IMPLEMENTATION OF MODERN MULTIDIMENSIONAL RISK MANAGEMENT IN INDUSTRIAL ENTERPRISE

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ABSTRACT

This paper characterizes many aspects and directions of implementation of modern, multidimensional enterprise risk management in the manufacturing enterprise in the pharmaceutical industry in Latvia. First time as the basis for this research was taken the only international risk management standard – *ISO 31000 -2018.*

The multisided risks, eight basic stages in process of implementation of enterprise risk management (ERM), two opposite directions of ERM operation and four parts of ERM implementation process have been presented. This research is concentrated on the second part of ERM implementation process – risk assessment and quantification. The key multisided risks were identified and prioritized in the manufacturing pharmaceutical enterprise by applying common metrics method: obtaining evaluations from the two highest levels of management (Board and senior line managers).

TOP 20 of key risks was created from *64* different risks and the convergence and difference between the risk rankings, evaluated by enterprise's Board and senior line management was obtained and analyzed. The main conclusion from the obtained results is that manufacturing enterprises in the pharmaceutical industry have specifics regarding exposure to multisided risks, where the main, key risk is *regulatory risk.*

Keywords: *risk management, risk appetite,risk dashboard reports*

INTRODUCTION

As the result of a reaction to the last global crisis, not only commercial banks but also industrial enterprises have started to pay serious attention to multisided (not only financial) character of risks that requires the implementation of modern multisided risk management.

There is no overall accepted definition of enterprise risk and enterprise risk management (ERM), therefore nowadays every enterprise is trying to form and implement ERM, what exactly meets its demands and needs.

The only international ERM standard *ISO 31000-2018* [1] defines:

"ERM is a comprehensive and integrated system for managing risks, that helps an entity to meet its business tasks and achieve its objectives by minimizing unexpected profit deviations and maximizing the value of the business."

Implementation of ERM in compliance with *ISO 31000:2018* standard is more established in industrial enterprises in USA and not widespread in Europe including Latvia.

In this paper, author presents the first results of the implementation of multidimensional ERM in the big pharmaceutical manufacturing enterprise in Latvia with an annual turnover of more than 100 million EUR.

Main attention is paid to the assessment of multisided risks: their identification and prioritization by enterprise Board and senior line management and ranking these risks by applying common metrics.

THEORETICAL APPROACH

Modern risk management is multidimensional [2] because it deals with multisided risks:

1.Business environment risk

2.Operational Risk

3.Supply chain risk

4. Business Continuity risk

5. Cyber risk

6.Stakeholder risk management.

7. Project, program and portfolio risk management.

8. Reputational risk, etc.

According to *ISO 31000-2018* for all mentioned forms of risks the process of ERM implementation consists of *eight basic stages*, through which the enterprise managers (Board, senior line management, operational units) have to go through to find answers on the following questions:

1. What enterprise is trying to achieve?
   (*Establishing a risk context*)
2. What could affect enterprise in achieving its objectives?
   (*Risk identification*)
3. Which of enterprise parts (things) exposed to risks are most important?
   (*Risk assessment)*
4. What enterprise shall do about the risks?
   (*Planning risk responses)*
5. Haven taken action, did it work?
   (*Implementing risk responses)*
6. Who and with whom in enterprise speaks about risks?
   (Communicating about risk)
7. What has changed after risk impact?
   (*Reviewing risk process*)
8. What has been learnt regarding risk impact?
   (Learning lessons regarding risk)

ERM generally operates in two main directions:

-*"top-down*" direction - from TOP management (Board, etc.), who sets the enterprise risk appetite and ability to take on risks in value creation process. Enterprise's Board is responsible for creating, approving and monitoring the risk policy, what provides clear levels of risk appetite (tolerance), establish a link between risk and compensation policies within the enterprise. Board is establishing an effective enterprise's ERM organizational structure, which enables a link between enterprise's business strategy and risk management.

- "*bottom-up*" direction - from operational units, which are maintaining and safeguarding the value created by company by realizing risk control. Enterprise's operational units are responsible for measuring and managing risks within their units and they need to be aware of the risks by generating the enterprise's growth and profits. They are taking daily decisions - which risks to accept and which risks to avoid. These decisions must be in line with the level of enterprise's risk appetite, determined by the enterprise's Board. Operational units are also responsible for matching risks in the pricing process, what enables the enterprise to obtain compensation for the risks it has taken.

