National market of diagnostic tests and test systems

T. S. Brytanova *A,B,D, A. V. Samko C,E, Ye. H. Knysh E,F

Zaporizhzhia State Medical University, Ukraine

A – research concept and design; B – collection and/or assembly of data; C – data analysis and interpretation; D – writing the article; E – critical revision of the article; F – final approval of the article

The aim of the work was to analyze the market of diagnostic tests and test systems that are in circulation in Ukraine.

Materials and methods. To achieve this goal, electronic and paper official sources of information were used, as well as pharmacy websites. The search, analytical, systematic, comparative and statistical methods and methods of mathematical and logical analysis were used in the work.

Results. Analysis of the modern market of diagnostic tests and test systems were allowed to establish the range and brand structure (90 manufacturers). The vast majority of them are outside Ukraine (85.5 %). Among foreign producers, the largest importer is China (19.5 %). In the course of work to determine the level of competition between manufacturers of similar groups of tests and test systems set the coefficient of tension. To determine the level of availability, price liquidity and solvency adequacy ratios were calculated.

Conclusions. The Ukrainian market of diagnostic tests and test systems was studied. It was established that the company structure consists of 90 manufacturers and 20 countries. The vast majority of products come from importing countries (85.5 %), where the leader is China (19.5 %). Analysis of competitiveness showed that the greatest competition was observed among companies that produce tests to determine pregnancy, glucose, ketones, nitrites and protein in the blood and urine (K*vi* = 0.96), and there was no test manufacturers for sperm testing (K*vi* = 0). The calculated price liquidity and adequacy of solvency ratios indicate high price competition and low availability for some groups of diagnostic tests and test systems.

Key words: pharmaceutical market, diagnostic tests, analysis, price situation.

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Національний ринок діагностичних тестів і тест-систем

Т. С. Британова, А. В. Самко, Є. Г. Книш

Мета роботи – аналіз ринку діагностичних тестів і тест-систем, що перебувають в обігу в Україні.

Матеріали та методи. Використали електронні та паперові офіційні джерела інформації, а також інтернет-сайти аптек. Застосовували пошуковий, аналітичний, систематичний, порівняльний і статистичний методи та методи математичного, логічного аналізів.

Результати. Аналіз сучасного ринку діагностичних тестів і тест-систем дав можливість встановити асортиментну та фірмову (90 фірм-виробників) структури. Більшість із них знаходяться за межами України (85,5 %). Серед іноземних виробників найбільший імпортер – КНР (19,5 %). Під час роботи для визначення рівня конкуренції між виробниками аналогічних груп тестів і тест-систем встановили коефіцієнт напруженості. Для визначення рівня доступності розрахували коефіцієнти ліквідності ціни та адекватності платоспроможності.

Висновки. Досліджено вітчизняний ринок діагностичних тестів і тест-систем. Встановлено, що фірмова структура складається з 90 фірм-виробників та 20 країн світу. Переважна більшість продукції надходить від країн-імпортерів (85,5 %), де лідером є Китай (19,5 %). Аналіз конкурентоспроможності показав, що найбільша конкуренція – серед компаній, які випускають тести для визначення вагітності, рівня глюкози, кетонів, нітритів, білка у крові та сечі (K*vi* = 0,96), у виробників відсутні тести для дослідження сперми (K*vi* = 0). Розраховані коефіцієнти ліквідності ціни та адекватності платоспроможності показують високу цінову конкуренцію та низьку доступність для деяких груп діагностичних тестів і тест-систем.

Ключові слова: фармацевтичний ринок, діагностичні тести, аналіз, цінова кон'юнктура.

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***E-mail:** goculyats@gmail.com

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Национальный рынок диагностических тестов и тест-систем

Т. С. Британова, А. В. Самко, Е. Г. Кныш

Цель работы – анализ рынка диагностических тестов и тест-систем, которые находятся в обороте в Украине.

Материалы и методы. Использованы электронные, бумажные официальные источники информации, интернет-сайты аптек. В работе применяли поисковый, аналитический, систематический, сравнительный и статистический методы и методы математического, логического анализа.

