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Risk Assessment and Quantification in Manufacturing Enterprise

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Abstract: In this research first time in Latvia a multidimensional risk assessment is carried out in the manufacturing enterprise in the pharmaceutical industry according to the only international risk management standard ISO 31000-2018. The key multisided risks were identified and prioritized in the manufacturing pharmaceutical enterprise by applying common metrics method: obtaining evaluations of risk occurrence and impact severity, made by the two highest levels of enterprise management (Board and senior line managers). TOP 10 of key risks was created from identified 64 different risks and the convergence and divergence in the risk rankings, evaluated by enterprise's Board and senior line management were obtained and analyzed. The main conclusion is that manufacturing enterprises in pharmaceutical industry have specifics regarding exposure to multisided risks, where the main, key risk is regulatory risk and not different financial risks. Different ranking of enterprise operational risks, investment assessment risks, technological innovations risks made by enterprise Board and senior line managers are signalling 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.

Key words: international risk management standard; multisided risks; regulatory risk; risk occurrence and severity

JEL code: G32

1. Introduction

There is no overall accepted definition of enterprise risk and enterprise risk management (ERM). The only international ERM standard ISO 31000-2018 (Hutchins G., 2018) 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 31000:2018standard in industrial enterprises has started only after global financial crisis (2009) mainly in USA (Fraser J., Simkins B., Narvaez K., 2014; Crouhy M., Galai D., Mark R., 2014) and is not widespread in Europe. There is no industrial enterprise in Latvia today, which has fully implemented ERM complying with ISO 31000:2018.

The risks to which industrial enterprise can be exposed are multisided; therefore a modern ERM has to be multidimensional (Hillson D., 2016):

1) Governance, Risk and Compliance (GRC);
2) Operational Risk Management (ORM);

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3) Supply chain risk management;
4) Business Continuity Management (BCM)
5) Project, Program and Portfolio Risk Management
6) Cyber Risk Management
7) Stakeholder risk management
8) Etc.

2. Theoretical Approach

According to ISO 31000-2018 the implementation of ERM consists of eight basic stages (Hutchins G., 2018). We have added the key question to which enterprise management has to find answer in each of the following eight stages:

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

The organizational structure of ERM implementation process consists of four parts (Hillson D., 2016) (see Figure 1):

Figure 1 The Organizational Structure of ERM Implementation Process (Hillson D., 2016)

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 by implementing ERM to adjust them to the enterprise's risk and business returnprofile?
4) *Dashboard Reporting and monitoring* — How an enterprise is implementing ERM decisions made after the risks have occurred (ex post) and what is the feedback link?

3. Methodology

There are five basic steps to be made in *Risk assessment and quantification* (Lam J., 2017):

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.

In this research we have made research regarding steps 2, 3, 5 in *Risk assessment and quantification* part of ERM process applied to the manufacturing pharmaceutical enterprise.

To make these steps we have obtained information regarding different risk impacts on many business spheres of the pharmaceutical enterprise and compiled it in the single list of risks (risk register). After completing this we have made ranking of different risks inside risk register, based on the aggregated results of their potential impact. Each risk place in the ranking has been set as the combination of two main parameters:

- Risk probability — with what a particular risk can occur;
- Risk severity — how severe (big) can be potential impact from a particular risk.

Both parameters for each risk have been 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 risk index was calculated by multiplying both parameters:

$$\text{Risk index} = \text{Risk probability} * \text{Risk severity} \quad (1)$$

The final values of key risk indexes have been calculated 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 pharmaceutical enterprise we have used as the template one of the most developed risk model structure — the *Protiviti* risk structure model[1] (see Table 1).

We have created questionnaires to enterprise Board members and senior line managers regarding 64 different risks (taken from *Protiviti* risk structure model), which can impact the manufacturing enterprise in pharmaceutical industry and asked them individually to evaluate (from 1 to 5) both risk probability and risk severity.

