| 1   | Dextromethorphan hydrobromide + Levocetirizine dihydrochloride | Tsetlo Plus Tablets | Evertogen Life Science Limited, India | N/A | N/A |
| 2   | Montelukast, Levocetirizine dihydrochloride | Alerhinol Plus Tablets | Bafna Pharmaceuticals Ltd., India | 364,00 | 3.39 |
| 3   | Diphenhydramine hydrochloride | Dimedrol-Darnitsa Tablets, Solution for injections | JSC “Darnytsia Pharmaceutical Firm”, Ukraine | 105,35 | 0.98 |
| 4   | Dimenhydrinate | Dimedrol Solution for injections | JSC Galichfarm, Ukraine | 70,00 | 0.65 |
| 5   | Clemastine fumarate | Tavegil Solution for injections, Tablets | Takeda Austria GmbH, Austria | 176,75 | 1.65 |
| 6   | Dimethyldene maleate | Fenokit Oral drops | JSC Sperko Ukraine, Ukraine | 308,00 | 2.87 |
| 7   | Dimetinden-Zdrovivie Oral drops, Tablets | Pharmaceutical company “Zdrovivie”, Ukraine | 282,63 | 2.63 |
| 8   | Edermik Oral drops | JSC “Farmak”, Ukraine | 280,00 | 2.61 |
| 9   | Fenistyl Oral drops | GSK Consumer Healthcare SA, Switzerland | 630,00 | 5.87 |
| 10  | Chloropyramine hydrochloride | Suprastin Solution for injections, Tablets | JSC Egis Pharmaceutical Plant, Hungary | 122,50 | 1.14 |
| 11  | Chloropyramine Hydrochloride | Solution for injections | GNCLS Research Plant, Limited Liability Company, Ukraine | 385,00 | 3.59 |
| 12  | Suprostylin Tablets | JSC “Lekhim – Kharkiv”, Ukraine | 52,50 | 0.49 |
| 13  | Cetirizine dihydrochloride | Rolinoz Tablets, Oral drops | Abc Farmaceutici Spa, Italy | 175,00 | 1.63 |
| 14  | Amertyl Tablets | Biopharm Co., Ltd., Poland | 123,55 | 1.15 |
| 15  | Zodak Oral drops, Tablets | Ltd. “Zentiva” Czech Republic | 159,95 | 1.49 |
| 16  | Allertec Tablets | Pharmaceutical plant “Polpharma” SA, Poland | 151,20 | 1.41 |
| 1 | 2          | 3                                      | 4                                         | 5    | 6    |
|---|------------|----------------------------------------|-------------------------------------------|------|------|
| Cetirin Tablets Dr. Reddy’s Laboratories Ltd., India | 126.18 | 1.18 |
| Cetirizine-Teva Tablets Merkle GmbH, Germany | 106.05 | 0.99 |
| Cetyryzine Tablets Ltd. “Astrafarm”, Ukraine | 90.30  | 0.84 |
| Hlentset Tablets Glenmark Pharmaceuticals Ltd., India | 103.25 | 0.96 |
| Tsezera Tablets KRKA, dd, Novo mesto, Slovenia | 525.00  | 4.89 |
| Zilola Tablets Ltd. “Gedeon Richter Poland”, Poland | 174.65 | 1.63 |
| Alerholik Tablets, Oral drops JSC “Technolog”, Ukraine | 192.50 | 1.79 |
| Tsetrylev Neo Tablets Hetero Labs Limited, India | 126.00  | 1.17 |
| Allervey Tablets Dr. Reddy’s Laboratories Ltd., India | 178.50  | 1.66 |
| Levzirine Tablets Hetero Labs Limited, India | 110.25  | 1.03 |
| Kontrahist Tablets JSC “Adamed Pharma”, Poland | 110.25  | 1.03 |
| Cetrimac Tablets MacLeods Pharmaceuticals Limited, India | 99.75  | 0.93 |
| Levocetyryzine Tablets Ltd. “Astrafarm” Ukraine | 134.75  | 1.26 |
| Tsetlo Tablets Evertogen Life Science Limited, India | N/A | N/A |
| Allergofree Tablets Simpex Pharma Pvt. Ltd., India | 262.50  | 2.45 |
| Lasin Tablets Hetero Labs Limited, India | N/A | N/A |
| L-May Oral drops JSC Sperko Ukraine, Ukraine | 194.25  | 1.81 |
| Erhotsetal Tablets JSC “Kyiv vitamin factory”, Ukraine | 103.25 | 0.96 |
| Aleron Tablets Emcure Pharmaceuticals Limited, India | 110.25  | 1.03 |
| L-Cet Tablets, Syrup Kusum Healthcare PVT LTD, India | 105.00  | 0.98 |
| Tsetsrylev Tablets, Syrup FDS Limited, India | 123.20  | 1.15 |
| Ksyzal Tablets UCB Farchim SA, Switzerland | 1750.00 | 16.31 |
| Alerzine Tablets, Oral drops JSC Egis Pharmaceutical Plant, Hungary | 183.40 | 1.71 |
| Cyproheptadine Tablets JSC Egis Pharmaceutical Plant, Hungary | 169.40  | 1.58 |
| Perytol Tablets JSC Egis Pharmaceutical Plant, Hungary | 169.40  | 1.58 |
| Loratadine Tablets, Syrup Pharmaceutical company “Zdorovie”, Ukraine | 39.38  | 0.37 |
| Lorizan Tablets JSC “Kievmedpreparat”, Ukraine | 89.25  | 0.83 |
| Claritin Tablets, Syrup Schering Plough Labo NV, Belgium | 71.75  | 0.67 |
| Loratadine Tablets JSC “Pharmaceutical company “Darnitsa”, Ukraine | 39.90  | 0.37 |
| Loratadine Tablets Ltd. “Astrafarm” Ukraine | 28.00  | 0.26 |
| Loratadine Tablets JSC “Lekhim – Kharkiv”, Ukraine | 23.45  | 0.22 |
### Continuation of Table

