

PRODUCT QUALITY MANAGEMENT AS A FACTOR IN THE INTERNATIONAL COMPETITIVENESS OF PHARMACEUTICAL ENTERPRISES OF UKRAINE

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Abstract. Under the market conditions, each pharmaceutical products manufacturing company is forced to form a competitive strategy and tactics of behavior in the business environment in order to increase the competitiveness of products and activities. Pharmaceutical products are produced mainly by a small number of developed countries. The share of the largest manufacturers of pharmaceutical products, which include the USA, Japan, France, Germany, Great Britain, Italy, Switzerland, Spain, the Netherlands, exceeds 75% [14]. Ukraine also has its own pharmaceutical production; however, it is dependent on the foreign manufacturers of pharmaceutical products and does not fully meet the needs of its population. Ukraine imports most of the pharmaceutical products from abroad, and the country can provide about 38 % of the population with its own pharmaceutical products. However, in recent years, the share of imported pharmaceutical products has been gradually decreasing, and the export of Ukrainian pharmaceutical products (both absolute and relative, both quantitative and qualitative) has grown. In our opinion, this indicates an increase in the international competitiveness of Ukrainian companies, achieved through product quality management.

The article is devoted to quality control issues affecting the sustainable business development and international competitiveness of enterprise. On the example of the pharmaceutical company "Farmak", researched domestic experience of production quality management system, and its affect on the international competitiveness of firm. Given the desire to integrate into the world economy, entrepreneurs should focus on changing targets global vector of development in the field of quality management as the sources of development of the enterprise. Concluded that the advantage of a systematic approach to quality management, which ensures improved consumer confidence in the quality and safety of manufactured products, market expansion, as well as improving the reputation of manufacturers of high-quality and safe products.

Keywords: international competitiveness, enterprise competitiveness, pharmaceutical products, pharmaceutical industry, GMP, quality management.

JEL Classification: D04, F10, L1, L65, M10

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Introduction. The competitiveness issue is universal in its nature and affects almost all business entities in all sectors of all countries, including manufacturers of pharmaceutical products of Ukraine. The development of the pharmaceutical industry and the pharmaceutical market is the basis for the steadiness and balance of the production and circulation of pharmaceutical products and, therefore, one of the elements ensuring the national security of the country, and largely the state of the economy. In modern conditions of direct interaction between Ukrainian and foreign entrepreneurs, the issue of the competitiveness of pharmaceutical companies in Ukraine has become central and real.

Literature review. A large number of publications, both foreign and Ukrainian, testifies to the urgency of the issue of ensuring competitiveness and analysis of the influence of various factors on it. Some aspects of the studied topics were displayed in the works of M. Porter [21], J.-J. Lambin [15], E.A. Beltyukov [1], M. Berdar [2],

A.R. Duns kaya [5], J. L. Zborovska [26], G. V. Kostiuk [14], V.S. Mazur [16], L.A. Pedorenko [20], G.M. Filyuk [7], G. I. Frolova [8] and others. However and despite this, the issue of the impact of quality management on the international competitiveness of pharmaceutical enterprises has not been studied enough, especially from the viewpoint of management.

Aims. The aim of the article is to estimate the impact of product quality management systems on the international competitiveness of enterprises in the pharmaceutical industry of Ukraine.

The aim of the article is, firstly, to show the importance of product quality management for the competitiveness of pharmaceutical companies, and secondly, to estimate the degree of influence of such management on the competitiveness and results of the company using the example of JSC "FARMAK".

Methods. The article uses logical, statistical, graphical, problem-oriented methods, as well as the method of comparative analysis.

Results. The international competitiveness of the enterprise is expressed by its ability to produce and sell products that meet all established requirements and are more attractive in price, quality and other non-price characteristics compared to similar products of competitors on the domestic and / or foreign markets. The main indicator of product attractiveness is the company's sales volume and its market share. The pharmaceutical market is one example of global markets that compete between local and international players [22].

Ukrainian companies are competing with foreign companies both on the domestic (domestically) and foreign (abroad) markets. Therefore, they are forced to take care of their own international competitiveness.

The competitiveness is the ability to compete and win the competition on the market [4, 21]. In the economic literature, authors often write about the competitiveness of an enterprise, industry, country. However, the direct subjects of competition are only business entities (mainly enterprises, companies). Such business entities make decisions on all issues related to competition on specific product markets, in particular, whether or not to enter into competition on a particular market, which competitive strategy to choose, how to implement the chosen strategy, and ultimately bear liability for such decisions, receiving profit or loss. At the same time, the competition of enterprises has the form of competition of the products themselves. Therefore, to ensure the competitiveness of enterprises, the properties and characteristics of the products they produce, and especially the quality of these products, are of great importance.

