National market of diagnostic tests and test systems

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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, nitrates and protein in the blood and urine (Kvi = 0.96), and there was no test manufacturers for sperm testing (Kvi = 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.
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
of competition between manufacturers of similar groups of diagnostic tests, the stress factor $Kvi$ was calculated by the formula:

$$Kvi = \frac{n - 1}{n},$$  \hspace{1cm} (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 ($Kvi = 0.96$). In second place were tests to determine ovulation and follicle-stimulating hormone ($Kvi = 0.95$). The third place was shared among tests for drugs and tests for troponin I, KK-MB, myoglobin ($Kvi = 0.92$).

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

\[
K_{liq} = \frac{P_{max} - P_{min}}{P_{min}} \times 100 \%, \tag{2}
\]

where \(K_{liq}\) – price liquidity ratio; \(P_{max}\) – maximum price; \(P_{min}\) – minimum price [13,14].

Data from the site Tabletka.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 \(K_{liq}\) 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:

\[
K_{as} = \frac{P}{W_{a.w.}} \times 100 \%, \tag{3}
\]

where \(K_{as}\) – solvency adequacy ratio; \(P\) – the average price of the drug for a certain period of time (October 2019); \(W_{a.w.}\) – 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 | Kliq | 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 Nr 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                 | 2.24 | 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 Nr50 (urine)                                            | Pharmasco Ltd       | 149.00                 | 130.71                 | 0.13 | 139.85                   | 1.30  |
| 14  | Cito Lab 3GK (urine) Nr100                                        | Pharmasco Ltd       | 336.00                 | 268.93                 | 0.97 | 302.46                   | 2.81  |
| 15  | Cito Lab 3GK (urine) Nr50                                         | 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) Nr50                                             | 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 Geselluchafftur 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 Nr 50                           | TOV Norma           | 30.00                  | 20.00                  | 0.50 | 25.00                    | 0.23  |
| 35  | Test to determine ouvation                                         | 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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Conflicts of interest: authors have no conflict of interest to declare.
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