

## **PECULIARITIES OF THE UKRAINIAN MEDICAL DEVICE MARKET**

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**Abstract:** The Ukrainian medical device market is gradually following the path of harmonization with the market of the European Union. Although there was a number of amendments to the Ukrainian regulations in accordance with the existing European directives, the overall legislative part is probably the simplest portion of the homework. To bring the state of the market up to the next level the government of Ukraine will need to take a new and reformatory approach in dealing with the peculiarities of this industry, consisting mostly of out-of-date equipment, shortage of high-value devices, general poor treatment conditions in state clinics and many more. Considering the above-mentioned, scrutiny of current market issues is a key means of identifying and prioritizing critical points that require repair actions.

**Key words:** medical equipment, medical device market, Ukraine, trends, current issues

**JEL:** I15, O14.

### **Introduction**

Country health care provision can be viable only based on high quality of the pharmaceutical industry and the medical device sphere, therefore

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state influence on economic relations between market participants comprised in designing legislative framework for functioning of these economy sectors, and their further regulation, is extremely important. It is the set of rules and economic processes that create peculiarities of an industry, which pertains to the medical field as well. Despite Ukraine's considerable scientific and intellectual potential in medical technology, the vast majority of high-tech products are imported. However, the domestic market faces a number of other problems, some of which are chronic, which is why scrutiny of its current state will help to find ways to solve urgent challenges.

On the one hand, modern research can rely on traditional Western studies that highlight possibilities of regulating the market of medical instruments in the US and the EU (D. Kramer, T. Maak, C. Altenstetter). On the other hand, the research analyzes the technological competition of goods and services produced by manufacturers, as F. Pamolli, M. Riccaboni, C. Oglialoro, and A. Kirisits do. Many works of the Ukrainian scientists, such as M. Ostapiuk, E. Garkusha, M. Malovanyi and others, are devoted to the study of this topic. The problem of providing health care facilities with medical equipment was investigated, among others, by R. Kartavtsev, I. Skyrda, O. Petishko, and T. Pantelieieva. The databases of the State Statistics Service of Ukraine and the World Health Organization were used to analyze the quantitative indicators.

Therefore, it should be noted that the purpose of the proposed study is a systematic analysis of the definition of characteristics and trends of the Ukrainian medical device market.

## **1. Ukrainian trends of transformation of the medical device market**

After Ukraine gained independence, it seemed that the best times would start for the medical sector due to the declared priority of social values. However, it did not happen, because the systemic crisis of the 1990s, and the past century, overall, significantly changed the structure, character and, most importantly, the technological support of those reproductive processes that determined not only success of the medical field, but also its

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international competitiveness. As of early XXI century the medical equipment market, which was developed globally, found itself deformed in Ukraine, as many Soviet-era enterprises had gone bankrupt, and hospitals, clinics and research institutions could not afford imported equipment because of the high cost. Only after 2010, when it became apparent that diagnostics and treatment would turn impossible due to the lack of instruments, the market was partially revived; not for long, though. For the most part, the critical situation applies to public health facilities, while private clinics are equipped with high-tech apparatus purchased at their own expense.

At the same time, in spite of the negative state of the public hospitals infrastructure, they account for the majority of patient visits, which is why the availability of tools for diagnosis and treating patients is an indispensable condition for social security of the Ukrainian citizens. The data in table 1 is shown to detail receipts of certain medical devices by hospitals in order to assess the level of technical equipment in public and municipal health facilities.

**Table 1**  
*Number of received technical devices by the health care units of the local state administrations in Ukraine, 2015-2018*

Year	2015	2016	2017	2018
Item name				
Hearing aids	2 286	2 748	2 569	2 997
Glucometers with speech output	1 394	139	320	150
Tonometers and thermometers with speech output	97	109	150	148
Artificial prosthetic heart valves	294	399	293	378
Pacemakers	237	224	123	149
Oxygen generators	910	761	437	671
Single-chamber cardioverter-defibrillators	4	2	6	32
Dual-chamber cardioverter-defibrillators	3	9	2	25

*Source: Medstat (2018).*

On the whole, the table illustrates the positive dynamics in the number of received technical instruments. However, even intensive purchase of the respective equipment cannot satisfy the need for diagnostics and treatment in hospitals of the forty-million country at all.