This is because pharmaceutical products are not quite ordinary goods. This kind of goods has a direct impact on consumer health, therefore quality in the pharmaceutical industry is of particular importance and acts as an object of state regulation. If a manufacturer does not comply with state requirements for the quality and safety of products, then such manufacturer simply cannot sell its products on the market. Thus, in order to be competitive and at least have the opportunity to be present on the market, pharmaceutical companies need to manage product quality,

which is due, firstly, to the state requirements, and secondly, to the competitive pressure.

Nowadays all known world manufacturers of pharmaceutical products manage their quality at all stages of the product life cycle and have appropriate management systems certified according to the international standards ISO 9001 (quality management systems), ISO 13485, GMP, GLP, GCP, GDP.

The main standard from this list for the pharmaceutical industry is the GMP (good manufacturing practice) standard, which has become mandatory in Ukraine since 2009.

The pharmaceutical industry of Ukraine today is represented by 115 business entities that are licensed to produce pharmaceutical products under production-line conditions. Since the beginning of 2011, the number of licensees has decreased by 22 entities, which is precisely due to the fulfillment in Ukraine of GMP requirements for the production of pharmaceutical products adopted in the European Union. Not all Ukrainian manufacturers were able to reach the level established by the standards for the production of pharmaceutical products adopted by the European Union. Another reason for the reduction in the number of business entities was the occupation of part of the territory of Ukraine in 2014.

The pharmaceutical industry occupies a significant place in the economy of Ukraine, since it is an important segment of the national market, largely determines the national and defense security of the country, is notable for its high science intensity and developed cooperation. Over the past eight years, the industry has shown a steady upward trend in monetary terms at the level of at least 15 % per year (Fig. 1).

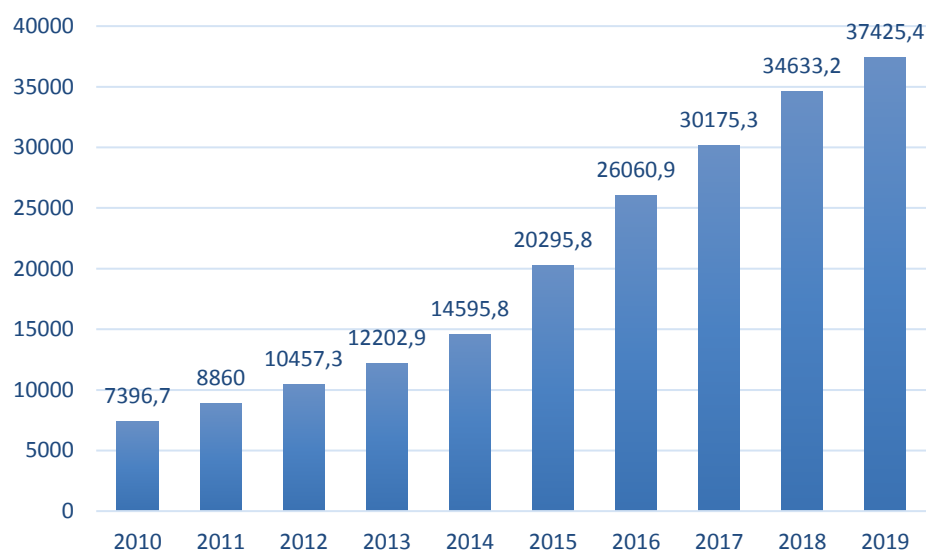


Figure 1. Manufacture of basic pharmaceutical products, 2010-2019 (in UAH million)

Source: calculated by the authors according to data (State Statistics Service of Ukraine, 2021)

According to the statistical data of the State Register of Medicines of Ukraine, which was formed by the state enterprise “State Expert Center of the Ministry of Health of Ukraine”, as of June 2021, Ukrainian pharmaceutical companies produced 30.7 % (4, 229) of the total number of pharmaceutical products registered in Ukraine (henceforth referred as the “pharmaceutical products” or “PP”) (Table. 1.) [23].

