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Risk Management in the Pharmaceutical Industry in Slovenian Companies

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***Abstract* — The pharmaceutical industry is one of the most competitive businesses in the world. Supply chain in this industry has been directed towards the production of large batches to avoid lack of supplies, and the achievement of regulatory requirements, at the cost of high level of inventory, higher costs and inventory write-off due to expiration or other reasons. In recent years this industry is facing major changes and challenges such as intense globalization processes, increased competition and innovations in technologies, which has broadened and deepened risks in supply chain.**
The paper reports the results of the study of the risk in distribution processes of Slovenian pharmaceutical companies, which was conducted among five companies and aims to draw attention to risks that arise in supply chain, to emphasize the importance of their management and to present a model for an effective assessment of risk in companies, developed at the Faculty of Logistics.

***Key words* — Risk, distribution, risk management, risk catalog.**

I. INTRODUCTION

The pharmaceutical industry is one of the most competitive businesses in the world. Besides the fact that it improves health and life quality of patients around the world, it is also vital for the world economy. With one trilion US dollars it represents the large proportion of the total global economic value [1]. In the modern business world, where companies must quickly adopt to changes on the market, the pharmaceutical industry started to face huge and complex changes [2], which have consequently broadened and deepened the risks in the pharmaceutical industry. Due to adverse consequences of events in supply chain, recalls of products from the market, delays and errors in deliveries, excessive inventories etc. happen [3], which affects the different stakeholders in the supply chain and its environment.

Although organizations have always faced risks in supply chain, the attention of risk management increased significantly in the last decade, as shown in numerous studies and books. Good basis for further research was introduced by Breen, who was researching a realistic understanding of the nature and prevalence of risk in the pharmaceutical supply chain. The results of the research yielded identification of 35 prevalent risks, which occur throughout the pharmaceutical supply chain such as lack of inventory visibility, unexpected increase in demand, lack of information, theft etc. [4].

In addition Jaberidoost, Nikfar, Abdollahiahiasl & Dinarvand were researching risks in pharmaceutical supply chain with perspective of production companies. They say their research is the first systematic review of risk management in supply chain in terms of production companies. They identified 50 risks, which were divided into seven categories [5].

In relation to risks that occur in pharmaceutical supply chain, the study of Brako, Asante & Akosah confirmed, that risks such as lack of inventory, theft, expiration of shelf life are closely linked with the pharmaceutical supply chain [6]. They draw attention to the fact that pharmaceutical companies are facing problems of inventory management [6], which was also confirmed by Kamath J. K., Kamath K. K., Azaruddin, Subrahmanyam & Shabharaya, who were studying evaluated risks in pharmaceutical companies in India and defined that the pharmaceutical supply chain mainly confront risks arising from four categories, namely risk of inventory management, regulatory risk, risk of counterfeits and financial risks [7]. Even though reference [7] also defined arising risks from category of counterfeits, in the study of Brako, Asante & Akosah, 59% of the respondents in the survey disagreed with the statement that their supply chain is faced with the risk of entering counterfeit drugs into their supply chain [6].

As we can see, the pharmaceutical industry, like any other is exposed to many risks in supply chain. It is clear that proper management of these can provide significant competitive advantage to companies. However, KPMG International says that pharmaceutical companies have slightly narrow perspective with regards to risk. According to their findings pharmaceutical companies still give the greatest emphasis on compliance with the rules and are not taking a holistic view of risks [8].

In addition Jaberidoost, Nikfar, Abdollahiahiasl & Dinarvand came to the conclusion that most of the identified (20 out of 50) risks from their research is associated with the supply and problems with suppliers. They emphasize that regulatory risk have a high level of importance in pharmaceutical supply chain according to the literature, but it was not detailed in the studies reviewed in this work [5]. Disadvantage was seen in this research, due to the fact that it is entirely based only on identification of risks, which were obtained from literature review and not from the actual data gained from production companies. It turned out that the mentioned researsh was later the basis of future study in which Jaberidoost, Olfat, Hosseini et al. performed the interviews with experts from Iranian pharmaceutical companies. In addition they identified 86 risks quality [9], of which 50 were already the subject of previous research [5], and 36 risks were newly identified. Risks were divided into 11 categories. Most of the risks from this study was connected to financial economic category. Authors are stating that during the research investigated companies were under influence of current political situation in the country, which was likely to affect the results of the survey, as situation has forced companies to focus more on risk management from financial and supply perspective and less from perspective of quality [9].