[1] Available online at: https://www.protiviti.com › files › insights › bulletin_v3_issue2_supplement.

We have calculated common risk indexes for these 64 risks by applying formula (1) and then formed TOP 10 of the main key risks in the risk register of pharmaceutical enterprise.

To find out the possible convergences or divergences in risk assessment and quantification from two senior levels of enterprise management we have compared the results obtained from the enterprise Board members and from the senior line managers (department directors etc.).

Table 1 ***Protiviti*** **Risk Structure Model**[2]

<table>
<tr><th>Environment risk</th><th colspan="3">Process risk</th><th>Information for decision making risk</th></tr>
<tr><td rowspan="11">Competitor
Customer wants
Technological innovation
Sensitivity
Shareholder expectations
Capital availability
Sovereign/political
Legal
Regulatory
Industry
Financial markets
Catastrophic loss</td><td>Financial</td><td>Empowerment
Leadership
Authority/Limit
Outsourcing
Performance incentives
Change readiness
Communications</td><td>Governance
Organizational culture
Ethical behavior
Board effectiveness
Succession planning</td><td rowspan="3">Strategic
Environmental Scan
Business Model
Business Portfolio
Investment valuation/ evaluation
Organization Structure
Measurement (Strategy)
Resource Allocation
Planning
Life Cycle</td></tr>
<tr><td>Price
Interest Rate
Currency
Equity
Commodity
Financial instrument</td></tr>
<tr><td>Liquidity
Cash Flow
Opportunity Cost
Concentration</td><td rowspan="2">Information technology
Integrity
Access
Availability
Infrastructure</td><td>Reputation
Image and branding
Stakeholder relations</td></tr>
<tr><td>Credit
Default
Concentration
Settlement
Collateral</td><td>Integrity
Management fraud
Employee fraud
Third-party fraud
Illegal acts
Unauthorized use</td><td>Public reporting
Financial reporting evaluation
Internal control evaluation
Executive certification
Taxation
Pension fund
Regulatory reporting</td></tr>
<tr><td colspan="3">Operations</td><td rowspan="2">Operational
Budget and planning
Product/Service Pricing
Contract Commitment
Measurement (operations)
Alignment
Accounting information</td></tr>
<tr><td>Customer satisfaction
Human resources
Knowledge capital
Product development
Efficiency capacity</td><td>Scalability
Performance gap
Cycle time
Sourcing
Channel effectiveness
Partnering</td><td>Compliance
Business interruption
Product/service failure
Environmental
Health and safety
Trademark/brand erosion</td></tr>
</table>

4. 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 (see Figure 2).

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

- *Environment risks* (regulatory, legal, customer wants), which by their nature are external risks;
- *Process risks, which* are internal risks consisting of:
  - *Operational risks* (human resources, product development, knowledge capital, partnering);
  - *Governance risks* (succession planning) ;
  - *Empowerment ris*ks (leadership, change readiness),
  - *Financial risks* (credit);
  - *Information for decision making risks* (investment evaluation, organization structure).

[2] Available online at: https://www.protiviti.com › files › insights › bulletin_v3_issue2_supplement.