Foreign pharmaceutical products accounted for 69.3% (9, 521). For comparison:

- 5 years ago (as of November 11, 2015) the ratio between the local and foreign pharmaceutical products registered in Ukraine was 29.9 % (3, 689) and 70.1 % (8, 648) respectively,

- 9 years ago (as of November 01, 2011) (13, 889 pharmaceutical products) – 34 % and 66 %.

**Table 1. Number of pharmaceutical products registered in Ukraine
(as of June 8, 2021)**

No.	Pharmaceutical products groups	Local	Foreign	Total
1	Finished pharmaceutical products (FPP)	3,637	7,156	10,793
2	Substance	346	1,802	2,148
3	In bulk	193	424	617
4	Packages in bulk	53	139	192
	Total:	4,229	9,521	13,750

**Source: calculated by the authors according to data (State Register of Medicines of Ukraine, 2021)*

As we can see, the number of pharmaceutical products of foreign production significantly exceeds the number of pharmaceutical products of local production in all years.

As for sales in Ukraine, according to the Limited Liability Company “Proxima Research”, in 2019 the foreign-made pharmaceutical products occupied 62.3 % of the market in monetary terms, and pharmaceutical products of Ukrainian manufacturers - 37.7 %. In packages, on the contrary, Ukrainian pharmaceutical companies held the lead - 71.3 %, while pharmaceutical products of foreign manufacturers accounted for 28.7 % [19, 13]. This ratio is a completely natural result of the product portfolio of Ukrainian pharmaceutical manufacturers, which do not yet produce pharmaceutical products for the treatment of complex diseases, such as oncology, etc., but are concentrated in the segments of simpler and cheaper pharmaceutical products.

The group of leading Ukrainian manufacturers of pharmaceutical products includes JSC “FARMAK” (with a 5.9 % share in sales on the Ukrainian pharmaceutical market), PJSC “Pharmaceutical Firm “Darnitsa” (3.7 %), “Arterium” Corporation (4.2%), Pharmaceutical Company “Zdorovye” LTD, PJSC “SIC “Borshchahivskiy Chemical Pharmaceutical Plant” [11].

Mostly, the Ukrainian manufacturers specialize in the production of low-cost generics. The good price-quality ratio of generic pharmaceutical products produced by Ukrainian manufacturers is considered their main competitive advantage. Is it true or not, however, the share of foreign pharmaceutical products in sales on the Ukrainian pharmaceutical market has been declining in recent years. Five years ago, their share was about 70 % of the market in monetary terms. Now, as already

mentioned, it is 62.3%. For Ukrainian companies, this is certainly a positive trend, which may indicate an increase in their competitiveness on the national market.

Positive trends for Ukrainian pharmaceutical companies are also observed in the export direction (see Table 2).

Table 2. Foreign trade in the field of pharmaceutical products in Ukraine, 2009-2020

Year:	Export			Import			Balance, millions, USD
	millions, USD	% in relation to the previous year	% in relation to the total export of Ukraine	millions, USD	% in relation to the previous year	% in relation to the total import of Ukraine	
2009	150.0	99.3	0.4	2,130.3	87.5	4.7	-1,980.3
2010	198.5	132.3	0.4	2,445.8	114.8	4.0	-2,247.3
2011	195.1	98.2	0.3	2,879.0	116.3	3.5	-2,683.9
2012	243.5	124.8	0.4	3,307.9	114.9	3.9	-3,064.5
2013	251.5	103.3	0.4	3,099.9	93.7	4.0	-2,848.4
2014	255.6	101.9	0.5	2,473.3	79.9	4.5	-2,217.7
2015	155.4	60.8	0.4	1,367.0	55.3	3.6	-1,211.6
2016	184.2	118.5	0.5	1,607.0	117.6	4.1	-1,422.8
2017	192.1	104.3	0.4	1,767.5	110.0	3.6	-1,575.4
2018	216.2	112.5	0.5	1,947.0	110.2	3.4	-1,730.8
2019	250.8	116.0	0.5	2,143.2	110.1	3.5	-1,892.4
2020	268.2	106.9	0.5	2,523.2	117.7	4.6	-2,255.0

Source: calculated by the authors according to data (State Statistics Service of Ukraine, 2021)

