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THEORETICAL FOUNDATION OF EVALUATION OF LOGISTICS RISK IN PHARMACY

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Key words: logistic risk; logistics; subjects of the pharmaceutical industry; logistic risks management; minimization of logistic risks

Subjects of the pharmaceutical industry (SPI) usually function in the conditions of uncertainty and dynamic environment. Pharmacy is characterized by logistic risks due to specific properties of drugs, active pharmaceutical ingredients and active substances. The aim of the research is substantiation of logistic risk significance affecting the quality of drugs, and development of the mechanism for their minimization. The research results were based on the use of methods of expert assessment, ascent from the general to the special, the relationship of qualitative and quantitative characteristics. The logistic risk in the pharmaceutical industry is an event that results in losses of SPI or makes the possibility of an adverse situation or irrelevant results related to flows within the pharmaceutical logistic chain when changing external and internal factors. Availability of a great number of logistic risks makes it necessary to reduce risk of the SPI logistic activity, and, consequently, to develop the risk management mechanism. The algorithm of the logistic risk management of SPI includes seven steps. At the first stage the analysis of SPI logistic operations is conducted, at the second stage their logistic risks and causes are analyzed. Based on this analysis the data sampling that characterize the logistic activity results of SPI is formed. At the third stage, there is quantitative and qualitative assessment of the logistic risks identified in the previous step. At the fourth stage the effect of the internal and external factors on the logistic risk is analyzed. Based on the previous analysis during the fifth stage the scenarios of development of the situation are developed in relation to the threat of the origin of certain logistic risk and the methods of estimation of logistic risks are selected. At the sixth stage logistic risk is estimated. Based on the previous analysis the necessity of calculation of the integral logistic risk is reasonable.

Subjects of the pharmaceutical industry (SPI) usually function in the conditions of uncertainty and dynamic environment. The important principle of their activity is high reliability, providing stability, flexibility and adaptation to changing operating conditions. Unlike other economic sectors the pharmaceutical industry is characterized by logistic risks with specific properties of drugs, active pharmaceutical ingredients (APIs) and active substances (for example, terms and conditions of storage and transportation, high probability of deterioration and damage during delivery, processing and storage of goods, etc.). Thus, according to the WHO about 25% of medical immunobiological preparations (MIP) are delivered spoiled to the consumer as a result of failure to observe the temperature condition in the process of their storage and transporting [2].

The aim of the research is substantiation of the logistic risk significance affecting the quality of drugs, and development of the mechanism for their minimization.

Materials and Methods

The research results were based on the use of methods of expert assessment, ascent from the general to the special, the relationship of qualitative and quantitative characteristics. Experts were various specialists of different profiles and enterprises of the pharmaceutical industry.

Results and Discussion

The results of the questionnaire have identified that the share of logistic risks includes a significant percent of the total value risk of SPI (15%) (Fig. 1).

Research of different scientific views has allowed to determine that the logistical risk in the pharmaceutical industry is an event that results in losses of SPI or makes the possibility of an adverse situation or irrelevant results related to flows within the pharmaceutical logistic chain when changing external and internal factors [1, 3-7]. Sources of logistics risks in the pharmaceutical industry are carriers, suppliers of substances, storage of drugs, intermediaries and pharmaceutical manufacturers (Fig. 2).

According to the results of the expert assessment of the significance of the logistic risk in management of flow processes at pharmaceutical enterprises, the most significant risks are risks arising at the stage of transportation and warehousing (Fig. 3). It is related to probability of spoilage of material resources and their loss of qualitative characteristics and, consequently, of profit of SPI.

A considerable part of the logistic risk determines that 91.5% of the respondents consider logistic risks to be important issues for the pharmaceutical industry.

89% of the respondents identify a significant influence of the logistic risks on the performance efficiency

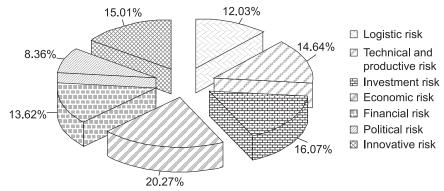


Fig. 1. The assessment of SPI risk significance.



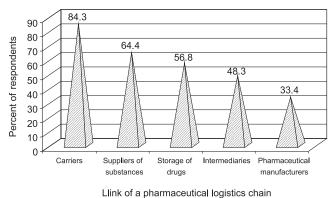


Fig. 2. The main sources of risk in the pharmaceutical

Fig. 2. The main sources of risk in the pharmaceutical logistics chain.

of SPI and approximately 85% of the respondents tell about the need for implementation of the logistic risk system for the SPI activity.