The organizational structure of ERM implementation process consists of *four parts* [3] (*Figure 1.):*

Figure 1. The organizational structure of ERM implementation process

1. Governance structure and policies - who is responsible for supervising risks and taking critical risk management decision?

2. Risk assessment and quantification - what are the decisions taken in risk management prior to risk exposure (ex- ante), what is the analytical contribution to ERM process?

3. Risk management - how to take specific decisions in implementing ERM to adjust the enterprise's risk and business return profile?

4. Dashboard Reporting and monitoring - how an enterprise is implementing ERM decisions made after the risks have occurred (ex post), what is the feedback link?

METHODOLOGY

In this paper we are concentrating on *Risk Assessment and quantification* part of ERM process in the manufacturing enterprise in pharmaceutical industry.

There are several basic steps to be made in enterprise risk assessment:

1. Establishing a business context while respecting the company's organizational objectives, tasks and regulatory requirements.

2. Identifying the key risks that can negatively hit business targets.

3. Assessing the key risks in terms of their probability to appear and the severity they can cause, by applying common metrics approach.

4. Evaluating of risk management strategies, including enterprise's operational plans.

5. Prioritizing of the key risks for its further analysis, quantification and mitigation.

We have made research regarding steps *2, 3, 5.*

To identify and prioritize multisided key risks in the enterprise we have created a single list of risks (risk register), that collects information from many areas measured by common metrics.

Based on the aggregated results of risk register we have prioritized the most critical risks for the enterprise by ranking them in one common table.

Particular risk place in the ranking is obtained from two main parameters:

- *probability* - with what a particular risk can occur,
- *severity* - how much a particular risk can impact,

The common risk index is calculated by multiplying both parameters:

*Risk index = Probability * Severity*

Both parameters for each risk are evaluated in the scale from *1* to *5* by:

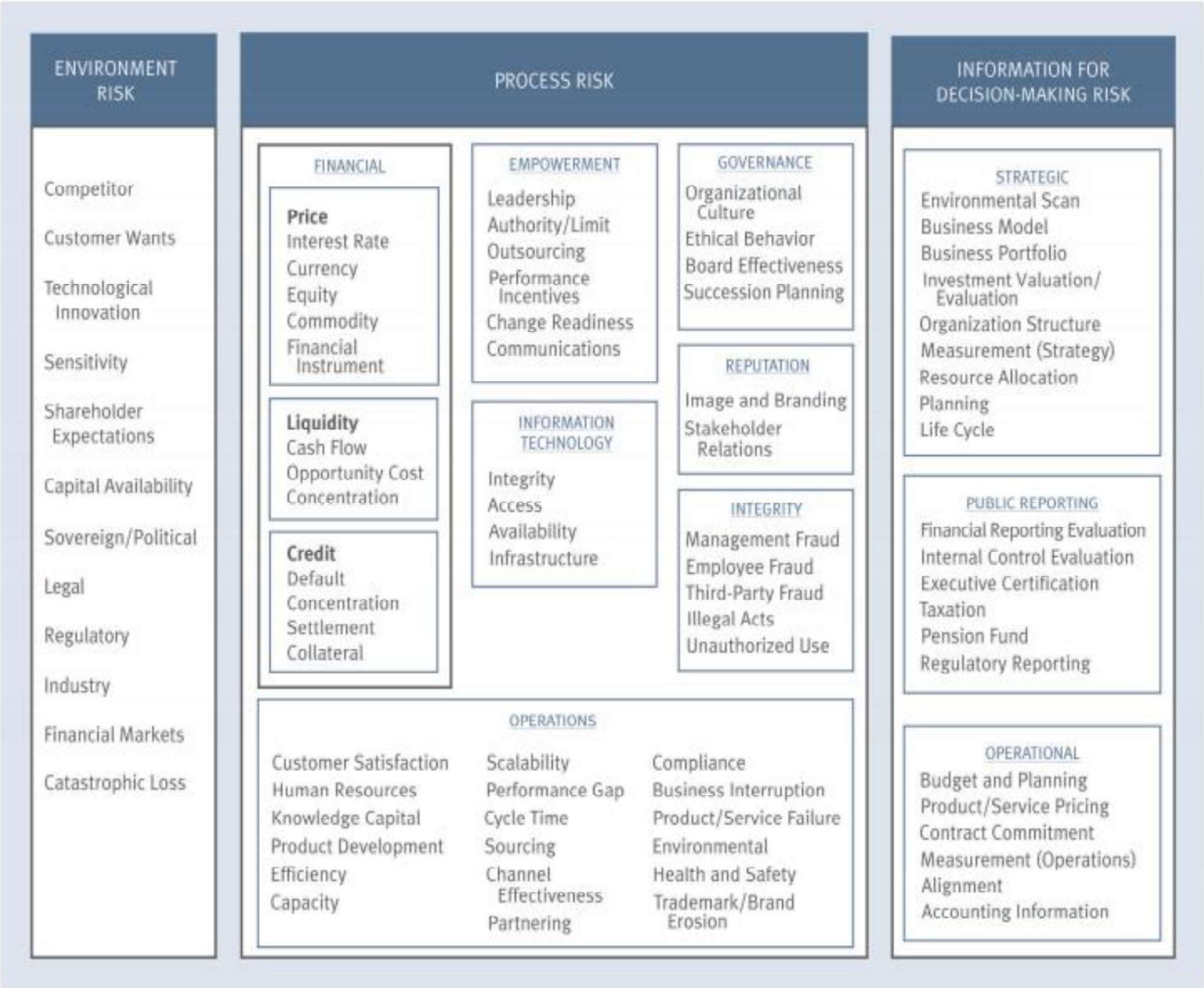
- Board members of the enterprise,
- Board members plus senior line managers (directors of all departments of the enterprise).