|    | 2                | 3                                | 4                                           | 5     | 6     |
|----|------------------|----------------------------------|---------------------------------------------|-------|-------|
| 1  | Loratadine       | Tablets                          | JSC “Farmak” Ukraine                        | 32.90 | 0.31  |
|    | Erolin           | Tablets                          | JSC EGIS Pharmaceutical Plant, Hungary      | 218.75| 2.04  |
|    | Lorano           | Oral Suspension, Tablets, ODT    | Sandoz Pharmaceuticals DD, Slovenia          | 250.25| 2.33  |
|    | Loratadine       | Tablets                          | JSC “Kievmedpreparat”, Ukraine              | 45.50 | 0.42  |
|    | Aleric           | Tablets                          | Us Pharma Ltd., Poland                      | 252.00| 2.35  |
|    | Lorfast          | Tablets                          | Cadila Pharmaceuticals Limited, India        | N/A   | N/A   |
|    | Loratadine-Stoma| Tablets                          | JSC “Stoma”, Ukraine                        | 43.75 | 0.41  |
|    | Loratadine       | Syrup                            | DKP Pharmaceutical Factory LLC, Ukraine     | 117.60| 1.10  |
|    | Mebhydrolin      | Diazoline                        | Tablets, Dragee                             | JSC “Farmak” Ukraine                        | 28.18 | 0.26  |
|    |                  | Diazoline-Darnitsa               | Tablets                                    | JSC “Pharmaceutical company “Darnitsa”, Ukraine | 29.75 | 0.28  |
|    |                  | Diazolin-SB-PHARMA               | Dragee                                     | JSC “Vitamins” Ukraine                       | 28.35 | 0.26  |
|    |                  | Diazoline For Children           | Granules for oral suspension                | GNCLS Research Plant, Limited Liability Company, Ukraine | 105.00 | 0.98  |
|    | Ketotifen        | Ketotifen                        | Syrup                                      | Borschagovsky Chemical and Pharmaceutical Plant Scientific and Production Center, Ukraine | 110.43 | 1.03  |
|    |                  | Ketotifen                        | Tablets                                    | GNCLS Research Plant, Limited Liability Company, Ukraine | 14.35  | 0.13  |
|    |                  | Ketotifen                        | Tablets                                    | JSC “Lekhim – Kharkiv”, Ukraine              | 25.03  | 0.23  |
|    |                  | Ketotifen So-farma               | Tablets                                    | JSC “Vitamins”, Ukraine                      | 26.25  | 0.24  |
|    | Fexofenadine     | Feksofen-Sanovel                 | Tablets                                    | Sanovel Ilac Sanayi ve Ticaret AS, Turkey   | N/A   | N/A   |
|    | hydrochloride    | Tigofast                         | Tablets                                    | Flamingo Pharmaceuticals Ltd., India         | 227.50 | 2.12  |
|    |                  | Altiva                           | Tablets                                    | Sun Pharmaceutical Industries Limited, India | N/A   | N/A   |
|    |                  | Fexofast                         | Tablets                                    | Micro Labs Limited, India                    | 194.25 | 1.81  |
|    |                  | Allegra                          | Tablets                                    | Sanofi Winthrop Industrie – Tours, France   | 352.45 | 3.29  |
|    | Desloratadine    | Allergostop                      | Tablets                                    | JSC “Fitofarm”, Ukraine                      | 68.25  | 0.64  |
|    |                  | Allergomax                       | Tablets, Syrup                             | Pharmaceutical company “Zdorovie”, Ukraine   | 105.88 | 0.99  |
|    |                  | Lordes                           | Syrup, Tablets                             | Nobel Ilac Sanayi is also ticaret A.S., Turkey | 197.75 | 1.84  |
|    |                  | Eridez-Darnitsa                  | Tablets                                    | JSC “Pharmaceutical company “Darnitsa”, Ukraine | 176.75 | 1.65  |
|    |                  | Alersis                          | Oral Solution                              | Laboratorios Normon SA, Spain                | N/A   | N/A   |
The analysis of AHD by the manufacturing countries revealed that almost 2/3 of the AHD market is occupied by imported drugs and only 1/3 by the Ukrainian ones (Fig. 2). Moreover, in 2014, this indicator was 50% / 50%, indicating...
a decrease of the share of the Ukrainian manufacturers in the segment of the pharmaceutical market studied [12, 18].