Availability of a great number of logistic risks makes it necessary to reduce risk of the SPI logistic activity, and, consequently, to develop the risk management mechanism [7-13]. The algorithm of logistic risk management of SPI is shown in Fig. 4.

At the first stage the analysis of SPI logistic operations is conducted, at the second stage their logistic risks and causes are analyzed. Based on this analysis the data sampling that characterize the logistic activity results of SPI is formed. At the third stage, there is the quantitative and qualitative assessment of the logistic risks identified in the previous step.

At the fourth stage the effect of the internal and external factors on the logistic risk is analyzed. Then during the fifth stage the scenarios of development of the situation are developed in relation to the threat of the origin

Logistic risk	Value		
	2011	2012	2013
Risk management of material flows	0.69619	0.71390	0.75009
Risk of logistic administration	0.45096	0.49618	0.53469
Risk management of financial flows	0.25167	0.29571	0.60383
Risk management of information flows	0.44300	0.75200	0.80700
Complex logistic risk	0.46045	0.56445	0.6739

The calculation results of the complex logistic risk

of certain logistic risk and the methods of estimation of logistic risks are selected. At the sixth stage logistic risk is estimated. Based on the previous analysis the necessity of calculation of integral logistic risk is reasonable. The structure of the integrated logistic risk index includes the risk management of material flows; the risk management of information flows; transportation risks; environmental risks. Complex indices for each type of risk should be calculated using taxonomic analysis. The results of the logistic risk components calculation for the pharmaceutical company A (for confidentiality) are given in Table 1.

At the seventh stage measures on minimization or prevention of the logistic risk are developed, and then the economic effect of the introduction of the drug management system and SPI logistic costs with implementation of this system is estimated. The complex of safety measures taking into account the specificity of the pharmaceutical industry are given in Table 2.

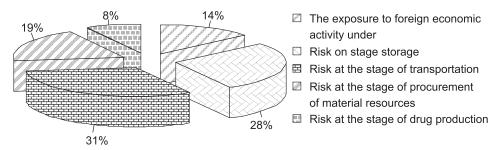


Fig. 3. The assessment of significance in the risk management of material flows in pharmacy.

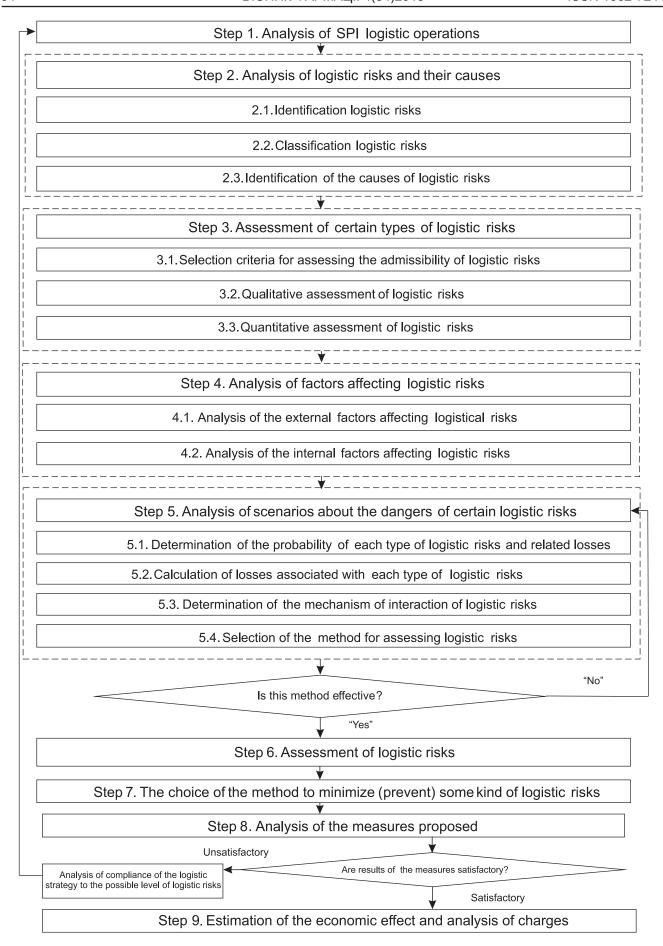


Fig. 4. The algorithm of SPI logistic risks.