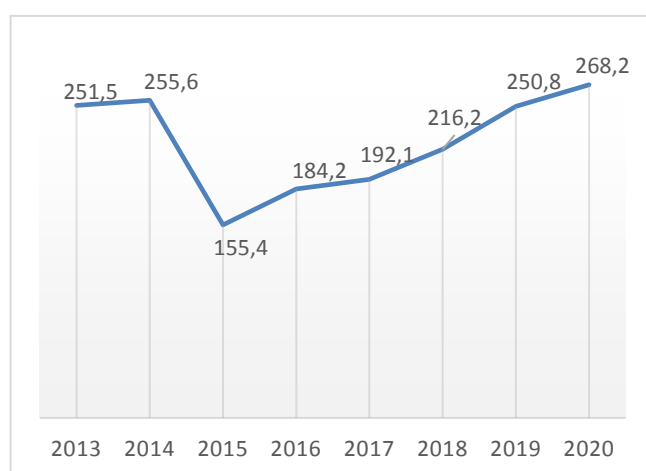


Figure. 2. Export of pharmaceutical products from Ukraine (millions, USD)

Source: calculated by the authors according to data (State Statistics Service of Ukraine, 2021)

As can be seen in Fig. 2 and from Table 2, the real shock therapy for Ukrainian pharmaceutical manufacturers was the closure of the Russian market after 2014. In 2015, PP exports from Ukraine decreased by 40 %.

However, already in 2016, export began to grow. In 2016, it amounted to 184.2 million USD, which is 18.5 % more than in 2015; in 2017 - 192.1 million USD, which is 4.3 % more than in 2016; in 2018 - 216.2 million USD, which is 12.5 % more than in 2017; in 2019 - 250.8 million USD, which is 16 % more than in 2018; in 2020 - 268.2 million USD [24].

At appropriate time, Russia accounted for the largest share of Ukrainian pharmaceutical exports in total sales. However, after deliveries to the aggressor country stopped, the companies were forced to start looking for other target markets for sales of their products.

Such behavior is characteristic of all Ukrainian manufacturers.

As the result, the share of post-Soviet countries (Uzbekistan, Russia, Belarus, Kazakhstan, Moldova, Azerbaijan, Georgia, Tajikistan and Kyrgyzstan) in the export of Ukrainian pharmaceutical products decreased from 88 % in 2009 and up to 66% in 2019, and in the structure of such export such countries as the Brazil, Iraq, Yemen, Libya, Cuba, Somalia, Colombia, the Philippines appeared [6]. Ukrainian enterprises significantly expanded the boundaries of export supplies (see Fig. 3). Shipments to Poland, Vietnam, Mongolia, and India (blood products) also increased significantly. Australia was added to the new markets in 2017 thanks to the efforts of the JSC “FARMAK”.

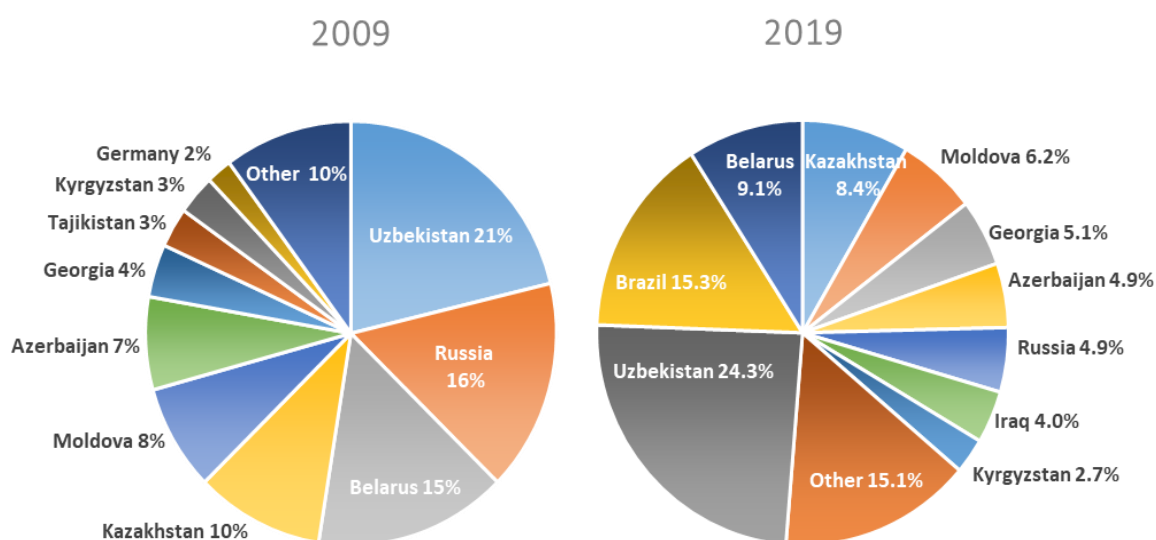


Figure 3. Countries of export of Ukrainian pharmaceutical products [6]

According to data of the research company Top Lead, in 2017 the products of Ukrainian pharmaceutical companies were bought in 50 countries of the world and in 2018 already in 81 countries [9].

