

Research of the Main Components of Risk Management in Pharmacy

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Abstract—A market economy characterized by existing of uncertainty and the possibility of choosing one or more development directions for the pharmaceutical market subjects causes risk situations. The reasons for their occurrence are usually the company affiliation, its size, form of ownership, legal status, technological integrity and degree of subordination, strategy, principles of the company, capital structure, resources and their use, quality and level of marketing, etc. Thus, the creation of an effective health care management system, and in particular of pharmacy, is impossible without the monitoring, accounting, assessment and management of risk situations arising from the practice. In connection with the above mentioned, the purpose of our study was to study the features of risk management in pharmacy.

The structure of risk factors in the activity of the pharmaceutical organization with its division into internal and external ones has been developed, which will allow timely determinate the possibility of occurrence of adverse situations and introduce measures for their prevention or minimization. The list of these entities is the basis for developing risk management standards in a pharmaceutical company.

Keywords—*pharmacy, risk management, risk sources, risk exposure entities, pharmaceutical organizations, medicines*

I. INTRODUCTION

Risk management aims to reduce the level of losses associated with economic risks. It is based on the results of planning and economic activity of the organization, identification and assessment of risk, economic analysis of the potential, internal and external environment of the company, current legislation. Therefore, the risks, which are an integral part of the strategic activity of the enterprise, deserve special attention for study.

II. PROBLEM STATEMENT

A review of periodicals has shown that sufficient attention is paid to risk issues, but so far there is a lack of information related to risk management in the pharmaceutical industry [1-5].

III. RESEARCH QUESTIONS

The generalization and classification of risk factors for the pharmaceutical sector were conducted, and the relationship between the risk factors and the constituents (indicators) of the organization's activity that were affected by them were established. The basic methods proposed for the risk management system of a pharmaceutical enterprise

are identified. The general risks inherent in pharmacy and those related solely to the particularities of professional activity are separated.

IV. PURPOSE OF THE STUDY

In connection with the aforementioned, the purpose of our study was to study the features of risk management in pharmacy.

V. EXPERIMENTAL

Methods of system analysis, historical, analytical, content analysis, marketing researches have been used in the work.

The systematic analysis method was used to investigate the role of risk management in ensuring the effective functioning of pharmaceutical institutions, their importance in health care and the well-being of society as a whole. The historical method has been used to track the development of risk management and risk issues. Surveys of experts (22 pharmaceutical industries in CIS countries, 267 retail pharmaceutical companies and 76 wholesale organizations) identified the main risks specific to the pharmaceutical sector. The questionnaire involved leading industry experts who are competent in these matters. The required sample size was calculated by the formula (1), modified to calculate a non-repeated sample:

$$n = \frac{1}{\frac{\Delta^2}{p(1-p)t^2} + \frac{1}{N}}, \quad (1)$$

where n — sample volume;

Δ — calculation error;

p — the fraction of the sign ($p=0,2$);

t^2 — the coefficient of confidence that corresponds to the likelihood of a feature appearing in the sample;

N — the general population.

The resulting form used t Student's statistics. The confidence level is 95%.

To determine the consistency of opinion, the Expert Group used the Kendall coefficient of concordance (2) (W):

$$W = \frac{12}{m^2(n^3 - n)} \sum_{j=1}^n (R_j - \bar{R})^2, \quad (2)$$

To assess the consistency of all experts' responses to all risks, the coefficients of concordance for each risk group have been calculated. The calculated values of the concordance coefficients for all groups are significant because they are greater than the corresponding critical values. The results obtained are in the range $W = 0.753086 \div 0.868313$, which confirms the consistency of the experts' answers. The information base of the researches consisted of normative legal and legislative international documents, directives, recommendations, rules, publications of domestic and foreign authors, data of the Internet.

VI. RESULTS AND DISCUSSION

The development of a market economy, entrepreneurship in general, and the pharmaceutical industry in particular, necessitate the use of ground approaches to elaborate and reduce risks. Existing types of risks depend on the specialization of the enterprise, on the state of the markets, consumer segments, selected methods of promotion of the goods, etc. The pharmaceutical sector is characterized by all types of risks inherent in any other commercial activity, as well as those risks that are caused by the peculiarities of the industry itself and the product.