Результаты. Анализ современного рынка диагностических тестов и тест-систем позволил установить ассортиментную и фирменную (90 фирм-производителей) структуры. Большинство из них находятся за пределами Украины (85,5 %). Среди иностранных производителей крупнейшим импортером является КНР (19,5 %).

В ходе работы для определения уровня конкуренции между производителями аналогичных групп тестов и тест-систем установили коэффициент напряженности. Для определения уровня доступности рассчитали коэффициенты ликвидности цен и адекватности платежеспособности.

Выводы. Исследован отечественный рынок диагностических тестов и тест-систем. Установлено, что фирменная структура состоит из 90 фирм-производителей и 20 стран мира. Подавляющее большинство продукции поступает от стран-импортеров (85,5 %), где лидером является КНР (19,5 %).

Анализ конкурентоспособности показал, что наибольшая конкуренция – среди компаний, которые выпускают тесты для определения беременности, уровня глюкозы, кетонов, нитритов, белка в крови и моче (K*vi* = 0,96), у производителей отсутствуют тесты для исследования спермы (K*vi* = 0). Рассчитанные коэффициенты ликвидности цены и адекватности платежеспособности свидетельствуют о высокой ценовой конкуренции и низкой доступности для некоторых групп диагностических тестов и тест-систем.

Ключевые слова: фармацевтический рынок, диагностические тесты, анализ, ценовая конъюнктура.

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Diagnostic tests and test systems can be valuable aids for diagnosis, but as screening tools to detect latent diseases in asymptomatic individuals, their usefulness is limited. The value of the test as a diagnostic tool depends on its sensitivity and specificity.

It should be noted that modern tests can detect a fairly large list of diseases. In particular, these are: HIV infection, syphilis, gonorrhea, chlamydia, hepatitis C, hepatitis B, tuberculosis, and others. Tests for cancer markers are also available, which can indirectly confirm the presence of prostate and bowel cancer. Some of them detect prostate-specific antigen in the blood, others determine the presence of internal bleeding, which may be a sign of bowel cancer. One of the newest tests are those that can confirm myocardial infarction, or rather the presence in the blood of a specific protein troponin, which appears in severe damage to the heart muscle.

Because in many cases the diagnosis of diseases is not desirable for the patient in treatment and prevention facilities, rapid diagnostic tests are a successful development in the field of medicine. Thus, availability and ease of use, anonymity, low cost, and speed are excellent for the preventive diagnosis of a number of diseases. This is especially important if there is a possibility of infection – such a rapid examination can be the first step in the diagnosis [1].

Aim

The purpose of the research is to analyze the market of diagnostic tests and test systems that are in circulation in Ukraine.

Materials and methods

Electronic and paper official sources of information and pharmacy websites were used to achieve this goal. The search, analytical, systematic, comparative, and statistical methods, methods of mathematical and logical analysis were used in the work [2–9].

Results

In the course of the work, diagnostic tests and test systems were systematized according to the purpose and type of products. Selected on the pharmaceutical market of Ukraine were contained 45 groups and 200 assortments items from 20 countries of the world that 90 pharmaceutical companies (*Fig. 1*).

Discussion

Data from the State Register of Medical Equipment and Medical Devices, information on the state registration certificate for expired medical devices (as of 2019) and data from the weekly "Pharmacy" were used to analyze the company structure [10,11].

Given the number of manufacturers of diagnostic tests and test systems from all countries, the rating of each country was set separately. Thus, the first place was occupied by China (17.78 %), which supplies it was products from 16 pharmaceutical companies. The second place was occupied by the USA (12.2 %), products come from 11 pharmaceutical manufacturers. Third place was shared by Germany (10.0 %) and Korea (10.0 %). They provided the market with goods from 9 manufacturers each (*Fig. 2*).

The ratio between domestic and foreign companies was 1:7.