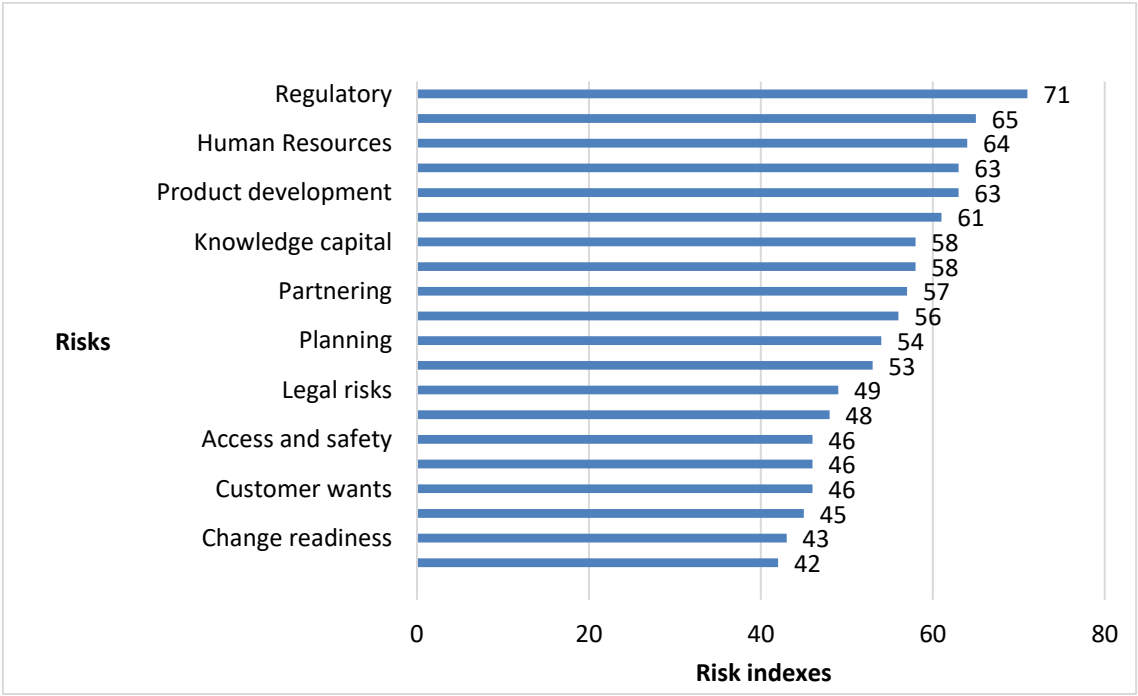

Figure 2 TOP 10 Risk Indexes in Pharmaceutical Enterprise (Identified and Prioritized by Board Members)

According to ISO 31000-2018 the impacts of all risks have to be calculated by applying the common metrics in financial means. However, our obtained results show, that the financial situation in this particular manufacturing pharmaceutical enterprise from the point of view of enterprise TOP management is strong and stable, while the Board is not ranking direct financial risks between TOP 10 risks (credit risk is only at 16th place).

The results of our research clearly show that the key risk in the pharmaceutical enterprise identified and prioritized by the enterprise's Board is regulatory risk (see Figure 2). This characterizes the specifics of pharmaceutical industry, where the existing pharmaceutical products have to be time after time reregistered by different state agencies and sometimes to be improved to align with changing regulatory rules and demands in particular country or countries. Moreover, 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 planning risks, which are also in TOP 10 (see Figure 2).

The enterprise's Board has highly ranked also different operational risks (human resources, knowledge capital) (see Figure 2). This means that Board is concerned about operational situation in the enterprise.

The main obtained result from risk assessment and quantification in pharmaceutical manufacturing enterprise is that the key risk is remaining the same — regulatory risk in both cases of evaluation (see Figure 1 and Figure 2). 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, and therefore the direct financial risks (financial market risk, credit risk, liquidity risk) have not been ranked between TOP 10 risks in both cases.