All the factors that determine the degree of risk are usually divided into two groups - objective (external) and subjective (internal). Recently, background factors (global) have been separated in the economic literature, which reflect the general situation in the economy, social sphere, etc. [6-8]. The selected groups of factors are closely related and interact with each other. For risk assessment and decision making, it is necessary to have complete information on the internal and external environment and risk carriers [9]. In accordance with this, we conducted a content analysis [6,8,10-14], which allowed us to identify the main sources of risk, to identify them, and to classify them by the degree of consequences (Fig. 1).

Each of these factors has a specific impact on the activities of the organization, touches different areas and has a different frequency of manifestation, and most importantly – a different degree of consequences. The following table summarizes the results of the content analysis and our own research, which reveals the link between the sources of risk and the objects most commonly affected (Table I).

In real economic situations, various methods of risk management that affect certain areas of activity of the enterprise can be used. Despite the large number of publications on the subject, there is no single approach among experts according to the classification of risk management methods [3,9,10,13,14]. One of the options used in business practice is to divide risk management methods into four types: avoidance, minimization, diversification, limitation. Another classification option includes the following options: evasion, dissipation, compensation, and localization. In our opinion, it is advisable to focus on the second option and include in the latter a method of limitation, which includes: setting the maximum volume of a commercial transaction per counterparty, setting the maximum amount of stocks, setting the maximum term or the amount of credit provided to the counterparty, setting a limit on borrowed funds. This addition is due to the fact that the above method is widely used by pharmaceutical companies as a crisis response. The

methods most commonly used by pharmaceutical organizations are presented in Fig. 2.

Risk management can be carried out on the basis of specially designed programs. After identifying the negative trends and factors, a set of measures has to be developed, which are applied to correct the condition of the business unit. The above methods of risk management are the basis for the formation of this complex. The final step is to compare the results of risk management with the projected indicators, ie controlling risk management.

We conducted a survey on the classification of risks in pharmacy and the separation of risks related especially to the professional field. Thus, the results of the studies provide the following insight into the risks inherent in the pharmaceutical industry as a whole (Fig. 3).

Some types of risks require special analysis because they have specific features caused by the particularities of pharmaceutical production and sales of medicines. Thus, the risks of research and development work include: interruption of research funding; excess cost estimates; lowering the investment value of the project; obtaining negative research results; failure to reach the planned parameters (efficacy, safety, properties, etc.) of the medicinal product; all kinds of problems when using new technologies; identification of adverse effects of the use of medicines. Examples of such risks may be those of pharmaceutical companies, such as stock market crashes, for example, due to problems in testing new drugs or problems with existing ones (identifying life-threatening side effects or interactions with other drugs after registration and release of a medicinal product, drug).

The largest group of risks are risks in the commodity circulation system, which include: the risk of wrong choice of the target segment of the consumer market; risk of insufficient segmentation of markets; risk of wrong choice of sales strategy; change in the prognosis level of population morbidity; risk of unsuccessful organization of sales network and system of promotion of goods to the consumer transport risks; the risk of improper organization and inappropriate marketing research results; the risk of inefficient advertising; the risk of entering into contracts with incapacitated partners; risk of delay by partners of current contractual obligations; the risk of mispricing; the risk of unforeseen or unfair competition; lack of necessary information from doctors and the population about medicines and their use; the risk associated with a lack of quality of medicines to certain standards. These are also storage risks: (a) damage or alteration of the properties of the medicinal product due to non-compliance with the conditions of storage; b) inefficient management of warehouse processes; c) expiry of the medicinal product.

Sales risks are a big part of all kinds of risks, the greatest of them and the losses from them can be very significant for the company.

A social group also poses a social risk. Typically, this type of risk includes: risk due to lack of staff qualifications; the risk of unfair treatment of staff; conflicts; the death or illness of any of the firm's staff.

