

UDC 615.322 : 615.451.2 : 615.244

L. I. VYSHNEVSKA, O. O. SHMALKO, V. A. MEHALINSKYI

National University of Pharmacy

MARKETING RESEARCH OF PHARMACEUTICAL MARKET FOR THE TREATMENT OF HEPATOBILIARY SYSTEM WITH A PERSPECTIVE DESIGN OF PLANT-BASED MEDICINAL PRODUCT

*In recent years, worldwide there is a clear tendency of increasing the number of hepatobiliary diseases (DHBS). According to the data of research of the local pharmaceutical market for the treatment of liver and gallbladder diseases it was revealed that Ukrainian producers represent 34 % of the analyzed medicines. The most group represented consists of mono- and combined phytopreparations – 47%. Among the plants that exhibit hepatoprotective, choleric activity, the most common are artichoke (*Cynara*), *Silybum marianum*, *Helichrysum arenarium*. The ranking of the foreign countries which supply medicines of analyzed group to Ukrainian pharmaceutical market has revealed that the leaders in regards with medicines represented are the following: India (15 %), Germany (13 %) and Russian Federation (8 %). Among pharmaceutical forms the most represented are capsules (28 %), tablets (25%) and injection solutions (13 %). Such dosage form as a syrup is represented by the only drug that indicates the relevance of developing original medicine with combined effect.*

Key words: liver and gallbladder diseases; marketing analysis; pharmaceutical market; syrups

STATEMENT OF THE PROBLEM

Over the past 20 years the trend is observed of increasing the number of hepatobiliary diseases in the whole world. Every year, from 500 thou up to 1 mln people suffering from a particular liver pathology are registered only in the CIS-countries. There is increased frequency of hepatobiliary pathology at a young age, 4.7 times more often in women than men. According to the European regional office of the WHO, the mortality rate from chronic liver disease is high in 43 countries of the region (more than 25 deaths per 100 thousand of population) in seven CIS-countries and five countries of the Central and Eastern Europe, equaled in average to seventeen in European region. For the past 10 years in five countries the mortality rate increased to more than 50 %. Particularly, from 2000 to 2010 years the incidence of chronic hepatitis in Ukraine increased to 76.6 %, prevalence within this period increased 2.2 times [3, 7-9].

The reasons of hepatopathy are hepatotropic viruses, exogenous toxic substances (alcohol, drugs, medicines, xenobiotics), impaired metabolism, immune status violation, genetic changes. Separately, the upward comorbidity in the structure of disease

incidence should be noted and taken into consideration.

ANALYSIS OF RECENT RESEARCH AND PUBLICATIONS

The issues associated with development and improvement of medicines for pharmacotherapy in HBSD, and also such formulations as syrups, are described in the research papers of the scientists as follows: S. M. Drohovor, D. V. Semeniv, T. D. Zvyagintseva, A. I. Tentsova, O. D. Nemyatykh, I. A. Tkachuk and others.

IDENTIFICATION OF ASPECTS OF THE PROBLEM UNSOLVED PREVIOUSLY

Within a complex pharmacotherapy of diseases of hepatobiliary system's organs different groups of medicines are applied, however among them special place the medicines play different by structure and action mechanism, but with pathotropism to the liver. Despite the fundamental scientific discoveries of the recent years in the field of hepatology, many aspects of the problem of treatment and prevention of liver disease remain unexplored. The biochemical mechanism of immediate protective activity of the most of hepatoprotectors is still unclear, but it is known that their mechanism and pharmaco-

© Vyshnevskaya L. I., Shmalko O. O., Mehalinskyi V. A., 2016

**THE RANGE OF MEDICALS APPLIED FOR THE TREATMENT OF THE LIVER
AND GALLBLADDER DISEASES ACCORDING TO THE ATC CLASSIFICATION**

