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Analysis of Influence of External and Internal Environment Factors on Pharmacy Production of Infusion Medicinal Drugs

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ABSTRACT

Background. Amid a reduction in the number of pharmacy organizations that have licenses to manufacture medicinal drugs, including in aseptic conditions, there is a need to analyze the reasons that hinder the improvement of the production function of pharmacies, aimed at improving the availability of medical care to patients of multidisciplinary medical organizations.

Objective. The objective of the work was to analyze the influence of external and internal environment factors on the organization of production activity of pharmacies of multidisciplinary medical organizations and to develop proposals to improve the organization of pharmacy manufacturing of medicinal drugs on the example of infusion solutions.

Methods. PEST-analysis method has been used as an instrument of scientific analysis of the influence of external and internal environment factors on the pharmaceutical production of medicinal drugs in a multidisciplinary medical organization.

Findings. On the example of pharmacy manufacturing of infusion medicinal drugs it has been established that the greatest influence on restraining the progressive development of the technological process is exerted by technological factors associated with the lack of modern effective equipment of production processes, in which the main provisions and requirements of good manufacturing practice (GoodManufacturingPractice - GMP) are structurally realized. The second most important place is occupied by a group of economic factors, which increases the economic attractiveness of manufacturing the most demanded range of medicinal drugs for the needs of the medical organization, which allows quite realistically, from the point of view of return on investment, to consider the modernization of the technological process of pharmacy manufacturing of medicinal drugs. The third place is occupied by political factors related to institutional issues of regulating the production activities of pharmacies. Social factors came in fourth place. They reflect the opinion of pharmaceutical workers, as they are responsible for the labor-intensive technological process and the output.

Conclusions. The research made it possible to outline the range of urgent tasks on improving institutional and organizational and technological approaches aimed at improving the efficiency and quality of production activities of pharmacies, as one of the reserves to improve the availability of medical care to patients of multidisciplinary medical organizations.

Keywords: medicinal drugs, infusion solutions, pharmacy manufacturing, expert evaluation, external and internal environmental factors.

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INTRODUCTION

Adoption in 2010 of the Federal Law "On Circulation of Medicinal Drugs" No. 61-FZ, which prohibited pharmacy production of registered medicinal drugs, significantly limited the production activity of pharmacy organizations [1, Art. 56]. This resulted in a sharp decrease in the number of pharmacy organizations with production function in Russia. Thus, according to the data of Roszdravnadzor (Federal Service for Supervision in Healthcare), in our country there are about 74 thousand pharmacy organizations of various types, of which about 2 thousand pharmacies (2.7%) have a license for the right to manufacture medicinal forms, including those in aseptic conditions, which are usually functional subdivisions of multidisciplinary medical organizations.

At the same time, the analysis of medicinal drugs consumption by multidisciplinary medical organizations indicates that its significant share (up to 30% in value terms) is a small nomenclature of infusion medicinal drugs, intended for use both in life-threatening conditions, and the planned treatment of a wide range of diseases. Despite the existing restrictions, pharmacies continue to produce infusion medicinal drugs according to individual prescriptions and requirements that are not produced by the pharmaceutical industry, which allows the use of individual dosage and takes into account the personal characteristics of patients (intolerance of individual ingredients, etc.). In order to regulate the production activities of pharmacy organizations, in 2015 the Ministry of Health of Russia approved the "Rules of Manufacturing and

Dispensing of Medicinal Drugs for Medical Use by Pharmacy Organizations, Individual Entrepreneurs Licensed to Pharmaceutical Activities" [2], which demonstrates the relevance of this type of pharmaceutical practice for the healthcare system.

Experience in providing medical assistance to victims of emergency situations and military conflicts shows that pharmacy production of infusion solutions is of paramount importance, as temporary factors of organization and conduct of procurement, logistics and other objective reasons can significantly reduce the current availability of medical organizations in the necessary infusion medicinal drugs. Thus, preservation and further development of the production function of pharmacies is an important factor in ensuring the availability of medical therapy.

However, at present the pharmacy production of medicinal drugs is not economically profitable for the domestic pharmaceutical business in comparison with the ordinary retail because of low profitability, the need for significant material investments in the technological process and high social responsibility [3, p. 8].

In connection with the aforesaid, the purpose of the present research has been defined as the analysis of influence of factors of external and internal environment on the organization of production activity of pharmacies of the multidisciplinary medical organizations and working out of offers on the refinement of the organization of pharmaceutical manufacturing of medicinal drugs on the example of infusion solutions.