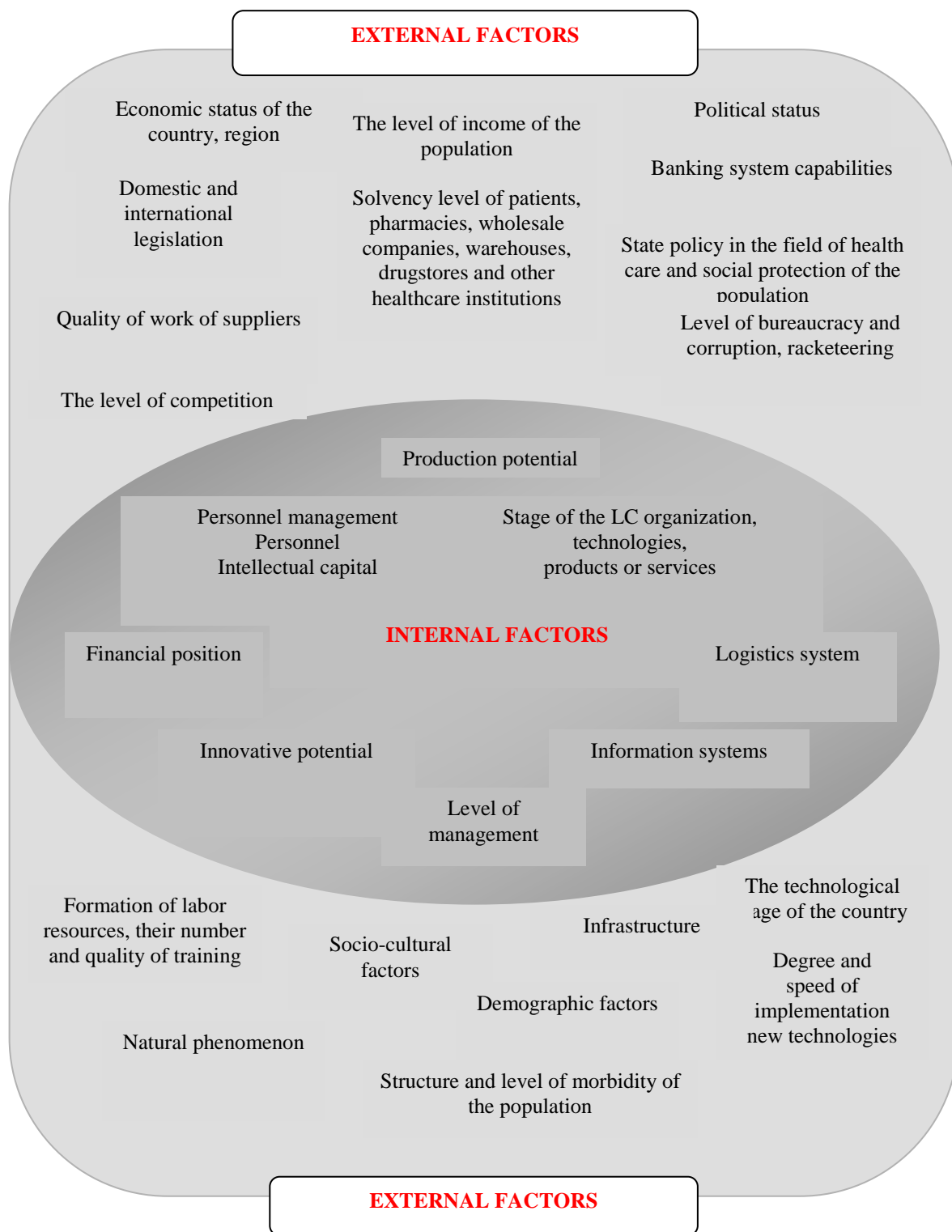


Fig. 1. Sources of key risks for the pharmaceutical organization.