Although there are risks in all activities of the supply chain [4, 6], we believe that risks in supply chain of pharmaceutical industry are still not sufficiently studied in all areas. Even though literature that touches our field of research exists (to determine what risks arise in the distribution of the pharmaceutical companies), for example study of Enyinda, Briggs & Backhar, about management of risks arising from outsourcing of global supply chain [10] and others already mentioned [4, 5, 6, 7, 8, 9], they do not pay attention to distribution as a whole. Mentioned studies touch our field slightly, from a point of view of the entire supply chain or from point of view of production entities. This is why we believe that our research will contribute an important part in understanding the risks that arise in the distribution and the supply chain in the pharmaceutical industry.

Goal of research was to find out whether pharmaceutical companies in Slovenia have implemented a comprehensive risk management system and what risks arise in the distribution of the pharmaceutical companies in Slovenia.

A. Supply chain and distribution

Logožar says, that supply chain includes tasks such as supply of materials, transforming them in semi finished and finished products and the distribution of finished products to customers. Supply chain is flow of materials, services, informations and payments, extending from raw material suppliers through factories and warehouses all the way to final customers as well as in the opposite direction [11].

When analyzing risks in the supply chain, we must be aware of resources that are crucial for their operation. Four primary resources, without which the processes in the supply chain cannot take place, are [12]:

1. The flow of goods and / or services.
2. Information.
3. Logistics infrastructure and superstructure.
4. People.

Each result of the risk that arise in supply chain can affect one or more resources of supply chain. If we want to effectively manage risks, we need to know what resources the individual risk impact.

Due to globalization, the origin and use of products are more and more remote, which affects the speed and security of distribution to customers. Distribution is a process that takes place within the supply chain and includes transportation, warehousing, inventory control, manipulation, order processing, etc.

B. Risks

Organizations of various types and sizes are faced with internal and external factors and influences that give rise to uncertainty about the time within which the organization will achieve its objectives - if any of the objectives will be achieved. The effect of the uncertainty of achieving the organization's objectives is "risk" [13].

If we want to treat risks, then we need to identify risks, analyze and evaluate them [14]. In phase of treating risks we determine, what will we do with individual risk. We have the following possibilities: we reduce risk, we accept it as it is (we have prepared a spare scenario if it occurs – so called plan »B«), we avoid risk and in some cases risk is transferred to a »third party«, if that is possible [13, 14].

Because similar risks appear through various organizations in the supply chain, the easiest way to identify risks for managers of the distribution process is to exchange informations about identified risks among themselves. One way to exchange such informations are publicly available risks catalogs in supply chain [15].

C. Risk catalog and risk assessment model

Studies on risk management in supply chain are popular, since they contribute to exploring new ways of managing risks in the supply chain. This also includes a model for effective risk assessment, which was developed at the Faculty of logistics. The final product is a catalog of risks in the supply chain and is accessible via the web [15]. The catalog is an excellent source of information, which companies can use as a guideline

for identifying risks and as a checklist to determine which of the risks they already identified within their organization [14, 15].

Identification of risks is the first step in the process of risk assessment. It must be carried out carefully because in case of overlooking a risk, the risk will not be discussed in next steps. The process of recognition is described in ISO 31010 [16], which was also used in the making of our catalog. Next we assigned values to each risk for five different parameters, which enable categorization of each risk. In every environment for a given organization or supply chain exist specific parameters, which are not included in general catalog. Five parameters, which are included in existing catalog and categorize risks [14, 15]:

- according to ISO 28000;
- in relation to impact on logistics assets;
- in relation to the risk takers – the public;
- depending on the origin and
- depending on the business or technological activity.

II. RESEARCH METHODS

In the research work we were focused on the study of risks in distribution of pharmaceutical companies in Slovenia. We wanted to know whether the surveyed companies deal with with the risks and what risks arise in the distribution of surveyed companies. Since the results of such research in Slovenia were not found, this research shows originality.

After reviewing and research of the theoretical work, we designed a questionnaire in the practical part, with which we collected data from five companies and analyzed them. The data was collected in the period from October 2015 to April 2016.

Primary list of companies for research was obtained from the database of companies, which deal with wholesale trade and brokerage of drugs and substances on Agency for Medicinal Products and Medicinal Devices of the Republic of Slovenia. There were 85 companies on the list [17], further research showed that 48 companies from the list actually do not conduct business in the field of our research and were thus eliminated from the list (veterinary companies, companies that provide only service activities and companies that deal with packaging or medical devices). We then sent a request of participation in our research to companies remaining on the list. Four companies were then further eliminated since it was determined that they were also not conducting business in the field of our research. Thus we had 34 companies left on our list and the survey was sent out to each of them. We received five completed surveys, 11 companies replied that they would not complete our survey because of reasons such as lack of time to complete the survey, fear of disclosure of secret information, the fact that they only reply to surveys for which they are legally obligated to etc. 18 companies never replied to our request of participation even though we contacted them multiple times.

On behalf of the companies the data was provided in the mentioned timeline by head of logistics (2 times), production and supply chain manager, director of wholesale and expert in transport.