LITERATURE REVIEW

The analysis of scientific literature on the subject of the study did not reveal works devoted to the analysis of the influence of external and internal environment factors on the pharmacy production of infusion medicinal drugs, which confirms the relevance of this study.

METHODS

PEST-analysis method has been used to analyze the economic efficiency of pharmacy production, marketing research of technological and consumer properties of infusion medicinal drugs in a multidisciplinary medical organization [4].

At the first stage, we identified the most significant, in our opinion, political, economic, social and technological factors of the external and internal environment factors that directly affect the technological process of pharmacy production and the final cost of the infusion solution.

To the category of political factors, we have referred the factors of political and legal environment which determine the order of normative legal regulation of production activity of pharmacy organization [5, p. 222].

When determining economic factors, we considered the aspects characterizing the technological process of pharmacy production of infusion solutions and determining their cost.

Considering social factors, first of all, we took into account consumer properties of infusion medicinal drugs from the point of view of their "usefulness" for patients, "convenience" of application for medical workers, "interest" of pharmaceutical workers in restoration of volumes of small-scale pharmacy production of infusion solutions.

The group of technological factors includes the factors of production environment, which allow to trace the necessary and possible changes in the main technological operations, which are used in the production environment of pharmacy organizations [6, p. 44].

In each category 3 factors were selected, which in our opinion, on the one hand, most fully reflect the impact of external and internal factors of the environment on the production activity of pharmacies, and on the other hand, do not burden the study with unnecessary data (Table 1).

Table 1. Factors affecting the technological process of pharmacy production of infusion medicinal drugs

Factors	Factor description
1. Political	
Factor 1.1	Requirements of Article 56 of the Federal Law No. 61-FZ of 12.04.2010 "On Circulation of Medicinal Drugs" which restricted the range of infusion solutions to be manufactured in pharmacies
Factor 1.2	Availability of necessary and sufficient set of general pharmaceutical articles regulating physical, chemical and microbiological parameters of quality and purity of infusion medicinal drugs, requirements to quality of water for injection, sterilization process, registration and storage of infusion solution
Factor 1.3	Availability of a set of regulatory legal documents regulating technological parameters of the entire cycle of pharmacy manufacturing of infusion solutions
2. Economic	
Factor 2.1	Total cost of pharmacy production infusion medicinal drugs compared to the purchase price of similar drugs. Availability of economic benefits of small-scale production of infusion medicinal drugs for own needs of multidisciplinary medical organization
Factor 2.2	Material, utilities and labor costs that form the cost of infusion medicinal drugs of pharmacy production
Factor 2.3	Costs of upgrading the pharmacy manufacturing process of medicinal druds including the Good Manufacturing Practice (GMP) elements. Prospects for a return on investment
3. Social	

Factors	Factor description
Factor 3.1	Improvement of physical accessibility of infusion solution for patients due to proximity of their manufacturing site to the end user
Factor 3.2	Possibility of operative change of assortment and volume of produced infusion solution for the needs of medical and diagnostic process
Factor 3.3	Increasing the work load and professional responsibility of pharmaceutical workers involved in pharmacy production of infusion solution
4. Technological	
Factor 4.1	Not full compliance of pharmacy premises with production area requirements, microbiological purity of air
Factor 4.2	Insufficient technical equipment of the technological process, availability of a significant share of "manual" operations that reduce the productivity of pharmaceutical workers
Factor 4.3	Possibility to introduce separate GMP-compliant production lines into pharmacy operations

Findings

The research was carried out on the basis of 1602 Military Clinical Hospital of the Ministry of Defense of Russia (Rostov-on-Don) - a large multidisciplinary medical organization licensed for pharmaceutical activities, including the right to manufacture medicinal drugs in aseptic conditions.

10 specialists were chosen as experts, 5 of whom were practitioners of the 1602 VKG pharmacy - senior pharmacists with more than 15 years of experience (these experts were assigned numbers from No. 1 to No. 5), and 5 people - from the management of the hospital, namely: Deputy chief medical officer for medical work (Doctor of Medical Sciences, expert No. 6), Medical supply deputy chief medical officer (PhD of Pharmacy, associate professor, expert No. 7), Chief accountant of the hospital (expert No. 8), Head of the center of anesthesiology, resuscitation and intensive care (PhD of Medical Sciences, expert No. 9), Head of the emergency surgery department (PhD of Medical Sciences, expert No. 10).