Taking into account the number of offers of all producing countries in the pharmaceutical market, the rating of each country was set separately (*Fig. 2*). To determine the level

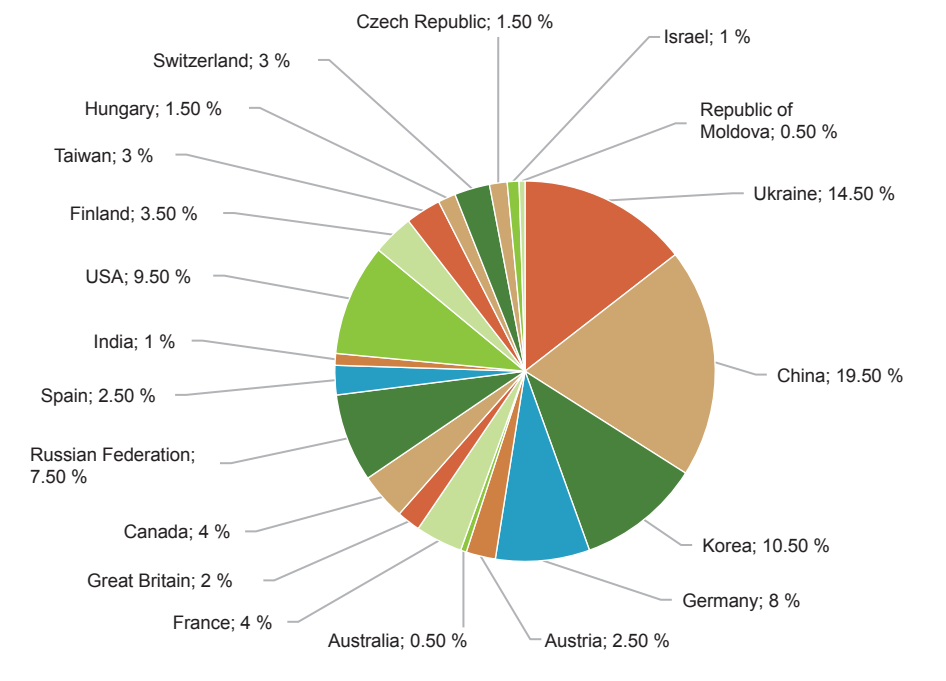

Fig. 1. Diagram of the distribution of diagnostic tests and test systems by country of origin.

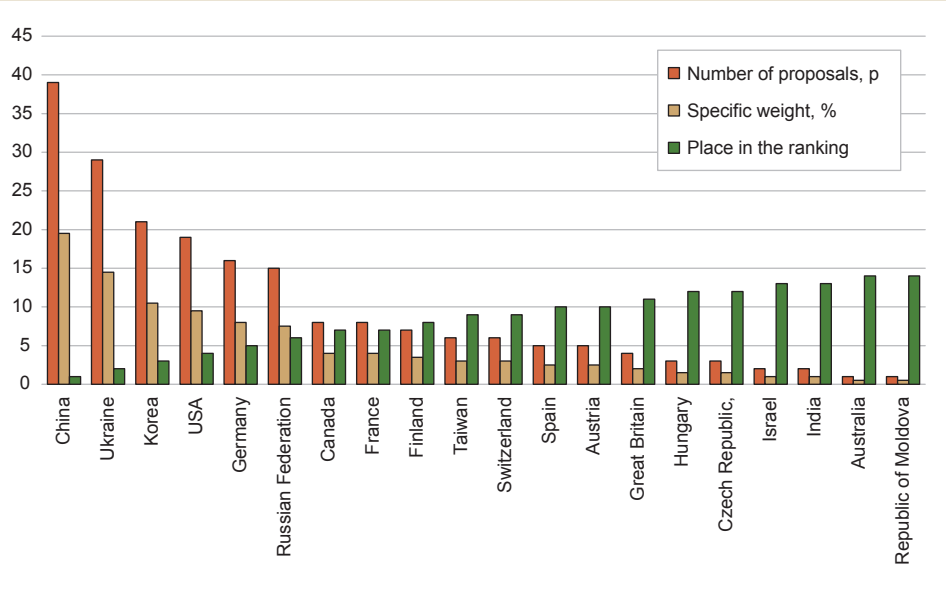

Fig. 2. Distribution of the range by country of origin.

of competition between manufacturers of similar groups of diagnostic tests, the stress factor K*vi* was calculated by the formula:

$$Kvi = \frac{n-1}{n}, \quad (1)$$

where n – number of all competing counterparts of firms [12].

