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Determinants of complaint handling process effectiveness in medical devices companies

Summary of doctoral dissertation

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1. Justification of the research topic selection

The medical device market is a fast-growing industry. The product portfolio, among companies, that design and manufacture medical devices, continues to grow due to the high demand for medical devices worldwide (Gacek, Bąk, Blacha- Stachowicz, Augustyniak, Liebert, Podbielska and Maniewski, 2013, p. 166). The value of the medical device market in Poland was estimated at PLN 17.5 billion in 2020 (POLMED, 2022). Due to the characteristics of medical devices, which need to be safe and effective in use, the medical devices market is highly regulated. Before placing a medical device on the market, the manufacturer is obliged to ensure that the marketed device is safe for the user and that the local requirements are fulfilled (WHO, 2017).

Medical device failures observed by the users should be reported, through complaints, to distributors or directly to medical device manufacturers. Reported complaints should be subjected to in-depth analysis to identify the root cause and eliminate the failure and its cause by implementing appropriate actions. The effectiveness of the complaint-handling process is critical to ensuring the safety and effectiveness of a medical device on the market. A review of the literature showed that there are no current research studies that address the topic of the effectiveness of the complaint-handling process among medical device manufacturers. This topic was considered important due to the significant role of medical devices. The quality and performance of medical devices are directly related to the health and life of the user. It should be highlighted that the quality of medical devices is, among other things, improved as a result of the complaint-handling process. Therefore, it is crucial to have this process effective by taking appropriate actions to eliminate the identified problem and prevent its recurrence (Tashi, Mbuya and Gangadharappa, 2016, p. 1).

As a result of complaints received, the manufacturer of a given medical device can monitor the resulting nonconformities that are revealed after the product is delivered to the customer. Often complaints are the only source of obtaining information regarding emerging problems during use. Continuous monitoring of reported problems, by keeping regular statistics, makes it possible to assess whether further action should be taken. It should also be noted that with the fast growth of this industry and the introduction of new, innovative products to the market, complaints provide valuable information regarding the quality of newly introduced medical devices. Quality means ensuring the safety as well as the effectiveness of these devices. This process is an important part of the improvement of the company's quality

management process, so a study is reasonable to identify and evaluate the determinants of the effectiveness of the complaints handling process (Pszczółkowska, 2021, p. 11; Ząbek, 2015a, pp. 10-17; Ząbek, 2015b, pp. 15-21).

2. Research problem, objectives and research hypothesis

Taking into account the arguments presented in chapter 1, the purpose of the conducted research was defined. The main objective of the dissertation was to identify and evaluate the factors impacting the effectiveness of the complaint-handling process in medical device companies in Poland. The specific objectives of this dissertation focused on:

- identification of the main determinants impacting the effectiveness of the company's complaint-handling process and assessment of their relevance;
- assessing the relevance of determinants impacting the effectiveness of the individual steps of the complaint-handling process;
- evaluation of the impact of the coronavirus pandemic on the effectiveness of the complaints-handling process;
- identification of tools and methods used to define root cause categories of reported complaints;
- identification of root cause categories of reported complaints in companies and identification of the most common root cause categories;
- identification of medical device quality improvement activities (corrections and corrective) initiated by the complaint process, and identification of the most important actions;
- identification of indicators used to evaluate the effectiveness of the complaint-handling process in medical device companies;

The following research hypotheses were defined and verified during the research:

- Hypothesis 1: Determinants of the effectiveness of the complaint-handling process in medical device companies are related to communication and the competence of people involved in the complaint-handling process.
- Hypothesis 2: Production errors (operators, machines, tools) are the most common category of identified root causes of complaints.

- Hypothesis 3: The most common corrective actions resulting from the complaint-handling process are related to the improvement of the product manufacturing process.

3. Dissertation structure and research method

The dissertation consists of two parts: theoretical and empirical. The theoretical part is a review of the literature consisting of three chapters.