Further, the significance of each factor was determined by expert evaluation. The experts expressed their opinions on a five-point scale. The higher the score, the higher the influence of the factor on the technological process. Then average values of experts' opinions on each investigated factor and weight share of each factor and each group of factors were determined through the function of bringing their average values to one by formula (1):

$$x_n = \frac{q_n}{\sum_{i=1}^{n} q_n}, \qquad (1)$$

where: x_n – weight share of average expert opinions; in the numerator: q_n – average value of expert opinions for a specific indicator; in denominator - sum of all average values of expert opinions q_n.

As a result of expert evaluation data processing by the calculated method the average values and weight shares of average expert opinions on the factors influencing the process of pharmacy manufacturing of infusion medicinal drugs were obtained (Table 2).

Table 2: Results of expert assessment of factors influencing the technological process of pharmacy production of infusion medication drugs

Factor No.	Expert No.										Average meaning	Weight share
	1	2	3	4	5	6	7	8	9	10		
Group 1 –Political factors												
1.1	2	1	3	3	2	1	3	1	2	2	2,00	0,0858
1.2	1	1	1	1	1	2	1	1	2	2	1,30	0,0558
1.3	1	1	1	1	1	2	1	2	2	2	1,40	0,0601
Total value by group 1											*4,70*	*0,1679*
Group 2 – Economic factors												
2.1	2	3	3	4	4	2	5	5	1	1	3,00	0,1288
2.2	2	2	2	2	2	1	1	1	1	2	1,60	0,0687
2.3	2	1	1	2	2	3	4	5	1	1	2,20	0,0944
Total value by group 2											*6,80*	*0,1954*
Group 3 –Social factors												
3.1	1	1	1	1	1	2	1	1	2	2	1,30	0,0558
3.2	2	2	3	3	2	1	2	1	3	3	2,20	0,0944
3.3	3	3	4	2	2	1	1	2	1	1	2,00	0,0858
Total value by group 3											*5,50*	*0,1365*
Group 4–Technological factors												
4.1	3	3	2	4	2	1	2	4	1	1	2,30	0,0987
4.2	2	2	3	3	3	2	3	3	1	1	2,30	0,0987
4.3	1	1	1	1	1	3	2	5	1	1	1,70	0,0730

Factor No.	Expert No.										Average meaning	Weight share
	1	2	3	4	5	6	7	8	9	10		
Total value by group 4											*6,30*	*0,2704*
Total value for all individual group factors											*23,30*	*1,0000*

As the experts involved not only employees of different specialties (pharmacists and doctors, financial workers), but also different levels of hospital management (pharmacy pharmacists, heads of leading medical departments, deputy hospital chief medical officers, chief accountant), it was initially clear that with a small number of respondents, all the opinions expressed by them will have a low level of consistency. This assumption was confirmed by Kendal concordance coefficient calculated by the formula (2):

$$W = \frac{12S}{m^2(n^3-n)}, \quad (2)$$

where: *W* – Kendal concordance coefficient, which establishes the level of agreement of the experts' opinion; S - sum of squares of differences of ranks (deviations from the average); m - number of experts; *n* - number of factors [7, p. 13].

The value of W = 0.26 obtained in our study, which indicates a low level of consistency of opinions of respondents (from 0.2 to 0.4 - low, over 0.8 - high), but at the same time the fullest possible cut of opinions of specialists was obtained, which allowed to obtain objective data on the impact of the environment on the pharmaceutical production of infusion medicinal drugs.

DISCUSSION

The data presented in Table 2 shows that among political factors experts have given their preferences to the influence of deterrent normative legal regulation for further development of organization of production activity of a pharmacy (factor 1.1 = 0.0858). In the analysis of economic factors priority was given to cost indicator of infusion medicinal drugs of pharmacy production which allows to reduce the burden on the budget of medical organization (factor 2.1 = 0.1288). Among social factors, the first place was given to the possibility of pharmacy production to react flexibly to changes in the assortment and volume of medications produced to meet the needs of medical and diagnostic process (factor 3.2 = 0.0944). Of the technological factors that hinder the development of pharmacy production, equal values were obtained by factors that determine the material and technical condition of pharmacy premises and technological equipment of production processes (factors 4.1 and 4.2 - 0.0987).

We propose a pyramid of significance of influence of internal and external environment factors on technological process of pharmacy manufacturing of infusion medicinal drugs. When building the pyramid, we used the final values of groups of political, economic, social and technological factors placed on the increase of influence (numerical value) from the base to the top (Figure 1).