TABLE I. TYPICAL SOURCES AND RISK EXPOSURE OBJECTS FOR A PHARMACEUTICAL ORGANIZATION

Typical sources of risk	The subject of risk exposure
INTERNAL FACTORS	
Production potential	Performance indicators; assets; resource; terms and schedule; ecology.
Personnel	Organization resources; product quality indicators; customer service standards; terms and schedule of work; intangible assets
Intellectual capital	Revenues, performance metrics; the level of implementation of new technologies; commodity policy; intangible assets (reputation).
Financial position	Income; profit; property status; costs; personnel; terms and schedule of work; indicators of successful management (survival, effectiveness); solvency; resource.
A stage of the LC organization, technology, product or service	Financial and economic indicators; income; costs.
Logistics system	Costs; customer service standards, intangibles (reputation, trade secret)
Information systems	Stability and efficiency of organization subsystems; intangible assets (reputation)
Level of management	Indicators of quality of products and services; indicators of efficiency of personnel management; professional responsibility
Innovative potential	Profit, performance; commodity policy; intangible values (reputation); ecology
EXTERNAL FACTORS	
Political status of the country	Income; costs (for the implementation of the activity); indicators of successful management (survival).
Level of bureaucracy and corruption	Income; indicators of successful management (existence and survival)
Banking system capabilities	Innovative potential; solvency of the organization; costs; cost-effectiveness indicators; indicators of successful management.
Economic status of the country, region	Income; profit; costs (for the implementation of the activity); personnel; performance metrics solvency of the organization; resource.
The technological stage of the country	Innovative potential; cost-effectiveness indicators.
Legislation in force	Profit; costs; personnel; resource; cost-effectiveness indicators; indicators of successful management (existence and survival).
International legislation	Income; costs (for the implementation of the activity); personnel; commodity policy; pricing policy; production and innovation potential of the organization.
State policy in the field of health care and social protection of the population	Income; indicators of successful management (performance).
Formation of labor resources, their number and quality of training	Income; innovative potential; intellectual capital; cost-effectiveness indicators; indicators of successful management (performance); intangible assets (reputation).
Infrastructure of the market	Income; personnel; cost-effectiveness indicators; indicators of successful management (performance)
The level of competition	Income; market share; cost-effectiveness indicators; indicators of successful management (performance).
The level of income of the population	Income; assortment and commodity policies; pricing policy.
Solvency level of patients, pharma-cies, wholesale companies, ware-houses, drugstores and other health-care institutions	Income; assortment and commodity policy; pricing policy.
Quality of work of suppliers	Production subsystem of the organization; logistics subsystem of the organization; intangible assets (reputation)
Socio-cultural factors	Income; commodity and assortment policies.
Structure and level of morbidity of the population	Income; commodity and assortment policies
Demographic factors	Income; commodity and assortment policies.
Natural phenomenon	Assets; resource; performance metrics ecology.