The final values of key risk indexes have been obtained as the sum of indexes given by:

- all Board members,
- all Board members and all senior line managers

To identify the key risks in the enterprise we have used one of the most developed risk model structure, that represents the multisided character of risks - the *Protiviti* risk model [4].

Table 1. Protiviti Risk Model



We have taken *64* significant parts of this model as the basis for registering multisided risks, which can impact the manufacturing enterprise in pharmaceutical industry. From these *64* parts of risk register we have formed *TOP 20* of the main key risks.

RESULTS

The first part of results in identifying and prioritizing risks is obtained from the answers and evaluations provided by enterprise TOP management - all Board members (Figure 2.)

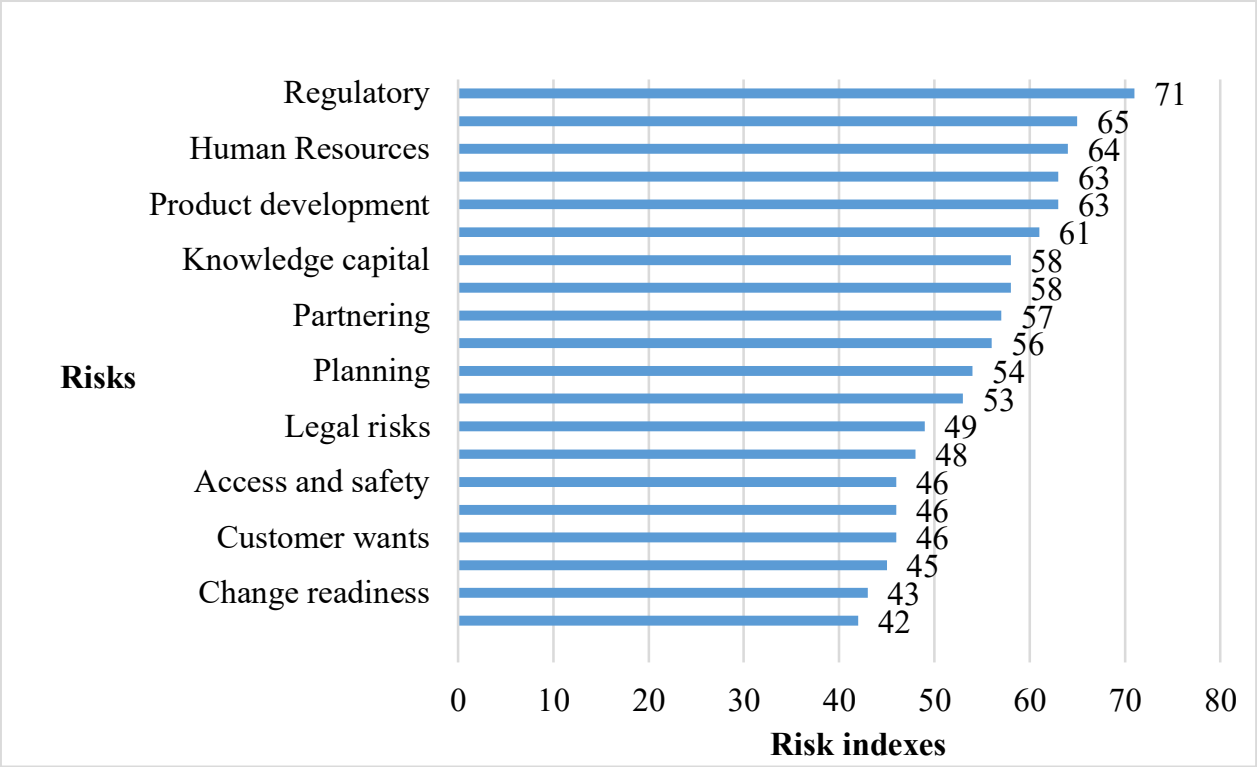


Figure 2. TOP 20 risk indexes in pharmaceutical enterprise

(identified and prioritized by Board members)

These results clearly show that risks, which can impact the manufacturing pharmaceutical enterprise, are really multisided:

- environment risks (in what business environment this particular enterprise is making its business) - regulatory, competitors, legal, customer wants, technological innovation are by their nature external risks.
- process risks (how the enterprise is exactly making its business) are internal risks consisted of:
- operational risks (how the enterprise exactly operates its business): efficiency, human resources, product development, capacity, knowledge capital, partnering, customer satisfaction,
- empowerment risks (leadership, change readiness),
- governance risks (succession planning),
- financial risks (credit)
- information for decision making risks (investment evaluation, organization structure)

According to modern multisided ERM approach (ISO 31000-2018) all these mentioned above risk impacts have to be calculated in financial means by applying the common metrics. However, obtained results show, that the financial situation in the manufacturing pharmaceutical enterprise is strong and stable, because the *direct financial risks* (credit risk) the enterprise's Board is not ranking between TOP 10 risks (*at 16th place*).

The main key risk in the pharmaceutical enterprise identified and prioritized by the enterprise's Board is *regulatory risk*. This result clearly characterizes the specifics of pharmaceutical industry, where the existing pharmaceutical products have to be time after time reregistered by state agencies and sometimes to be improved to align with changing regulatory

rules and demands in particular country or countries. For new products the procedure of their registration is even more complicated and is 100% depending on regulatory decisions. Therefore *regulatory risk* to certain extent matches with *product development* and *succession planning risks*, which are also in TOP 10 (see Figure 2.)

The additional result, that enterprise's Board has highly ranked different *operational risks* (efficiency, human resources, knowledge capital, capacity), shows, that Board is concerned about operational situation in the enterprise and not only about strategic position of the enterprise.