Among the foreign manufacturers, India had a stable leading position (17.2 %). The total contribution of the European Union countries was 39 %, among them the largest share (16.4 %) was in the countries of Eastern and Southern Europe (Hungary, Greece, Poland, Latvia) (Fig. 3) [18].

According to the results of marketing analysis of this group of drugs for 2014 the following distribution of AHD by international non-proprietary names (INNs) was observed at the pharmaceutical market of Ukraine. Loratadine (21 %) held the leading position among the trade names (TN) registered. The 2nd, 3rd and 4th positions were taken by Desloratadine (16 %), Levocetirizine (15 %) and Cetirizine (13 %) (Fig. 4) [12, 13].

In 5 years (as of 2019) the following changes were observed: Loratadine lost 6 % of the total amount of the TN registered and its leading position; the first positions were taken by Desloratadine, which number of TN increased by 9 % and was 25 %, and Levocetirizine with the number of TN increased by 5 % and reached the mark of 20 % (Fig. 5) [18].

The data obtained show an increase in quantity of the third-generation drugs (Levocetirizine, Desloratadine), indicating that health professionals and patients are increasingly guided by the safety profile considerations when choosing a course of treatment of allergic diseases.
The long-term administration and frequent need for treating children also contribute to the choice of safer drugs [6].

It is important to note that there are no plant-based anti-allergic drugs at the Ukrainian pharmaceutical market.

In accordance with the WHO statistics about 80 % of the world’s population prefers drugs based on the plant components [20]. Herbal medicines have several advantages over synthetic ones, first of all, due to their complex action on several links of the pathogenesis of the disease. If the potent substances, such as alkaloids or cardiac glycosides, are absent in the plant raw material, the action of the herbal products is soft and safe, allowing them to be used for a long time [20, 21].

The economic factor is significant for the population of our country. Socio-political changes in recent years have led to a decrease in the standard of living of the population and have made medicines (especially imported) unaffordable to the majority of the population.

To account for this factor, the analysis of the AHD market was performed using the solvency index reflecting a percentage of the average monthly disposable income required for the AHD treatment course (1).

In order to obtain the unified results the study of affordability was performed among solid dosage forms – tablets and dragee presented the most widely at the domestic market of AHD.

The results of the calculations are presented in Table.

According to the results in Table the most of AHD are highly affordable for the working population of Ukraine. The Swiss drug “Fenistil” and the Belgian drug “Erius” have the medium affordability. The drug “Xysal” of the Swiss production has appeared to be unaffordable, its average treatment course costs about 1750,00 UAH. The average value of Cas is 1.77 %; it indicates the availability of the AHD market in total.

**Conclusions and prospects for further research**

1. The analysis of the literature sources has revealed the high incidence of allergic diseases among the population of Ukraine.

2. By analyzing the assortment of antihistamine drugs it has been found that the most common dosage form of AHD is a solid form – tablets and dragee; their number is 71 % of the total drugs registered.

3. Based on the results of the marketing research there is a tendency of increasing a number of the third-generation AHD and decreasing a number of older generations; it indicates the importance of the safety profile in the treatment of various types of allergies.

4. According to the results of the AHD affordability study based on the methodology recommended by the WHO a high availability of the most AHD for the working population of Ukraine has been determined.

5. Over the last 5 years, there has been a decrease in the share of the domestic manufacturers (by 11 %) at the pharmaceutical market of Ukraine; it indicates the import dependence of the market and the need to create new domestic AHD.

6. The absence of the plant-based anti-allergic drugs at the pharmaceutical market of Ukraine has been found; it indicates the prospect for further research in the direction of developing an herbal medicine for the systemic treatment of allergic diseases.

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