According to the results obtained (*Table 1*), the greatest competition from manufacturers of tests for pregnancy, glucose, ketones, nitrites and protein in the blood and urine (K*vi* = 0.96). In second place were tests to determine ovulation and follicle-stimulating hormone (K*vi* = 0.95). The third place was shared among tests for drugs and tests for troponin I, KK-MB, myoglobin (K*vi* = 0.92).

It should also be noted that at the time of the study of diagnostic tests and test systems, the competitiveness index was equal to 0 in tests for sperm testing.

Important characteristics of diagnostic tests and test systems were the liquidity ratio and the solvency adequacy ratio. The price liquidity ratio reflects the degree of competition in the pharmaceutical market and to some extent characterizes the availability of a medical device.

This indicator was calculated as the ratio of the difference between the maximum and minimum price to the minimum

Table 1. Indicators of the coefficient of intensity of diagnostic tests and test systems

№	Name of test groups and test systems	K*vi*
1.	Pregnancy test strip	0.96
2.	Tests to determine ovulation and follicle-stimulating hormone	0.95
3.	Tests to determine troponin I, KK-MV, myoglobin	0.92
4.	Tests for syphilis	0.8
5.	Tests for rotavirus infection	0.86
6.	Tests to detect antibodies to H. Pylori	0.75
8.	Tests to detect adenoviral infection	0.75
9.	Tests to detect Giardia	0.5
10.	Tests to detect pathogens of influenza virus	0.75
11.	Tests for drugs	0.92
12.	Tests to detect hepatitis A, B, C virus	0.89
13.	Tests for the diagnosis of acute pancreatitis	0.67
14.	Tests for the diagnosis of tuberculosis	0.5
15.	Tests for HIV 1 / HIV 2	0.89
16.	Tests to detect nicotine in the urine	0.5
17.	Tests to detect amniotic fluid	0.67
18.	Tests to determine the level of glucose, ketones, nitrites and protein in the blood and urine	0.96
19.	Test for detection of salmonella antigens in feces	0.5
20.	Tests to determine malaria	0.67
21.	Tests to determine inflammatory processes	0.5
22.	Tests for the diagnosis of allergies	0.67
23.	Tests to determine cholesterol levels	0.5
24.	Tests for syphilis	0.8
25.	Tests for hemoglobin and transferrin in feces	0.83
26.	Tests for Denguevirus	0.5
27.	Tests to detect tumor markers	0.83
28.	Test kits for newborn screening	0.5
29.	Tests for sperm testing	0
30.	Tests to determine the pH of the vaginal environment	0.5
31.	Tests to determine TORCH infection	0.67

price of a medical device. The liquidity ratio was calculated by the formula:

$$Kliq = \frac{Pmax - Pmin}{Pmin}, \quad (2)$$

where *Kliq* – price liquidity ratio; P*max* – maximum price; P*min* – minimum price [13,14].

Data from the site Tabletki.ua as of October 2019 were used for analysis [2].

The results of the analysis are presented in *Table 2*.

As can be seen from the *Table 2*, the liquidity ratio for half of the diagnostic tests and the test system was within the value of 0.5. The highest value of Cliq in Citolab K (urine) № 50 (6.12), Cito test (4.34), Cito test HCV (3.32), HIV 1/2 strip for ketones detection № 25 (2.24), Test cassette for the simultaneous detection of 5 drugs (urine) (1.38), Test cassette for the simultaneous detection of drugs (urine (1.27), Cito test *H. pylori* Ag (1.09). Non-price competition is typical for Test for determining the sex of the child (0.029), Cito Test pH (vaginal environment) (0.037) and Menopause Test (0.04).