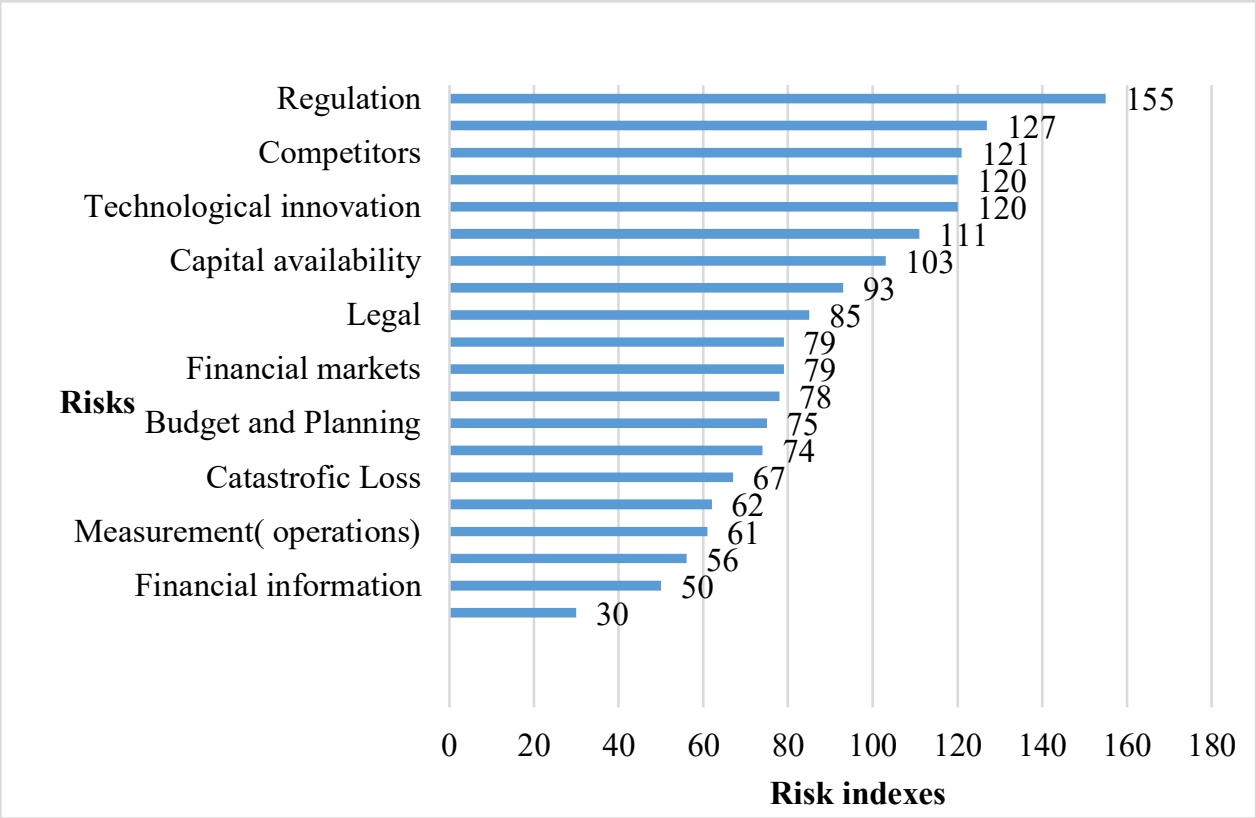


Figure 3. TOP 20 risk indexes in pharmaceutical enterprise

(identified and prioritized by Board members and senior line management members-directors of departments)

By adding to enterprise Board the senior line managers (directors of departments) in the process of identifying and prioritizing multisided risks our main idea was to find and analyze the differences by significantly widening the basis of risk evaluators in the enterprise.

The main result is that the key risk in pharmaceutical manufacturing enterprise is remaining the same – *regulatory risk* in both cases of evaluation.

This fact additionally emphasizes the specifics of pharmaceutical industry, where the manufacturing enterprises are very much exposed to risks coming from regulatory decisions in particular country or countries.

Results also show that enterprise's senior line management similarly to enterprise's Board is evaluating enterprise's financial situation as strong and stable, because the *direct financial risks* (financial markets, credit) have not been ranked between TOP 10 risks.

However, we have also identified the differences in risk assessment made by the enterprise's Board and senior line management:

- line managers have ranked the *investment assessment risk* higher (2nd place) as Board members (12th place), what could reflect that line managers have some thought that Board's made decisions about investment have contained significant risks, what could happen also in the future.
- Board has identified between TOP 10 risks the enterprise's operational performance factors (*efficiency,* human *resources, capacity, knowledge capital),* which are not even included in TOP 10 by senior line managers.
  This shows that the assessment of enterprise's operational capacity, its efficiency is quite different on these two higher levels of enterprise's management, what could create problems in the future.