A05	Medications used in liver and gallbladder diseases		
	A05A	Drugs applied in biliary insufficiency	
		A05AA	Bile acids preparations
			A05AA02 Ursodeoxycholic acid
			Ukrliv, Ursifalk, Ursochol, Choludexan, Ursoliv, Ursilizin, Ursomax, Ursosan
		A05AX	Other medicines applied in biliary insufficiency
			A05AX 10 Other preparations including combinations
			Allochol, Artichhol, Cholosas, Chophytol, Artibel, Artichoke, Helichrysum, Cholagogae species, Cholagogae species № 2, Corn columns with stigmas, PM Sirin, Raphacholin, Salfat, Flamin – Zdorovye, Cholagol, Chole-gran, Cynarix
	A05B	Preparations applied in liver diseases	
		A05BA	Hepatotropic drugs
			A05BA01 Arginine glutamate
			Arginine, Glutargine
			A05BA03 Silymarin
			Darsyl, Carsyl, Legalon, Sylibor
			A05BA06 Ornithine oxoglurate
			Hepa-Merz, Gepatox, Larnamin, Ornitox
			A05BA50 Different preparations
			Bicyclol, Galstena, Hepadif, Dalmaxin, Prohepar, Phosphogliv, Enerliv, Antral, Hepasin, Gepar compozitum, Lesfal, Liv 52, Livolin Forte, Lioliv, Sylibi Mariani Fructus, Phospholip, Hepeel, Essentiale, Essliver
			A05BA53 Silymarin combined
			Hepabene, Levasil
	A05C	Preparations for the treatment of biliary pathology combined with lipotropic substances	
			Eslidyn

dynamics are integrated and have membrane stabilizing, anti-toxic, anti-inflammatory, choleric, antiviral, anti-oxidative, immunomodulating, hypotonic and the other effects. Consequently, despite the success in development of treatment methods of chronic liver diseases with medical preparations which influence direct the cause factors, the pharmacotherapy of this nosologic group remains one of the topical issues of the current medicine [3, 5, 6].

OBJECTIVE STATEMENT OF THE ARTICLE

The aim of the experimental work was to investigate the range of medications to treat the liver and gallbladder diseases represented at the pharmaceutical market of Ukraine, and to determine the position of domestic producers regarding feasibility of creating a new original drug for the treatment of hepatobiliary system's diseases.

PRESENTATION OF THE MAIN MATERIAL FOR THE RESEARCH

Analysis of the range of medicines has been conducted in accordance with the State Register of Medicinal Products of Ukraine and the WHO ATC classification system. As information sources, the State

formulary of medicines was used, Compendium 2015 – pharmaceuticals, and the program complex of the weekly report “Pharmacist online.ua” [1, 2, 4].

With the aim of determining the feasibility of creating new drugs to treat diseases of the hepatobiliary system the range of drugs was analyzed represented at the pharmaceutical market of Ukraine [1, 2, 4].

According to the ATC classification system, the drugs to treat the liver and gallbladder diseases belong to the A05 – preparations which are applied for the treatment of liver and gallbladder diseases. The structure of the group is: A05A – preparations used in the biliary pathology; A05B – drugs used in the liver diseases treatment; A05C – drugs for the treatment of biliary pathology in combination with lipotropic compounds.

The results of research of the range of medicals applied in the treatment of the liver and gallbladder diseases according to the ATC classification are presented in the Table.

According to the data given in the table, the pharmaceutical market of Ukraine is represented by 98 titles of the medical preparations applied for the treatment of liver and gallbladder diseases. This segment of the market represented by a wide range of manufacturers and pharmaceutical com-