Table 2 The ways of minimization of logistic risks in the pharmaceutical industry

Type of logistic risks	Prevention measures	
Risk of the incorrectly selected logistic strategy of SPI	Revision of the logistic strategy, a detailed market analysis	
Risk of the unbalanced allocation of the SPI resources	Verification of optimality of the flow process management, identification and analysis of its defects; purchase of material resources for the future use; control over resource flows and observance of norms of their charges; analysis of accounting, correlation with the planned and basic levels	
Risk of inconsistency of co-operation between SPI subdivisions in relation to resources handling	Analysis of causes of the problems of co-operation, control of the work of subdivisions by managers at all levels; identification and elimination of causes of conflict situations and creation of a favourable climate in the team; the use of motivation in the process of management; effective co-operation of the SPI subdivisions in the process of the logistic risk management	
Risk of the material resource management	Limitation Reservations Preventive control of resources Insurance of logistic risks	
Risk of insufficient control at all stages of the flow process management	Supervision of the SPI work from the purchase of the raw material and materials for dispensing drugs; qualitative analysis of normative documents, statistical and book-keeping accounting	
Risk of an accident	Insurance of the SPI property in an insurance company	
Risk management of information flows	Collection and analysis of information; creation of the management information system; the study of normative documents and laws Protection of commercial secret	
Risk of unsatisfactory implementation of the contract terms	Careful selection of the logistic partner; collection of the necessary information about a firm-competitor; introduction of the system of penalties for each commitment in the agreement; indication of terms for consideration of controversial issues, terms of payment of penalties and mortgage payments in the agreement	
Risk of procurement and distribution of drugs	Drawing up the protocol that includes terms of changes in the agreement, the size of compensation in case of failure from signing of the contract	
Risk of breaking relations with logistic partners	Analysis of breaking relations; a careful choice of the logistic partner; integration of participants of the logistic pharmaceutical chain	
Risk of logistic administration	Logistic personnel training Selection of the professional staff of the logistic personnel Creation of the pharmaceutical logistic information system Creation of the optimal organizational structure of SPI	

CONCLUSIONS

- 1. The relevance of the SPI logistic risk management has been investigated.
- 2. The definition of the SPI logistic risk has been suggested.
- 3. The sources of risk in the pharmaceutical logistic chain have been investigated; the SPI risk and the significance of the risk management of material flows in pharmacy have been estimated.
 - 4. The algorithm of SPI logistic risks has been offered.

REFERENCES

- 1. Снченко С.В. // Моделювання та інформаційні системи в економіці. 2006. Вип. 74. С. 280-292.
- 2. Офіційний сайт Міністерства охорони здоров'я України [Електронний ресурс] Режим доступу: http://www.moz.gov.ua.
- 3. Посилкіна О.В., Сагайдак-Нікітюк Р.В. Логістичний менеджмент фармацевтичного підприємства. X.: НФаУ, 2011. — 748 с.
- 4. Сагайдак-Нікітюк Р.В., Посилкіна О.В. // Укр. журн. клін. та лабораторної медицини. 2010. Т. 5, №1. С. 8-12.
- 5. Христофоров А.В. // Управление развитием. 2005. Спецвипуск №3. С. 171-172.
- 6. APICS Dictionary. 8 ed. Chicago: American Production and Inventory Control Society, 2008. 84 p.
- 7. Arvis J.-F., Mustra M.A., Ojala L. et al. Connecting to Compete 2012 Trade Logistics in the Global Economy. Washington: The World Bank, 2013. P. 15-21.
- 8. Kajuter P. // Ekonomische, regulatorische und konzeptionelle Grundlagen. 2007. P. 13-17.