- line managers have ranked enterprise's technological innovation risk, much higher (5th place) as Board (20th place).
  This shows that line managers, who are much closer to the different sides of production, sales etc. in the enterprise, are more concern about the necessity of technological innovation in the enterprise. The absence or delay in technological innovations could cause *competitors risks*, which line managers have ranked higher (3rd place) as Board (8th place).

CONCLUSION

The obtained results clearly show that risks, to which a manufacturing enterprise can be exposed, are multisided: *external – business environment risks*, *internal- operational, governance risks and information for decision-making risks.*

The obtained results clearly show the specifics of risk exposures in manufacturing enterprises in the pharmaceutical industry, where *regulatory risk* regarding pharmaceutical production is the major key risk.

This is emphasized with the result that *regulatory risk* is identified and prioritized both by enterprise's Board and senior lime managers.

The obtained result that directs *financial risks* (*credit, liquidity, financial market*) are not ranked between TOP 10 risks is reflecting the strong and stable financial situation in the particular enterprise.

These two results mentioned above demonstrate some convergence in risk assessment at two highest management levels in the enterprise.

However, the results of different ranking of enterprise's *operational risks*, *investment assessment ris*ks, *technological innovations risks* made by enterprise's Board and senior line managers are signaling that exactly in these directions of enterprise's business activities is necessary to review the strategic and operational planning with the aim to mitigate the potential risk impacts.

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