Ukrainian companies are also making efforts to participate in international global tenders such as the WHO, UNICEF, UNFPA.

All this testifies to the increase in the international competitiveness of pharmaceutical manufacturers from Ukraine, which was made possible primarily due to their responsible attitude to product quality management.

A typical example in this regard is the JSC “FARMAK” (but not only this company).

There are no compromises for JSC “FARMAK” in quality matters. This is a joint philosophy of each employee and the company as a whole. Each year, the company undergoes about fifteen external inspections and audits. Nineteen

production sites of JSC “FARMAK” were certified for the compliance with the GMP requirements by the State Service of Ukraine on Medicines and Drugs Control. The systems were implemented and certified in accordance with the ISO 9001, ISO 13485, ISO 22000, ISO 14000, and OHSAS 18001 [17].

The integrated quality system operates at the enterprise and considerable attention is paid to quality control at the stage of development, testing and manufacture of products that are constantly being improved. JSC “FARMAK” has implemented a comprehensive quality control system in accordance with the GMP standards and the requirements of ISO 9001 (quality management system) and ISO 13485 (quality management system for medical devices). The quality control team is responsible for testing and ensuring that all substances, excipients, packaging materials and manufactured products are in accordance with approved specifications.

The key responsibility for quality in the company is assigned to the Service of the Director of Quality matters and provides for the regulatory compliance of all quality systems, independent control at all stages of production and certification of products by the Authorized person. The presence of such department does not reduce the role and liability of other employees, but rather is the central link in the multifunctional quality chain - from pharmaceutical products development to delivery to the consumer [17].

The pharmaceutical quality system built in the company over the past 23 years has gained European recognition. Today, all productions of finished pharmaceutical products of the JSC “FARMAK” have a national GMP certificate; fourteen of them are certified by the European regulatory authorities of Croatia, Poland and Germany. 95 % of the products of JSC “FARMAK” are produced at these certified production sites [18]. No other pharmaceutical company in Ukraine has such level of European recognition. In addition, quality management systems for medical devices and dietary supplements of the company comply with ISO 9001, ISO 13485, ISO 22000 standards and allow to develop these areas of activity. These systems guarantee product quality and form consumer confidence.

There are various methods with which the impact of quality management system on the state of affairs of the company can be evaluated [12, 25]. In accordance with ISO 9001, such impact on the competitiveness of the company is best assessed in two ways:

- by performance,
- by effectiveness.

In ISO 9000:2000 standard, the term “performance” is defined as the degree to which the planned results are achieved, and “effectiveness” is defined as the ratio between the results achieved and the resources expended.

Let us to assess the effectiveness of the quality management of JSC “FARMAK”.

At the present-day stage of development, JSC “FARMAK” in its activity seeks to achieve the following strategic goals: (1) to become one of the influential regional pharmaceutical market participants, strengthening its leading position in Ukraine and increasing its presence on the markets of neighboring countries; (2) to increase the

effectiveness of all processes, and to increase the production capacity; (3) to expand the geography of exports; (4) launch on the market new products with significant commercial potential that are underrepresented on the local pharmaceutical market; (5) to introduce measures to increase the effectiveness of marketing and sales; (6) to deepen the cooperation with strategic partners; (7) to increase export to the markets, to expand the possibilities of representative offices on the main markets, including the opening of new representative offices or affiliates; (8) to develop partnership projects on export markets [11].

By the end of 2019, JSC “FARMAK” continues to maintain leadership in the ranking of sales on the domestic pharmaceutical market with a share of 5.9 %, among marketing organizations in terms of pharmacy-sold pharmaceutical products in monetary terms with a share of 6.1 % and with an increase of + 16.2 % in sales in monetary terms, in export with a share of 22.6 % of total sales of the company and 18 % in total exports of all companies of the pharmaceutical industry of Ukraine.