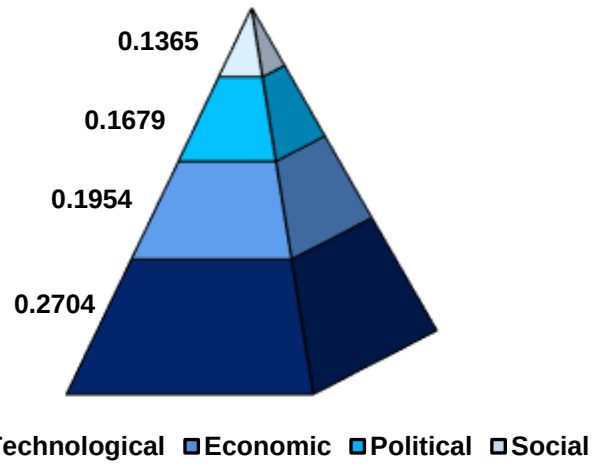

Figure 1. Pyramid of significance of factors influencing the technological process of pharmacy production of infusion solution, pieces

The analysis of the data presented in Figure 1 shows the prevailing influence of technological factors. According to pharmaceutical workers' opinion, arrangement of pharmacy production premises in accordance with modern requirements and technical re-equipment of medicinal drugs production activities directly affect personnel productivity and quality of the final product. The necessity of large financial investments into pharmacy modernization is confirmed by the opinion of the financial officer - chief accountant of the hospital.

The second most important is the group of economic factors. Reduction of production process costs, and, as a consequence, increase of economic attractiveness of small-scale production of the most demanded assortment of medicinal drugs, including infusion solutions, allows quite realistically, from the point of view of return on investment, to consider questions of re-equipment of a production site and modernization of technological process of small-scale pharmacy production of infusion medicinal drugs, with inclusion of GMP elements.

Out of the group of political factors which took the third place in the pyramid of significance, the greatest attention of experts was focused on compliance of organization of pharmacy manufacturing of infusion solutions with the legislative requirements, namely, Article 56 of the Federal Law No. 61-FZ dated 12.04.2010 "On Circulation of Medicinal Drugs". It should be noted that our research did not set tasks to substantiate organizational, economic, marketing and other factors that could serve as a basis for launching the procedure of amending Article 56. This paper tested the hypothesis that from an economic point of view, small-scale pharmacy production of medicinal drugs for their own needs of medical organizations is entitled to a full existence. Legislation that restricted the right to pharmacy production of medicinal drugs, registered in our country, was adopted almost 10 years ago, and it is likely that in these socio-economic and technical and technological conditions, it can be adjusted towards the development of production function of pharmacies of large multidisciplinary medical organizations.

The group of social factors occupies the last place among all analyzed groups. Among the experts on this group of factors, the opinion of practitioners of a pharmacy organization is singled out, as they are responsible for the labor-intensive process and the results.

Considering social factors and discussing them with pharmaceutical workers, we concluded that re-equipping a pharmacy with modern technological equipment will make the work of pharmacists and senior pharmacists more efficient and attractive. According to pharmaceutical workers, the modernization of small-scale production of infusion medicinal drugs for own needs of the medical organization will significantly reduce the amount of hard physical labor associated with the reception of infusion medicinal drugs that are admitted to the hospital in a centralized manner or purchased locally, their unloading, storage, safety and quality control during storage, leave to medical units. Thus, according to accounting data, in 2017, 1602 Military Clinical Hospital received 255.58 thousand bottles of infusion medicinal drugs Their total weight, including transport packaging, was about 196.79 tons and the volume was 383.37 $м^3$.

In addition, the availability of small-scale production of medicinal drugs in the multidisciplinary medical organization will significantly reduce logistics costs, mainly to pay for transportation costs, and in case of emergency situations accompanied by a violation of medicinal drugs supplies, will ensure reliable physical accessibility of patients on the nomenclature of infusion pharmacy production of medicinal drugs.

CONCLUSION

On the basis of the analysis of external and internal environment factors influencing institutional, organizational and technological conditions of pharmacy production of medicinal drugs, the directions of its economic efficiency increase due to increase of pharmaceutical workers' labor productivity and infusion medicinal drugs quality by means of modernization of pharmacy organizations' technological equipment and their equipping with modern technological complexes, in which the main provisions and GMP requirements are structurally realized, are justified.

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