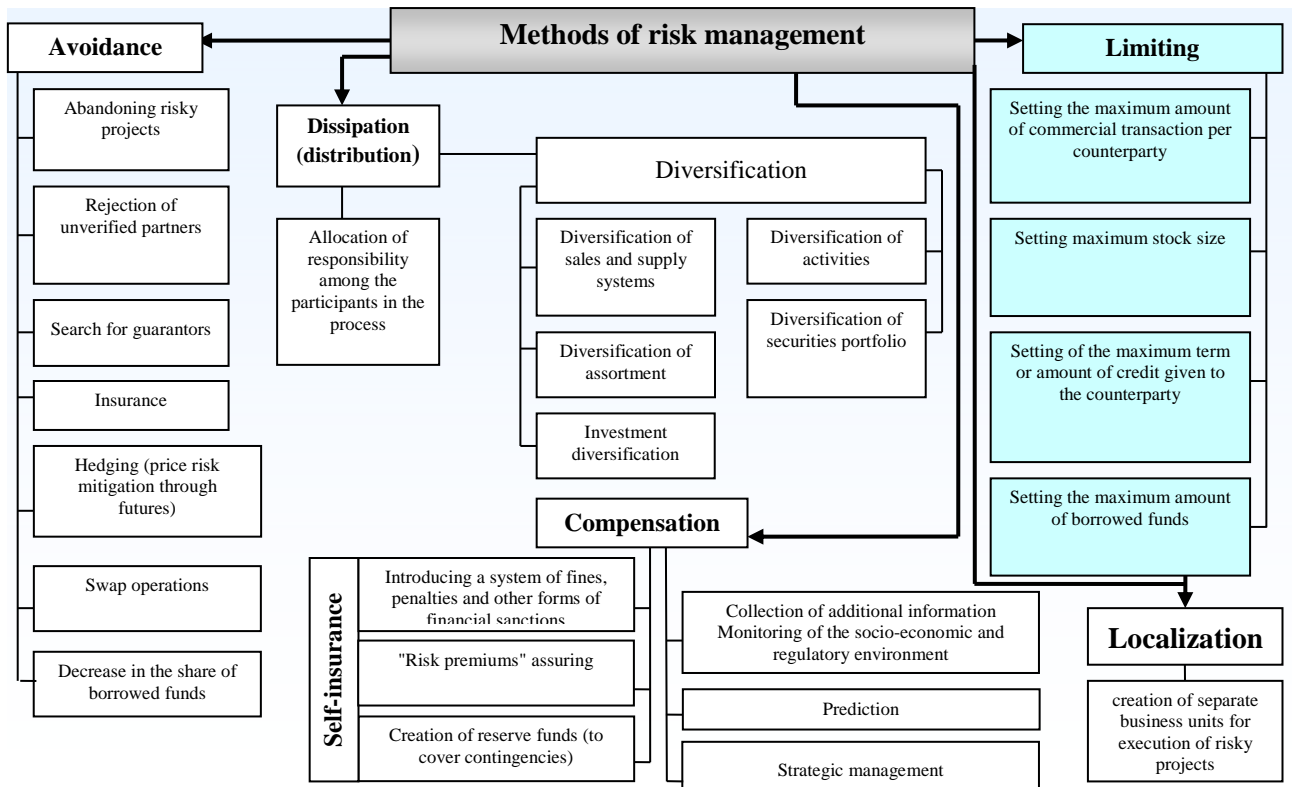


Fig. 2. Methods of risks management.

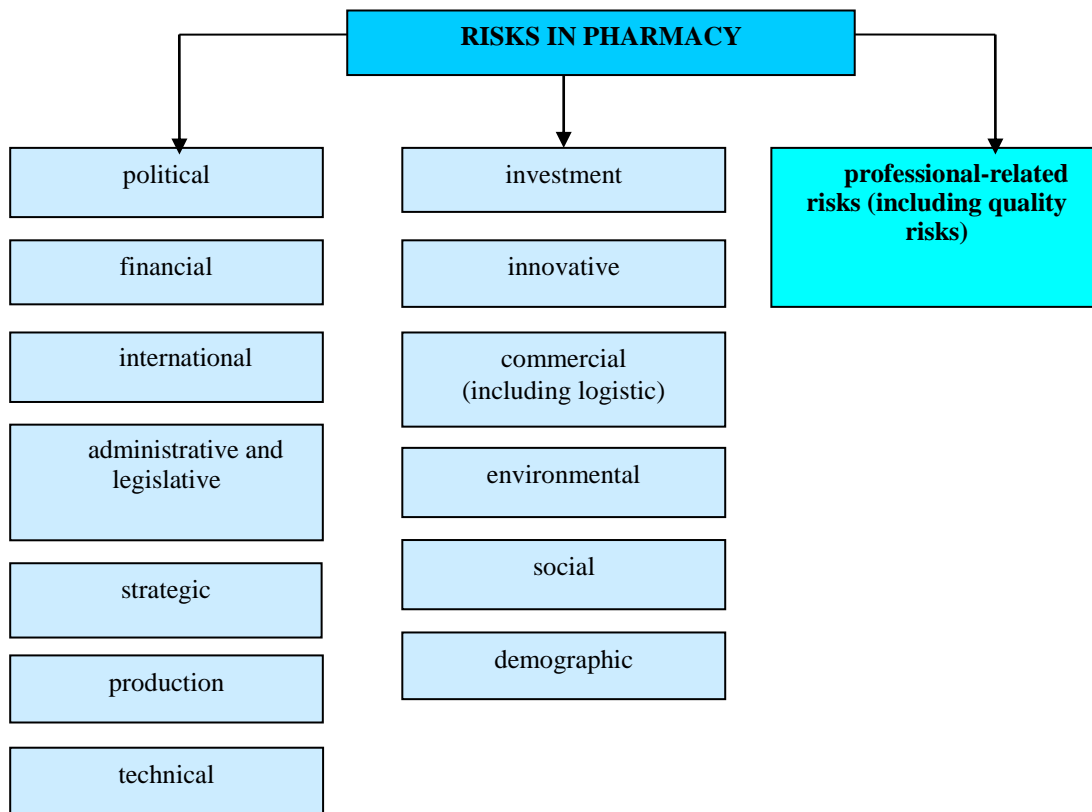


Fig. 3. Pharmaceutical risk profile.