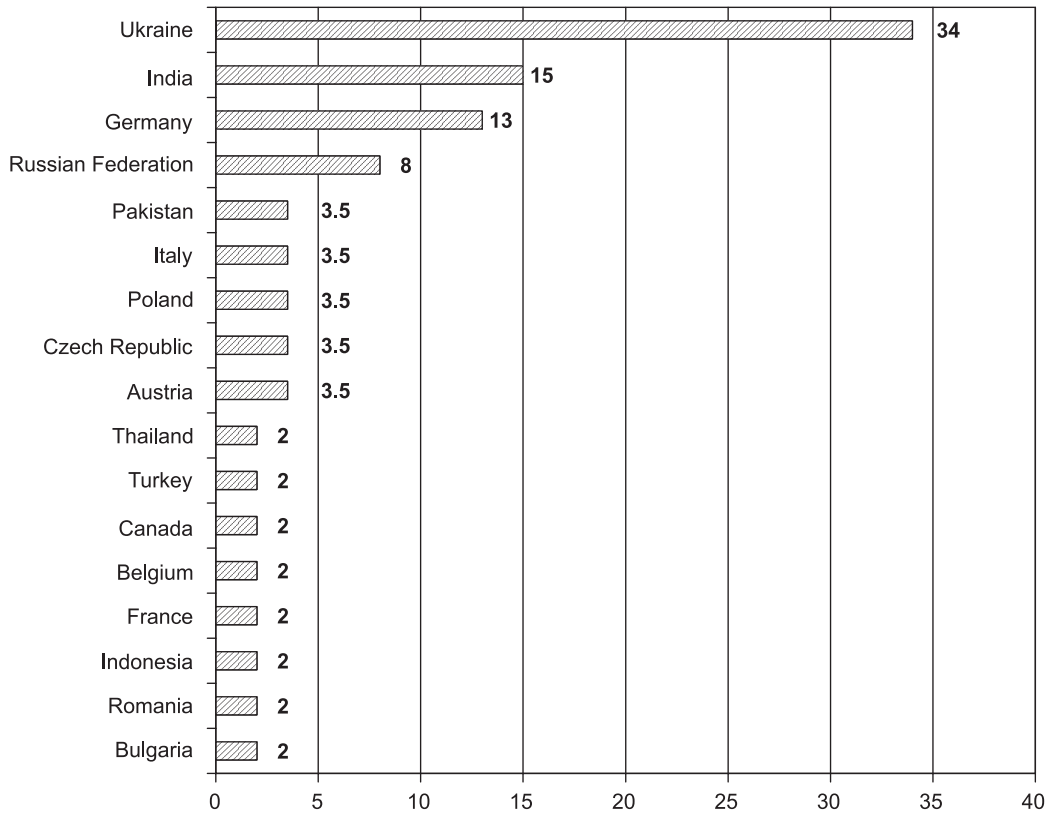


Fig. 1. The valid part of countries-manufacturers (%) of preparations affecting the hepatobiliary system

panies, is covering a variety pharmaceutical groups of preparations.

The part of manufacturers of drugs for the treatment of HBSD at the pharmaceutical market of Ukraine is shown in the Fig. 1.

According to the research shown in the Fig. 1 it was determined that the top position belongs to domestic producers (34 %), a significant part of the market includes also producers from India (15 %), Germany (13 %) and Russia (8 %).

Classification of the drugs used for the treatment of liver and biliary system diseases by origin is shown in the Fig. 2.

As shown in the Fig. 2, the most widely-spread group (47 %) consists of the plant origin drugs that is

caused by their complex activity (anti-inflammatory, choleric, hepatoprotective, detoxification, etc.). 18 % of drugs of domestic and foreign manufacturers is represented by the group of derivative bile acids, that indicates the prevalence of gallbladder pathology.

The most common plants in composition of phytopreparations is shown in the Fig. 3.

According to the data represented in the Fig. 3, the most common plant in the structure of phytopreparations is globe artichoke (*Cynara*). The preparations on the basis of *Helichrysum arenarium* are quite wide-represented. In the structure of preparations occur Coriander, *Tanacetum* and *Rosa*. The combined herbal medicines constitute 38% of the whole range.

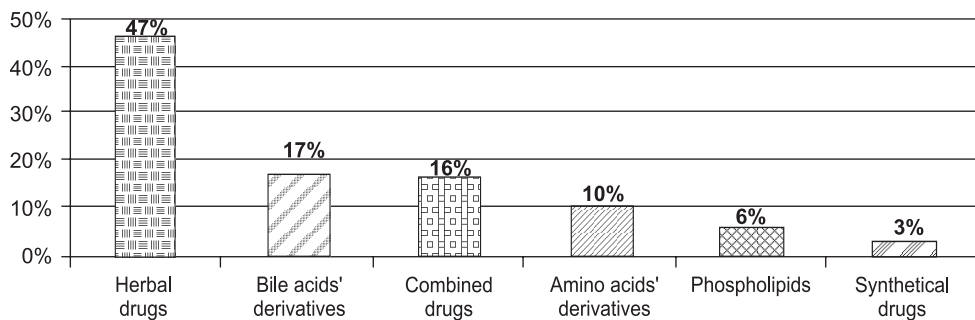


Fig. 2. Classification of preparations for the treatment of hepatobiliary diseases by origin