Limitations of research:

- The study was limited only to the pharmaceutical companies in Slovenia.
- The study was restricted only to the risks identified in the distribution system.
- Due to time constraints, we analyzed only the responses that we received in the specified time period.

The questionnaire was composed of two sets of questions. With the first set of questions we wanted to investigate what risks arise in the distribution of the surveyed companies. To help companies with identifying risks, we also attached a link to the risk catalog, which is a great source of information, as it contains logistical risks that have been identified in companies from various fields of activity [15]. The second thematic section consisted of questions that gave answers to how the surveyed companies manage risks.

The results of research will contribute to the completion of existing, publicly available risk catalog in supply chain [15].

III. PRESENTATIONS OF RESULTS

Risk management is crucial for achieving company's objectives. In order for organizations to ensure risk management, the company's management must define and support the risk management policy so that the policy is in line with the objectives, organizational culture, performance indicators and that it is done in accordance with the law [14]. The results of our study shows, that four out of five surveyed companies follow such direction and one company has a policy on risk management in preparation and will be implemented in the near future as shown in Table 1.

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Table 1: The policy and guidance on risk management

Do you have in your or parent company policy and guidance on risk management which you follow?	
Answer	Number of answers
Yes.	4
No, but they are in preparation and will be implemented in the near future.	1
No.	0

Source: From the research.

Various studies show that the focus of the pharmaceutical industry remains in compliance with the rules and not on an integrated approach to risk management and that the problems associated with laws and regulations, represent the greatest threat to their business [8]. According to the results given in Table 2, we can assume, that our pharmaceutical companies recognize the importance of comprehensive approach to risk management, since all responding companies in addition to compliance with regulations, also focus on an integrated approach to risk management.

Table 2: Compliance with regulations or holistic approach to risk management

Does your company still focus only on compliance with laws and regulations or also on the new comprehensive approach to risk management?	
Answer	Number of answers
We focus only on compliance with laws and regulations.	0
We focus also on the new comprehensive approach to risk management.	5

Source: From the research.

The survey showed that three out of five companies have team members, who are dealing with risks among other responsibilities that they have. They are appointed from various organizational departments of the company. One company has such an organizational group in the parent company, which is not in Slovenia, and one company hired external experts for dealing with risks and thus do not have any of their staff dealing with risks, as shown in Table 3.

Table 3: Organizational group, which deals with the risk

Do you have in your company's organizational group, which deals with the risk?	
Answer	Number of answers
Yes. We have an organizational group that deals exclusively with risks.	0
Yes. We have team members from different organizational groups, who are also dealing with risks.	3
No. Organizational group, which deals with the risks is in the parent company.	1
No. We consult with external contractors for dealing with risks.	1
No. We are not dealing with risks.	0

Source: From the research.

Reactive risk management refers to situations, in which the risks are not pre-treated. We respond to them after they occur or when we detect them. European Medical Agency says that risk management in the pharmaceutical industry is oriented to be more reactive than proactive [18].

According to the survey results given in Table 4, we can assume that investigated companies realize the importance of a proactive risk management. Four out of five surveyed companies take a proactive approach to risk management and one company manages risk primarily reactive. A proactive approach to risk management in the supply chain is definitely better, say Waters [19].

Table 4: Proactive or reactive oriented risk management

Is your company's risk management oriented more reactive or proactive?	
Answer	Number of answers

Reactive (we are responding to events that have already happened).	1
Proactive (potential events are assessed (also detected) in advance).	4

Source: From the research.

Companies are more and more dependent on the ability to cope with uncertainties (which are essential element of risk) and successfully manage them. According to the survey results given in Table 5, we assume that companies are well aware of the negative effects of individual uncertainty in business processes of the company.

Table 5: With integrated risk management to reduce the impact of negative consequences

Do you think that with use of integrated risk management, we can avoid or reduce risks and so we can reduce the impact of negative consequences?	
Answer	Number of answers
Yes.	5
No.	0
I don't know.	0

Source: From the research.

Also majority of the surveyed companies agree with the statement, that the achievement of the company's objectives strongly depends on a successful risk management, as shown in Table 6.

Table 6: With successful risk management to achievement of corporate goals

Do you agree with the statement that the achievement of company objectives heavily depends on effective risk management?	
Answer	Number of answers
I completely agree with the statement.	4
I partly agree with the statement.	1
I don't agree with the statement.	0

Source: From the research.

Table 7 shows the most recognizable risk in our study.