- 9. Kersten W., Schroeder M., Singer C. et al. // Proceedings of the 24th Annual Conf. "Nordics Logistics Research Network". Finland, 2012. 443-457.
- 10. Kersten W., Schröder M., Singer C. et al. Risk management in logistics. Empirical Results from the Baltic Sea Region from 2010 until 2012. Hamburg: Hamburg University of Technology, Institute of Business Logistics and General Management, 2012. 116 p.
- 11. Manuj I., Mentzer J.T. // Intern. J. of Physical Distribution & Logistics Management. 2008. –№38 (3). –P. 192-223.
- 12. Tuzkaya U.R. // Intern. J. of Environmental Sci. and Technol. 2009. №6 (2). P. 277-290.
- 13. Wyman O. All rights reserved Factoring «Risk» into Transportation and Logistics Sourcing [Електронний ресурс]. Режим доступу: http://www.oliverwyman.com/content/dam/oliver-wyman/global/en/files/archive/2011/OW MTE 2009 ShipperSourcing.pdf

ТЕОРЕТИЧНІ ЗАСАДИ ОЦІНЮВАННЯ ЛОГІСТИЧНИХ РИЗИКІВ У ФАРМАЦІЇ Р.В.Сагайдак-Нікітюк, О.В.Доровський

Ключові слова: логістичний ризик; логістика; суб'єкти фармацевтичної галузі; управління логістичними ризиками; мінімізація логістичних ризиків

Суб'єкти фармацевтичної галузі (СФГ) звичайно функціонують в умовах невизначеності і динамічності зовнішнього середовища. Для фармації характерна наявність логістичних ризиків, пов'язаних зі специфічними властивостями лікарських засобів, активних фармацевтичних інгредієнтів та діючих речовин. Метою дослідження є обґрунтування значущості логістичних ризиків, що впливають на якість лікарських засобів, і розробка механізму їх мінімізації. Результати дослідження ґрунтувалися на використанні методів експертної оцінки, прийомів сходження від загального до конкретного, взаємозв'язку якісних і кількісних характеристик. Логістичні ризики у фармацевтичній галузі – це подія, яка призводить до збитків СФГ або зумовлює можливість виникнення несприятливої ситуації чи невідповідного результату, пов'язаних з рухом потоків упродовж логістичного фармацевтичного ланцюга при зміні зовнішніх і внутрішніх факторів. Наявність значної кількості логістичних ризиків викликає необхідність розробки механізму управління ризиками. Алгоритм управління логістичними ризиками СФГ містить сім етапів. На першому етапі проводиться аналіз логістичних операцій СФГ, на другому етапі аналізуються логістичні ризики та причини їх виникнення. На третьому етапі здійснюється кількісна та якісна оцінка логістичних ризиків. На четвертому етапі аналізуються зовнішні та внутрішні фактори впливу на логістичний ризик. На п'ятому етапі розробляються сценарії розвитку ситуації щодо загрози виникнення певних логістичних ризиків і обираються методи їх оцінки. На шостому етапі оцінюється логістичний ризик, на сьомому – розробляються заходи з мінімізації або запобігання логістичному ризику.

ТЕОРЕТИЧЕСКИЕ ОСНОВЫ ОЦЕНИВАНИЯ ЛОГИСТИЧЕСКИХ РИСКОВ В ФАРМАЦИИ Р.В.Сагайдак-Никитюк, А.В.Доровской

Ключевые слова: риск; логистика; субъекты фармацевтической отрасли; управление логистическими рисками; минимизация логистических рисков

Субъекты фармацевтической отрасли (СФО) обычно функционируют в условиях неопределенности и динамичности внешней среды. Для фармации характерно наличие логистических рисков, обусловленных специфическими свойствами лекарственных средств, активных фармацевтических ингредиентов и действующих веществ. Целью исследования является обоснование значимости логистических рисков, влияющих на качество лекарственных средств, и разработка механизма их минимизации. Результаты исследования основывались на использовании методов экспертной оценки, приемов восхождения от общего к частному, взаимосвязи качественных и количественных характеристик. Логистические риски в фармацевтической отрасли – это событие, приводящее к убыткам СФО или предопределяющее возможность возникновения неблагоприятной ситуации или несоответствующего результата, связанных с движением потоков на протяжении всей логистической фармацевтической цепи при изменении внешних и внутренних факторов. Наличие значительного количества логистических рисков обусловливает необходимость разработки механизма управления рисками. Алгоритм управления логистическими рисками СФО содержит семь этапов. На первом этапе проводится анализ логистических операций СФО, на втором этапе анализируются логистические риски и причины их возникновения. На третьем этапе осуществляется количественная и качественная оценка логистических рисков. На четвертом этапе анализируются внешние и внутренние факторы влияния на логистический риск. На пятом этапе разрабатываются сценарии развития ситуации относительно угрозы возникновения определенных логистических рисков и выбираются методы их оценки. На шестом этапе оценивается логистический риск. На седьмом этапе разрабатываются мероприятия по минимизации или предотвращении логистического риска.