During 2012 - 2019, JSC “FARMAK” was one of the most active local pharmaceutical manufacturers of the Ukrainian market in the development, registration and introduction of new products on the market, based on the number of new unique commodity items launched on the Ukrainian market, according to the data of the Limited Liability Company “Proxima Research”. At the end of 2019, the product portfolio of JSC “FARMAK” consisted of pharmaceutical products that are based on 177 INN (international nonproprietary name) and are represented by 401 nomenclature items in the company’s price list. Each year, the company launches an average of 20 new pharmaceutical products on the market, and another 100 pharmaceutical products are in development [11].

The company supplies products to 28 countries, has been operating on the EU markets for more than 20 years, in particular: Poland, Bulgaria, Latvia, Lithuania, Hungary, Great Britain, Germany and Slovakia. In the EU, 37 pharmaceutical products of the JSC “FARMAK” are registered. Seven more are in the registration process. The JSC “FARMAK” is currently undergoing the FDA inspection to enter the US market - the toughest regulatory and most solvent pharmaceutical market throughout the world.

Now let us to assess the quality management system of JSC “FARMAK” in terms of effectiveness.

The main and essential feature of production efficiency at JSC “FARMAK” is achievement of the goal, provided that the resources are reduced.

Over the past 5 years, labor productivity in production increased by 20-40 %, labor intensity decreased by 12 %, losses of raw materials and supplies for 9 months of 2019 decreased by 6.4 million UAH. In addition, for the 9 months of 2019, due to the economical use of material resources and waste reduction, the consumption rates for raw materials and materials were reduced for 504 stock items, which gave an economic effect of 3.2 million UAH. The manufacturing departments are working on improving the methods and forms of organizing production, and thanks to this, it was possible to reduce the duration of the production cycle in 258 technological processes. Today, JSC “FARMAK” consists of six manufacturing departments,

nineteen production and packaging lines of finished pharmaceutical products that meet the requirements of GMP. These are modern and high-quality capacities that make it possible to produce annually up to 3 billion of tablets, 100 million of ampoules, 160 million packages of sterile and non-sterile pharmaceutical products in bottles, 6 million packages of embrocations, 53 million of soft gelatine capsules, 200 million of tablets (pills), 180 million of hard capsules, 10 million of sachets, 15 million of injectors (medical syringes), 140 tons of active pharmaceutical ingredients. Moreover, this is possible thanks to approximately 800 highly skilled employees motivated for success [3].

In December 2018, a modern FPP-2 was launched, the capacity of which allows producing up to 2 billion tablets (pills) per year. New high-tech equipment allowed to increase the productivity and reduce the complexity of certain technological processes on the production site up to 50 %.

Today, in the measure never given before, the competitiveness of production is determined by the use of key digital management systems and innovative technologies of planning, organization and control. In August 2019, the OR SOFT information system (Germany) was introduced at the production site, which significantly improved the organization of technological processes, analysis and accounting for implementation of the shift-daily tasks, established run times and time rates, reduced the response time to equipment and systems downtime [3].

As the part of efforts related to environmental protection, the company, based on past experience and work in 2018, decreased the gas consumption per UAH of released products by 3.14 % compared to 3 % of the planned; compared with the same period in 2017, by 0.94 % reduced the electricity consumption per UAH of released products. These and other results of the company's efforts in the field of quality management convincingly prove their positive impact on the competitiveness of the company [10].

Discussion. The results of the analysis show export of ukrainian pharmaceutical product is increasing, and the sales geography is expanding. The share of imported pharmaceutical products on the pharmaceutical market of Ukraine is gradually decreasing. Such strengthening of the positions of Ukrainian products on the domestic and foreign markets indicates an increase in the international competitiveness of Ukrainian pharmaceutical companies, and the fact that this occurred after the transition of the pharmaceutical industry of Ukraine to European quality management standards allows us to say the main cause of increasing the international competitiveness of Ukrainian pharmaceutical companies is the efforts that companies are making in the field of quality management.

Thus, the results of the analysis confirmed the conclusion that the main factor of increasing the international competitiveness of Ukrainian pharmaceutical companies is product quality management.

Conclusion. As the performed analysis and the experience of the JSC "FARMAK" shows, a quality management system is the main factor on which the success of the pharmaceutical company is based and as the result, its international competitiveness is strengthened annually. At the same time, the main directions of

the continuous development of the quality management system are integration of quality management with other specialized management systems, automation of information collection processes, implementation of information technologies in staff management processes to increase the employee involvement in the company's affairs and a greater integration of the individual goals of employees with the general goals of the company, equipment modernization and investments in the creation and development of new products. Thanks to a modern approach to quality management, the companies increase efficiency and effectiveness, increase the share of exports and enter new markets.

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