Taking this into account, it would be appropriate to make further analyses in order to provide statistics on the number of public and private entities that carry out medical practice: as of October 6, 2017, about 3 900 licenses were issued by the Ministry of Health of Ukraine for local and municipal institutions of Ukraine. At the same time, 16 664 licenses were obtained by private entities (MoH of Ukraine, 2017). Of course, this also entailed the need for technological equipment. So, in 2017 one state health care institution received 0.66 hearing aids, 0.08 glucometers with speech output, 0.04 tonometers and thermometers with speech output, 0.08 artificial heart valve prostheses, 0.03 pacemakers, 0.11 oxygen generators, 0.002 single-chamber cardioverter-defibrillators and 0.0005 dual-chamber cardioverter-defibrillators. Obviously, that number of individual devices was not enough to meet urgent needs.

The analysis of foreign trade indicators quite eloquently presents the critical state of purchase of this group of goods, creating doubtful prospects. Such contradictions are clearly reflected by the foreign trade turnover of Ukraine in the field of medical devices. Of course, the list of goods given in table 2 cannot claim to be fully exhaustive, however, it allows to detect trends in imports of medical equipment.

Considering the figures in the table above, it appears to be that the main trend in the domestic market lies in the importation, actively increasing over the last 5 years, which indicates the inability of Ukrainian manufacturers to fully meet the needs of domestic consumers. This tendency is dangerous for the state, because apart from the outflow of foreign currency from the country and deterioration of the foreign trade balance, the risk of further technological backwardness and movement towards the third world countries is also increasing. It is also worth noting that most funds are spent on the purchase of equipment for mechanical and ozone therapy, oxygen and aerosol therapy, artificial respiration and reanimation, equipment for ultrasound scanning, as well as syringes and needles. The presence of the latter among the priority needs leads to another disappointing conclusion, because these

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products are not of high-tech origin, and could be manufactured without restrictions in Ukraine, as well as exported to other countries of the world.

*Table 2*  
*Imports of medical devices from the EU members into Ukraine by product categories in thousands of US dollars, 2015-2019*

Year Product	2015	2016	2017	2018	January- July 2019
Contact lenses and lenses for eyeglasses	3 538.2	4 035.3	4 647.0	6 341.6	3 135.5
- from other countries	6 496.3	7 222.1	8 880.6	14 900.9	7 897.6
Microscopes	222.7	345.0	754.0	545.9	243.5
- from other countries	314.1	679.4	827.1	982.9	644.5
Electrocardiographs	417.8	567.5	834.3	1 366.2	490.7
- from other countries	944.0	1 201.7	1 574.7	1 473.8	1 457.8
Ultrasound scanning equipment	2 932.2	4 197.4	5 227.1	8 554.5	5 777.0
- from other countries	7 235.4	12 078.9	15 812.2	18 981.0	8 267.7
Magnetic resonance imaging	1 714.7	1 736.4	2 078.1	3 892.9	2 552.6
- from other countries	3 007.8	4 023.9	15 366.3	2 128.4	1 200.7
Other electro-diagnostic apparatus	1 437.8	1 712.0	1 997.1	-	1 508.2
- from other countries	2 746.1	2 712.5	5 395.4	-	3316.9
Equipment using ultraviolet or infrared radiation	523.7	718.2	1 517.8	1 723.1	943.3
- from other countries	565.5	557.2	911.7	470.8	816.1
Syringes and needles	13 862.5	13 370.7	12 159.7	15 811.2	8 710.2
- from other countries	24 431.9	25 025.2	24 887.5	42 597.7	20 316.6
Mechanotherapy and other equipment	3 228.9	8 329.9	9 922.6	12 286.1	3 101.5
- from other countries	7 807.3	11 269.6	21 533.7	16 527.9	12 698.8
Cardiac stimulators	1 095.2	809.9	989.6	800.7	281.9
- from other countries	1 782.3	3 331.8	5 234.6	5 511.0	4 394.7
Computed tomographs	460.7	704.9	1 364.5	2 630.2	3 650.3
- from other countries	6 517.5	8 885.3	13 889.2	7 112.8	4 633.3
<b>Total</b>	<b>91 282.6</b>	<b>113 514.8</b>	<b>155 804.8</b>	<b>164 639.6</b>	<b>96 039.4</b>

*Source: compiled by author based on State statistical service of Ukraine, 2019.*

The list and quantity of goods exported from Ukraine to the European countries are given in table 3. It includes the main categories of exported medical products manufactured in Ukraine.