It should be noted that one of the relative indicators of socio-economic accessibility of diagnostic tests and test systems was the solvency adequacy ratio, which was determined by the formula:

$$Ka.s. = \frac{P}{Wa.w.} \times 100\ \%, \quad (3)$$

where *Ka.s.* – solvency adequacy ratio; *P* – the average price of the drug for a certain period of time (October 2019); *Wa.w.* – average salary for a certain period (according to the State Statistics Service of Ukraine).

As of October 2019, the average salary was UAH 10727 [13,15].

Calculated indicators of show that among the diagnostic tests and test systems more available to consumers were the Test for determination of urine pH № 50 (0.23), Test for determination of menopause (0.30), Test strip for ketones detection № 25 (0.33), Cito Test pH (vaginal environment) (0.50). The least available for consumers were the Test for measuring the level of cholesterol, uric acid in the blood (4.47), the Test for the determination of amniotic fluids (4.41), the Test cassette for the simultaneous detection of drugs (urine) (3.60). High values of may be due to the high cost of these products and originality in the pharmaceutical market of Ukraine.

Conclusions

The Ukrainian market of diagnostic tests and test systems was studied. It was established that the company structure consists of 90 manufacturers and 20 countries. The vast majority of products come from importing countries (85.5 %), where the leader was China (19.5 %).

Analysis of competitiveness showed that the greatest competition was observed among companies that produce tests to determine pregnancy, glucose, ketones, nitrites and protein in the blood and urine (K*vi* = 0.96), and there was no test manufacturers for sperm testing (K*vi* = 0).

The calculated price liquidity and adequacy of solvency ratios indicate high price competition and low availability for some groups of diagnostic tests and test systems.

Table 2. The results of the analysis of indicators of socio-economic accessibility of diagnostic tests and test systems of the retail pharmacy network