Table 7: Risks

Identified risk	Number of companies
Delays in supply	4
Destruction of value of goods	3
Long lead times	2
Theft of goods	2
Dependency on a single supplier	2
Breakdown of air conditioning	2
Payment indiscipline	2
Slow movements of materials through the supply chain	2
Interrupted supply of goods to customer	2
Custom barriers	1
Long period of storage goods	1
Disturbance or shutdown of wireless networks	1
Task not completed	1

Non-optimal limitations of transport	1
Norms are not correctly formed	1
Unskillful use of equipment	1
Inappropriate or incorrect information system	1
Accidents involving warehouse manipulation equipment	1
Work accidents involving employees	1
Adverse reactions of customers on the launch of new product	1
Inappropriate storage conditions	1
Inappropriate conditions of transport	1
No business contingency plan	1
Interrupted heating system	1
Scanner not operating	1
Shortage of cash	1
Shortage of stock	1
Lack of key capable employees	1
Damage of cranes, lifts	1
Goods damage during loading / unloading	1
Increased production costs	1
Traffic accident	1
Too much time spent on bad customers	1
Disclosure of confidential information	1
Change of ownership at the supplier	1
Bad quality of products	1
Change in legislation or regulation	1
Change of ownership at the customer	1
Exchange rate differences - change rates	1
High or low environment temperature	1
The impact of weather events	1
Employees do not identify with the company's vision, no sense of belonging	1

Source: From the research.

IV. DEBATE

In our research project, we conducted a survey among five Slovenian pharmaceutical companies in which we studied the risk in distribution processes of their supply chain. The aim of the research was to gain insights into the risks that arise in the process of distribution in the pharmaceutical industry in Slovenia and at the same time to determine whether the companies are dealing with risks in a holistic approach or whether they still give the most attention to risk management from perspective of compliance with regulations, as found in the survey by KPMG International [8]. Results of our research do not confirm KPMG International findings. All researched companies in our study stated that in addition to compliance with regulations they are all also dealing with the holistic approach to risk management and also follow principles and instruction on risk management (4 out of 5 – 1 company will implement such principles in the near future). Our results also confirm the findings of the study of Brako, Asante & Akosah, where 98% of respondents (experts from pharmaceutical companies in Ghana) agreed that they are able to recognize the risks that companies are facing whenever they occur [6].

Although Kamath J. K., Kamath K. K., Azaruddin, Subrahmanyam & Shabharaya in the study concluded that risks from regulatory point of view are the most important risks for management in pharmaceutical supply chain [7], the surveyed companies in our study did not focus much attention to those risks (they point out only 3 risks from regulatory category).

With this research we have identified a total of 54 risks (42 were unique), which were recognized in the process of distribution in the Slovenian pharmaceutical companies. The risks that have been most frequently identified are: delays in delivery, loss of value of the goods, long delivery time of the goods, dependence on one supplier, failure of air conditioning systems, payment defaults, slow flow of materials through the supply chain and interrupted supply of goods to the customer.

Disruptions of supply are major source of risks says Bren [4], which is also indicated by the results in our research – 27 identified risks from our research had an impact on the flow of goods or services. Although the perspective of his study focused on the supply chain as a whole,

18 out of 35 risks identified by Breen were also used in the study of Jaberidoost, Nikfar, Abdollahiahiasl & Dinarvand that researched risks from the production point of view in pharmaceutical companies [5]. This shows that some of the risks from the holistic point of view of the supply chain are also part of the individual entities (such as production, distribution etc.).

Many risks reported in studies [5, 9] were defined as internal risks of the companies resulting from internal processes, employees, mismanagement etc. After ISO classification [14], which is also included in the risk catalog [15], these kinds of risks are categorized among operational risks. The result of our study has shown that 30 identified risks were arising from internal perspective of the companies, 24 of which are categorized as operational risks.

The findings definitely indicate the similarity of the risks that arise through various aspects (entities) of supply chain in the pharmaceutical industry. Nevertheless, at each stage of the supply chain, risks are arising that are unique for each entity in the supply (for example accidents involving manipulation of storage devices, inadequate storage conditions, traffic accidents etc.). Since some effects of risks, transfer through the entire supply chain, we believe that for successful risk management is crucial, to identify and understand the risks that are arising, not only from the perspective of supply chain as a whole but also from the perspective of individual entities. That is why it would make sense to repeat the study in a larger sample of companies in the international environment and encourage pharmaceutical companies to exchange information on the risks in their supply chain – in the process of distribution or other individual processes of the supply chain, as well as broader – through publicly accessible web portals.

Potential risks that arise in the pharmaceutical supply chain don't affect only companies but also affect the general public. Therefore, for example, the occurrence of low quality drug or the absence of a particular drug on the market could endanger the lives of patients. Results of our research in practice yields companies doing better business since they are aware of potential risks and how important it is to manage them (not only for them but also for the general public). With the research project we want to encourage businesses to use the risk catalog, in which identified risks are described. With the risk catalog, companies can facilitate the work in dealing with risks – especially in the identification and analysis of risks.

AUTHORS

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