**Table 3**  
*Exports of Ukrainian medical devices to the EU members by product categories in thousands of US dollars, 2015-2019*

Year \ Product	2015	2016	2017	2018	January- July 2019
Contact lenses and lenses for eyeglasses	-	-	8.1	-	43.9
- to other countries	182.8	104.0	146.8	217.9	131.3
Microscopes	0.5	18.7	0.6	0.3	0.1
- to other countries	17.3	15.9	2.6	21.6	30.3
Electrocardiographs	402.7	669.7	413.1	593.0	240.3
- to other countries	315.3	260.2	205.8	297.4	64.6
Ultrasound scanning equipment	30.6	87.0	52.7	244.7	22.3
- to other countries	58.2	167.6	59.7	122.4	19.6
Magnetic resonance imaging	-	-	1.7	0.4	34.2
- to other countries	81.0	-	-	1.2	-
Other electro-diagnostic apparatus	580.1	957.8	964.4	-	903.5
- to other countries	825.4	636.0	460.7	-	293.2
Equipment using ultraviolet or infrared radiation	81.2	5.9	26.8	90.5	85.2
- to other countries	114.9	115.8	28.6	133.9	17.9
Syringes and needles	113.6	138.7	633.7	967.8	542.6
- to other countries	532.8	448.5	603.1	852.5	431.0
Mechanotherapy and other equipment	226.6	1 008.5	104.5	163.7	36.8
- to other countries	1 235.4	2 139.5	1 194.3	2 229.1	1 028.2
Cardiac stimulators	-	-	-	-	0.5
- to other countries	-	-	-	-	-
Computed tomographs	14.9	5.4	-	-	-
- to other countries	175.0	-	-	-	-
<b>Total</b>	<b>4 988.3</b>	<b>6 779.2</b>	<b>4 907.2</b>	<b>5 936.4</b>	<b>3 925.5</b>

*Source: compiled by author based on State statistical service of Ukraine, 2019.*

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We should note that the volumes of the above-mentioned economic operations are extremely low, which is convincingly confirmed by the last annual figure of \$ 5.9 million for 2018. To understand the real scale, it is worth mentioning that all aggregate exports of Ukrainian goods according to the latest available data in 2017 amounted to \$ 17 533.4 million (State statistical service of Ukraine, 2017), while the share of medical devices in the same year amounted to only 0.034%. Despite this, the most in demand products among the EU member states were electro-diagnostic apparatus which included incubators, spirometers, etc., syringes and needles, electrocardiographs. Given the dynamics of trade in these categories of products, it seems logical to prioritize development of this particular production. At the same time, comparing tables 2 and 3 it can be affirmed that the Ukrainian medical device market is not self-sufficient and needs regular replenishment with foreign goods.

In modern Ukraine there is no comprehensive system for licensing of medical equipment. However, the first attempts to regulate the market have already emerged. The decree of the Cabinet of Ministers of Ukraine No. 753 of October 2, 2013, which introduced a technical regulation on medical devices, was developed on the basis of the Council Directive 93/42/EEC of 14 June 1993 on medical devices (Cabinet of Ministers of Ukraine). This CMU resolution establishes a procedure for state registration and assessment of compliance of medical devices before placing them on market. As of November 29, 2019, more than 3, 200 Ukrainian companies registered about 6, 000 types of medical devices (State service of Ukraine on medicines and drugs control), but these figures give only a relative idea of the real scale of the national market, since a significant number of goods are put into circulation without registration by state competent authorities.

### **2. Comparative analysis of Ukrainian and EU markets**

MedTech Europe, a European trade association representing the medical technology industry, calculated member states' expenditures on medical technology based on the data from the World Health Organization, Eurostat, and BMI Research, which were found to fluctuate

within the range of 5 to 10 % of the total health care budget (Medtech Europe, 2018). Using this approach, we illustrate the basic social indicators of Ukraine in table 4.