Administrative and legislative risks include: imperfection and instability of the legislative framework of the country governing pharmaceutical and business activities; the introduction of a deferral or moratorium on different types of payments; unfavorable changes in the tax legislation; restrictions on currency conversion; problems related to property rights issues; enterprise conflicts with legislation, administrative bodies; risks of insufficient patenting of all types of solutions used in the creation of new medicines; risks of patent infringement obtained by the firm; risks of not ensuring patent purity; risks associated with parallel patenting and illegal imitation; the risk of espionage; risk of transfer to competitors of leading specialists, carriers of know-how, etc. The instability of the legislation regarding the pharmaceutical industry, medical care, insurance medicine is obvious. It is in a mobile state, and until these areas of our lives have acquired their final shape, they will be a constant source of risk for business entities.

Much attention has recently been paid to the quality of medicines, problems of counterfeiting and espionage. Demographic risks, such as changes in birth rates and death rates, and changes in household incomes, can also have some impact on an organization's activities.

There is also a group of risks that arise in the process of developing an enterprise strategy. These are: risks of unjustified prioritization of the strategy; risks of incorrect forecasting of the situation on the capital procurement and supply markets; risks of inadequate assessment of consumer needs and production capabilities.

A large and influential risk group is created by supply risks, which may be caused by the absence of suppliers of rare or unique resources; lack of suppliers in terms of projected purchase prices; absence of suppliers of planned quality of raw materials; refusal of suppliers from the supply contract; the need to conclude a supply contract on unfavorable terms; delaying the procurement campaign; miscalculations in terms and methods of delivery; supply of raw materials in quantities that are not secured by appropriate sales of finished products.

Risks of breach of schedule are associated with breaches of revenue schedule - cost schedule and production schedules.

International risks that are particularly threatening for enterprises engaged in significant foreign economic activities include: design risks in the import and export of medicines; leasing risks; discrepancy between international and domestic market requirements for the production and quality of medicines.

Practically, each of the subjects of the pharmaceutical market faces financial risks - currency, credit and investment.

The list of production risks is widespread: changes in the physicochemical parameters of a medicinal product due to technological process disturbance; change of physicochemical parameters of medicinal product due to imperfection of technological process; deterioration or alteration of the properties of raw materials due to storage conditions; decrease in production volumes due to decrease in labor productivity, equipment breakdown, lack of

required quantity of raw materials of certain quality, etc.; waste of materials, raw materials, fuel, water, energy; increase in transport and other types of costs; mismatch between production efficiency and wages; interruptions with fuel, energy, water; physical and moral deterioration of equipment; the risk of an accident due to non-compliance with safety rules.

The most specific group of risks in the pharmaceutical industry are those related to the professional field. They may include:

- deviation from the predicted incidence rate;
- irrational prescribing of medicines by doctors;
- lack of necessary information about medicines and their use by doctors and the population;
- identifying the negative effects of the use of medicines;
- risks associated with parallel patenting and illegal imitation;
- the risk of insufficient patenting of all types of solutions used in the creation of medicines;
- failure to reach the planned parameters (efficacy, safety, properties, etc.) in drug development;
- obtaining negative research results;
- the risks to people involved in clinical trials;
- the risk associated with the non-compliance of the quality of medicines received in the retail network with certain standards;
- environmental risks;
- change of physicochemical parameters of the medicinal product due to impaired or imperfect technological process;
- deterioration or alteration of the raw material properties due to storage conditions;
- waste of raw materials due to its poor quality;
- the risk of an accident or occupational disease due to non-compliance with safety rules;
- lack of suppliers of raw materials of the required quality;
- discrepancy between international and domestic market requirements for the production and quality of medicines;
- the emergence of all kinds of problems when using new technologies.

Thus, the number and nature of the risks identified indicate that it is not possible to establish an effective health care management system, and in particular pharmacy, without risk monitoring, accounting, assessment and management.

VII. CONCLUSION

1. The structure of risk factors in the activity of the pharmaceutical organization with their division into internal and external ones has been developed, which will allow timely to identify the possibility of occurrence of adverse situations and introduce measures for their prevention or minimization.

2. The relationship between risk factors and the objects (constituents and performance indicators of the

organization) that fall under their influence has been established.

3. The methods proposed for the risk management system of a pharmaceutical enterprise have been identified on the base of generalized literature data on risk management techniques.

4. It has been highlighted and illustrated the examples of risks associated with the professional pharmaceutical field. These include: non-rational use of drugs by physicians, identification of negative consequences of the use of drugs, failure to achieve the planned parameters (efficacy, safety, etc.) in the development of drugs, risks associated with the inappropriate bioequivalence of generic drugs, and others.

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