#	The name of the medical device	Manufacturer	Retail price, max, UAH	Retail price, min, UAH	K*liq*	Average retail price, UAH	Ca.s.
1.	Cito Test Rota	Pharmasco Ltd	91.10	129.10	0.42	123.94	1.16
2.	Cito Test *H. pylori* Ag	Pharmasco Ltd	133.13	278.15	1.09	184.91	1.72
3.	Test strip for ketones detection № 25	TOV Norma	24.99	81.07	2.24	35.19	0.33
4.	Test cassette for the simultaneous detection of 5 drugs (urine)	Alfa Scientific Designs, Inc.	146.85	349.15	1.38	228.04	2.13
5.	CitoTest Giardia	Certest Biotec S.L.	195.5	173.47	0.12	182.6	1.70
6.	Cito Test HBsAg (blood)	Pharmasco Ltd	127.0	72.94	0.74	93.74	0.87
7.	Test cassette for the simultaneous detection of drugs (urine)	Alfa Scientific Designs, Inc.	256.80	583.10	1.27	385.84	3.60
8.	Cito Test HCV (blood)	Pharmasco Ltd	28.50	123.10	3.32	116.72	1.09
9.	Cito Test FOB (feces)	Pharmasco Ltd	95.34	121.35	0.27	110.11	1.03
10.	Cito Test for *H.pylori*	Pharmasco Ltd	192.53	226.50	0.18	226.50	2.11
11.	Cito Test Myoglobin (blood)	Pharmasco Ltd	264.50	233.29	0.13	147.40	1.37
12.	Cito Test Troponin 1 (blood)	Pharmasco Ltd	284.00	117.86	1.40	198.90	1.85
13.	Cito Lab G №50 (urine)	Pharmasco Ltd	149.00	130.71	0.13	139.85	1.30
14.	Cito Lab 3GK (urine) №100	Pharmasco Ltd	336.00	268.93	0.97	302.46	2.81
15.	Cito Lab 3GK (urine) №50	Pharmasco Ltd	149.00	125.06	0.19	137.30	1.27
16.	Тест для визначення статі дитини	Intelligender	350.00	340.00	0.03	345.00	3.21
17.	Cito Test pH (vaginal environment)	Pharmasco Ltd	55.00	53.00	0.04	54.00	0.50
18.	Test to detect antibodies to Mycobacterium tuberculosis	BioTech USA	100.00	89.03	0.12	94.5	0.88
19.	Cito test Influenza A+B (nasal smear)	Pharmasco Ltd	266.90	234.00	0.14	250.45	2.33
20.	Citolab K (urine) №50	Pharmasco Ltd	21.21	151.05	6.12	133.41	1.24
21.	Test to determine ovulation	Pharmasco Ltd	177.70	139.00	0.27	158.35	1.47
22.	Test for the determination of amniotic fluids	Oy Medix Biochemica Ab	484.50	462.68	0.04	473.59	4.41
23.	Cito Test HIV 1/2	Pharmasco Ltd	27.26	147.00	4.39	107.31	1.00
24.	Cito Test FOB-Transferrin (feces)	Pharmasco Ltd	123.98	173.35	0.40	151.76	1.41
25.	Cito lab pH (vaginal discharge)	Pharmasco Ltd	41.27	69.75	0.69	51.37	0.48
26.	Cito Test Rota-Adeno (feces)	Pharmasco Ltd	120.00	237.20	0.98	192.70	1.80
27.	CitoTest Syphilis (blood)	Pharmasco Ltd	95.00	81.24	0.16	88.12	0.82
28.	Test to determine menopause	AXIOM Gesel Ischaftfur Diagnostica	170.00	163.00	0.04	166.30	1.55
29.	Test strips to determine protein in the urine	YD Diagnostics CORP.	110.00	105.00	0.05	107.50	1.00
30.	Cito Test Strep A	Pharmasco Ltd	162.50	131.87	0.23	150.25	1.40
31.	Test to determine menopause	Pharmasco Ltd	35.00	29.40	0.19	32.20	0.30
32.	Test to determine markers of the blood coagulation system	Response Biomedical Corp.	180.00	165.00	0.09	172.50	1.60
33.	Test to measure the level of cholesterol, uric acid in the blood	Wellion	600.00	389.00	0.54	479.66	4.47
34.	Test to determine the pH of urine № 50	TOV Norma	30.00	20.00	0.50	25.00	0.23
35.	Test to determine ovulation	Atlas Link Technology Co., Ltd	284.00	164.78	0.72	224.39	2.09
36.	Rab Test (RabiesAg)	Quicking Biotech Co., Ltd	254.00	240.00	0.06	247.00	2.30

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Information about authors:
Brytanova T. S., PhD, Teaching Assistant of the Department of Management and Pharmacy Economics, Zaporizhzhia State Medical University, Ukraine.
ORCID ID: 0000-0003-1805-4552
Samko A. V., PhD, Senior Lecturer of the Department of Management and Pharmacy Economics, Zaporizhzhia State Medical University, Ukraine.
ORCID ID: 0000-0002-3182-5588
Knysh Ye. H., Dr. hab., Professor, Head of the Department of Management and Pharmacy Economics, Zaporizhzhia State Medical University, Ukraine.
ORCID ID: 0000-0002-8002-6117

Відомості про авторів:
Британова Т. С., канд. фарм. наук, асистент каф. управління і економіки фармації, Запорізький державний медичний університет, Україна.
Самко А. В., канд. фарм. наук, старший викладач каф. управління і економіки фармації, Запорізький державний медичний університет, Україна.
Книш Є. Г., д-р фарм. наук, професор, зав. каф. управління і економіки фармації, Запорізький державний медичний університет, Україна.

Сведения об авторах:
Британова Т. С., канд. фарм. наук, ассистент каф. управления и экономики фармации, Запорожский государственный медицинский университет, Украина.
Самко А. В., канд. фарм. наук, старший преподаватель каф. управления и экономики фармации, Запорожский государственный медицинский университет, Украина.
Кныш Е. Г., д-р фарм. наук, профессор, зав. каф. управления и экономики фармации, Запорожский государственный медицинский университет, Украина.

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