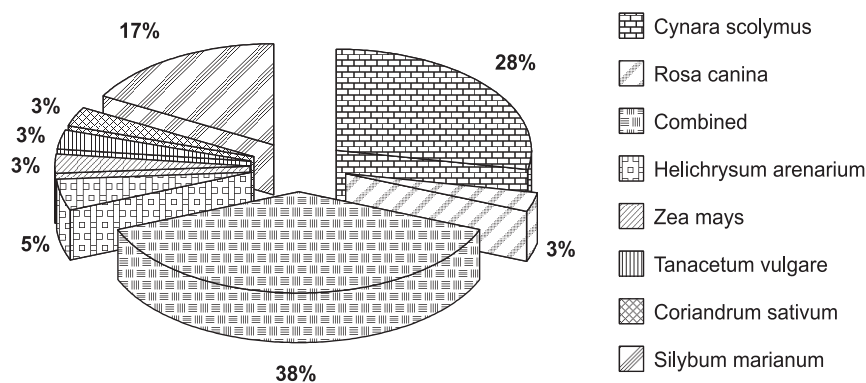


Fig. 3. Plants the most wide-spread in the composition of mono- and combined herbal remedies are presented at the pharmaceutical market of Ukraine

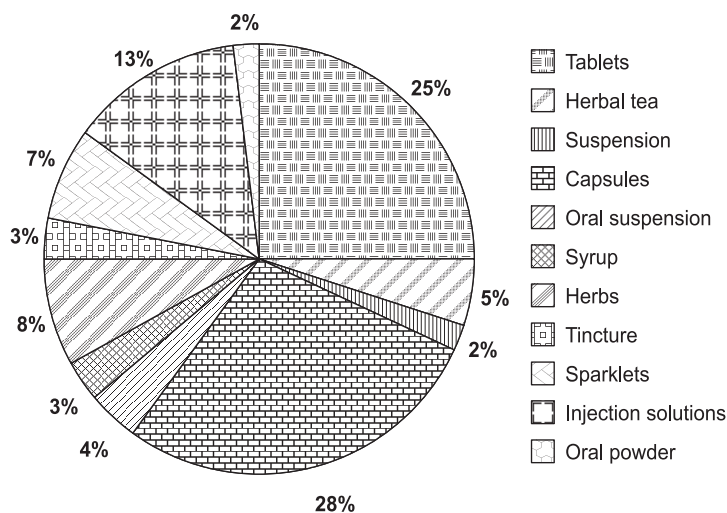


Fig. 4. Formulations of drugs to treat liver and gallbladder diseases

The distribution of drugs by pharmaceutical form is shown in the Fig. 4.

As shown in the Fig. 4, the most numerous dosage forms are capsules (28 %), tablets (25 %) and injectable form (13 %). Formulations in the form of herbal drugs and multicomponent compositions together occupy 12 % of the market.

CONSLUSIONS

1. Based on the research of domestic pharmaceutical market of drugs for the treatment of liver and gallbladder diseases it is revealed that Ukrainian producers represent 34 % of the analyzed drugs.
2. The most represented group is mono- and combined herbal preparations – 47 %. Among the most common plants that exhibit hepatoprotective, choloretic effect, is the artichoke (Cynara), Silybum marianum, Helichrysum arenarium.
3. Ranking of the foreign countries-suppliers of the drugs of examined group at the pharmaceutical market of Ukraine has shown that leaders

in terms of medicines represented are India (15 %), Germany (13 %) and Russia (8 %).

4. Among the most dosage forms are capsules (28 %), tablets (25 %) and injecting solutions (13 %). Syrups are represented by just one preparation.
5. The research conducted let to determine the main directions of improvement the range of drugs to treat the liver and gallbladder diseases.

REFERENCES

1. Державний реєстр лікарських засобів України [Електронний ресурс] / МОЗ України. – К., 2015. – Режим доступу : <http://www.drlz.kiev.ua>.
2. Державний формуляр лікарських засобів / ред. кол.: М. Л. Аряєв, В. Г. Бебешко, Т. А. Бухтіарова та ін. – К., 2015. – Вип. 7. – 845 с.
3. Звягинцева Т. Д. Хронические диффузные заболевания печени: патогенетические подходы к лечению / Т. Д. Звягинцева, С. В. Глущенко // Здоров'я України. – 2010. – № 1. – С. 46-47.