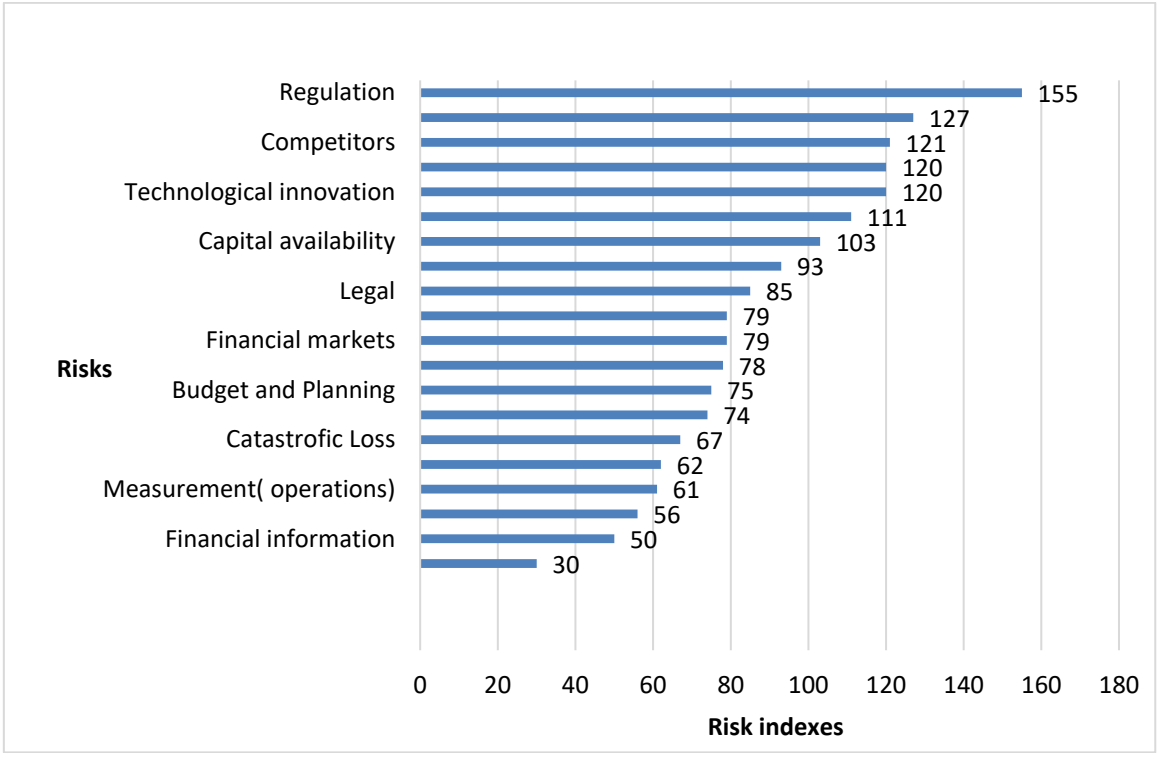

Figure 3 TOP 10 Risk Indexes in Pharmaceutical Enterprise (Identified and Prioritized by Board Members Plus Senior Line Management Members (Directors of Departments))

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

- Line managers have ranked the investment assessment risk essentially higher (2nd place) as Board members (12th place), what could reflect that line managers, who are nearer to the situation on the ground , have expressed their position , that Board's made decisions about investment have already contained significant risks, and this could happen also in the future;
- Board has identified between TOP 10 risks the enterprise's operational performance factors (*human resources, knowledge capital),* which have not even been 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).

5. Conclusions

The risks, to which a manufacturing pharmaceutical enterprise can be exposed, are really multisided: external (business environment risks) and internal (operational, governance risks).

The specifics of risk exposures in manufacturing pharmaceutical enterprises are that regulatory *risk* is the

major key risk in pharmaceutical industry.

The financial situation in this particular pharmaceutical enterprise at the time of our research is enough strong and stable and the direct financial *risks* (credit, liquidity, financial market risks) are not ranked between TOP 10 risks by both senior levels of enterprise management.

Some convergence in risk assessment and quantification on both highest management levels in the enterprise demonstrates acknowledgeable common attitude regarding enterprise exposure to the main key regulatory risk.

However, the obtained divergence in the risk assessment and quantification regarding enterprise's exposure to the different type of operational risks, investment assessment risks, technological innovations madeby enterprise's Board and senior line managers is signaling that exactly these enterprise's business processes and activities is necessary to review by making decisions in strategic and operational planning with the aim to mitigate the potential risk impacts in the future.

Results obtained from the risk assessment and quantification are not valid forever and according to ISO 31000-2018 this part of ERM has to be a permanent process to be performed on the regular basis with the objective to find out possible changes on the time scale.

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