*Table 4*  
*Population and health expenditures in Ukraine, 2012-2016*

Year \ Indicator	2012	2013	2014	2015	2016
Population, in millions	45.6	45.4	42.9	42.8	42.6
Health care expenditure per capita, UAH	2 389.2	2 549.7	2 744.9	3 626.6	4 262.8
Total health care expenditure, as % GDP	7.5	7.6	7.4	7.8	7.6
Share of state expenditure in total health expenditure, %	57.2	56.2	51.7	48.7	44.8
Total expenditures on medical devices (estimate), UAH in millions	8 171.1	8 681.7	8 831.7	11 641.4	13 619.7

*Source: State statistical service of Ukraine.*

Health care expenditures per capita in Ukraine have a positive trend, driven by both an increase in the health budget and a parallel decline in population. Such expenses in 2016 amounted to UAH 4 262.8 per person or 150.7 EUR by the average exchange rate of 2016 (National bank of Ukraine, 2016). For comparison purposes, in the same year EU countries spent an average of 2 459.7 EUR per person, which is 16 times as high as the Ukrainian number. The total financing of the Ukrainian medical device sphere in 2016 totaled to 13.6 billion UAH which was equaled to 319.7 UAH per capita. It would be overly optimistic to expect innovative inventions and high-quality medical technology advances at this level of financial support, however, the potential for development remains and is most likely based on scientific and human capital. Table 5, with similar indicators for the European Union countries, can serve as a proof.



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**Table 5**  
*Population and health expenditures in the EU, 2012-2016*

Year	2012	2013	2014	2015	2016
Indicator					
Population in the EU, in millions	504.1	505.2	507.0	508.6	510.3
Average health care expenditure per capita among the EU member states, EUR	2 274.5	2 309.7	2 352.5	2 424.1	2 459.7
Average health care expenditure among the EU member states, as % GDP	8.4	8.5	8.5	8.4	8.4
Average share of state expenditure in total health expenditure among EU Member States, %	73.0	72.7	72.6	72.3	72.6
Expenditure on medical products (estimate), EUR in millions	85 991.4	87 514.5	89 453.1	92 465.6	94 140.0

*Source: compiled by author based on World Health Organization.*

The health expenditures among the EU countries during 2012-2016 tended to increase along with the population growth. While the average ratio of such expenditures to GDP over the reviewed period was 7.6 % in Ukraine, the member states of the Union financed healthcare at the rate of 8.4 % of GDP. It is also interesting that public funds cover an average of 72.6 % of total EU spending, while in Ukraine this figure is only 51.7 %. In addition to the above, as of 2016, 184.5 EUR per each EU citizen were directed solely on medical devices.

One of the actual ways to improve the state of the national medical technology industry is to use and implement a scientific resource of Ukrainian specialists. Patenting inventions and engaging business in their practical application would greatly contribute to the commercialization of domestic developments and the intensification of the high-tech industry growth. In table 6 the number of applications for inventions of Ukrainian developers is

shown, which will help to assess the relevance of obtaining intellectual property rights.

**Table 6**  
*Applications for inventions in medical technology, 2012-2016*

Applicants	National applicants					Foreign applicants				
Year	2012	2013	2014	2015	2016	2012	2013	2014	2015	2016
Number of applications	157	234	201	212	175	48	55	43	46	34

*Source: Ukrainian Intellectual Property Institute*

Considering the population and scientific potential of Ukrainian health workers and engineers, the above figures appear rather meager. For comparison, the total number of applications filed with the European Patent Office for Medical Technology Patents was 13 090 (European patent office, 2017). It is important to underline that ineffective means of protection of intellectual property rights carry risks for holders of patents that were already granted. In our opinion, it evidences the fact that these problems are of complex origin and lie not only in the small number of Ukrainian scientists, but, among other things, in the normative framework of the process.

### **Conclusion**

Ukrainian medical equipment market has evolved fairly quickly, ranging from near to full supply of goods manufactured in the former USSR to almost complete negligence over their purchase at the turn of the millennium. The bankruptcy of a large part of the machine-building enterprises of the relevant profile, the lack of working capital in hospitals, a 10-year decline of GDP, the loss of technicians who serviced the equipment and many other subjective factors have caused great damage to the formation of a civilized market of medical devices.

The active restoration of some production processes in Ukraine, state funding of certain medical programs, availability of working capital in medical institutions allowed to increase the necessary manufacturability, but still the structure, character and dynamics of the domestic medical equipment

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market remains unsatisfactory. It is possible to increase the competitiveness of production at the expense of additional investments, technologies and human capital in this sphere, for which Ukraine has sufficient opportunities.

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