4. Компендиум 2015 – лекарственные препараты / под ред. В. Н. Коваленко. – К.: Морион, 2015. – 1408 с.
5. Ивашкин В. Т. Болезни печени и желчевыводящих путей: руководство для врачей / В. Т. Ивашкин. – М.: ИД «М-Вести», 2005. – 536 с.
6. Ильченко А. А. Заболевания желчного пузыря и желчных путей / А. А. Ильченко. – М.: Анахарсис, 2006. – 448 с.
7. The Burden of liver disease in Europe. A review of available epidemiological data / M. Blachier, H. Leleu, M. Peck-Rado-savljevic et al. // J. Hepatol. – 2013. – Mar; 58(3). – P. 593-608.
8. Trends in mortality from chronic liver disease / U. Fedeli, F. Avossa, S. Guzzinati et al. // J. Ann. Epidemiol. – 2014. – Jul; 24(7). – P. 522-526.
9. The global burden of liver disease: the major impact of China / F. S. Wang, J. G. Fan, Z. Zhang et al. // Hepatol. – 2014. – Dec; 60(6) – P. 2099-2108.

УДК 615.322 : 615.451.2 : 615.244**Л. И. Вишневская, А. А. Шмалько, В. А. Мегалинский****МАРКЕТИНГОВЫЕ ИССЛЕДОВАНИЯ РЫНКА ПРЕПАРАТОВ ДЛЯ ЛЕЧЕНИЯ ГЕПАТОБИЛИАРНОЙ СИСТЕМЫ С ПЕРСПЕКТИВОЙ СОЗДАНИЯ ЛЕКАРСТВЕННОГО СРЕДСТВА НА РАСТИТЕЛЬНОЙ ОСНОВЕ**

В последнее время во всем мире прослеживается четкая тенденция к увеличению количества заболеваний гепатобилиарной системы. На основании проведенного исследования отечественного фармацевтического рынка лекарственных средств для лечения заболеваний печени и желчного пузыря установлено, что украинские производители репрезентуют 34 % препаратов анализированной группы. Наиболее представленной группой являются моно- и комбинированные фитопрепараты – 47 %. Наиболее распространенными растениями, проявляющими гепатопротекторное, желчегонное действие, являются артишок, расторопша, бессмертник. Ранжирование иностранных стран-поставщиков лекарственных препаратов исследуемой группы на фармацевтическом рынке Украины показало, что лидерами по объему репрезентованных лекарственных средств являются Индия (15 %), Германия (13 %) и РФ (8 %). Среди лекарственных форм наиболее представлены капсулы (28 %), таблетки (25 %) и инъекционные растворы (13 %). Такая лекарственная форма как сироп представлена только одним препаратом, что указывает на актуальность разработки оригинального препарата комплексного действия.

Ключевые слова: заболевания печени и желчного пузыря; маркетинговый анализ; фармацевтический рынок; сиропы

УДК 615.322 : 615.451.2 : 615.244**Л. І. Вишневська, О. О. Шмалько, В. А. Мегалінський****МАРКЕТИНГОВІ ДОСЛІДЖЕННЯ РИНКУ ПРЕПАРАТІВ ДЛЯ ЛІКУВАННЯ ГЕПАТОБІЛІАРНОЇ СИСТЕМИ З ПЕРСПЕКТИВОЮ СТВОРЕННЯ ЛІКАРСЬКОГО ЗАСОБУ НА РОСЛИННІЙ ОСНОВІ**

Останнім часом у всьому світі простежується чітка тенденція до зростання кількості захворювань гепатобіліарної системи. На основі проведеного дослідження вітчизняного фармацевтичного ринку лікарських засобів для лікування захворювань печінки та жовчного міхура встановлено, що українські виробники репрезентують 34 % препаратів аналізованої групи. Найбільш представленою групою є моно- та комбіновані фітопрепарати – 47 %. Серед рослин, які виявляють гепатопротекторну і жовчогінну дію, найпоширенішими є артишок, розторопша, цмин. Ранжування іноземних країн-постачальників лікарських препаратів досліджуваної групи на фармацевтичний ринок України показало, що лідерами за обсягом репрезентованих лікарських засобів є Індія (15 %), Німеччина (13 %) та РФ (8 %). Серед лікарських форм найбільш представленими є капсули (28 %), таблетки (25 %) та ін'єкційні розчини (13 %). Така лікарська форма як сироп представлена лише одним препаратом, що вказує на актуальність розробки оригінального препарату комплексної дії.

Ключові слова: захворювання печінки та жовчного міхура; маркетинговий аналіз; фармацевтичний ринок; сиропи

Адреса для листування:

61002, м. Харків, вул. Пушкінська, 53.

E-mail: shmalko.a@gmail.com,

liliiavyshnevsk@gmail.com.

Національний фармацевтичний університет

Надійшла до редакції 08.09.2016 р.