The first chapter refers to the characteristics of the medical device market. A review of the definitions of medical devices and in vitro diagnostic medical devices on the basis was prepared based on the legal acts and normative requirements that are in force around the world. A particular focus was given to the definitions described in the European Union regulations (2017/745 and 2017/746). The medical device classification has been analyzed in detail due to the risks of their use. The first chapter presents also an analysis of the global medical device market, including a detailed analysis of the medical device market in Europe and Poland. The value of the medical device markets in each country around the world is presented, and the largest device manufacturers are presented, as well as the factors that affect the growth and value of this industry. The second subsection analyzes the impact of the coronavirus pandemic on the medical device industry. The next subsection characterizes the Polish medical device market, taking into account the value of this market and the factors that shape this industry.

The second chapter reviews the legal and normative requirements for medical devices. The currently applicable requirements were analyzed on the example of individual countries around the world. Poland, as a member of the European Union, is obliged to apply the requirements therein, so the requirements for medical devices established by the European Parliament and the Council of the European Union were analyzed in detail.

The third chapter is a characterization of the complaint-handling process. The definition of complaints was provided, as well as a review of the legal requirements and consumer rights for dealing with complaints in Poland. The following chapter defines and characterizes the various steps in the complaint handling process based on the requirements of the international standard ISO 13485: 2016- 04: "Medical devices — Quality management systems — Requirements for regulatory purposes".

The next, fourth chapter of this dissertation is the empirical section. It presents the results of the research, conclusions and recommendation.

The research study was conducted using a survey method. This allowed the verification of hypotheses and the formulation of conclusions and recommendations, which are presented at the end of this doctoral dissertation. The conclusion is a summary of the theoretical and empirical parts.

4. Test results and conclusions

The research conducted has led to conclusions and recommendations for medical device companies:

1. The effective complaint-handling process affects the quality of medical devices. The quality of medical devices means that the device is safe for use and meets its performance specification. Therefore, the complaint handling process should be coordinated by quality department representatives, who are responsible for ensuring the required high quality of the devices. The competence of the quality department employees, both in terms of the process of dealing with complaints, as well as the ability to use appropriate tools and quality methods, allows the process to be carried out efficiently.

2. It is crucial for companies to set a timeframe for the complaint-handling process, taking into account legal and customer requirements, as well as the company's capabilities. The relationship between the complainant and the manufacturer should also be taken into account. If the complaint is submitted by the company (B2B), a comprehensive analysis is required to communicate corrective and corrective actions, which affects the timing of the entire process. Prioritizing complaints based on the determination of potential risks associated with the use of a device with a reported problem is key to ensuring the safety of medical devices on the market. For medical devices with a customer-reported problem that poses a high risk associated with its use (given the harm and probability of the problem), the time to analyze the complaint and make a decision should be as short as possible. Prompt response to high-risk complaints minimizes the possibility of a high-risk medical incident.

3. Electronic complaint databases, used by all surveyed companies, have a major advantage over paper complaint forms. By recording complaints in dedicated electronic databases, as well as Excel spreadsheets, companies can easily modify and supplement the information entered on a given complaint, ensuring easy processing and monitoring.

4. When designing the process of dealing with complaints in medical device companies, it is important to consider the factors that significantly affect the effectiveness of the process. It should be taken into account that for each step of the process, individual factors have different relevance.

To ensure the effectiveness of the complaint handling process, it is necessary in the first place to ensure the comprehensiveness of information regarding the reported problem by collecting detailed information from the customer regarding the problem and ensuring a good communication process within the company. Equally important is a sense of responsibility regarding the reported problem, which can be achieved through clearly established responsibilities within the organization regarding the various stages of the complaint-handling process.

5. Considering the various steps in the complaint-handling process, it can be seen that various factors affect the effectiveness of these steps to varying degrees. However, there are groups of factors that should be taken into account when planning the complaint-handling process at medical device companies. These include proper knowledge of the product, the customer's description of the perceived problem, adequate personnel (human resources) familiar with complaints procedures and the prevailing work atmosphere, the flow of information between different units in the company about the complaints process and also effective audits (internal and external) of the medical device complaints process.

6. It should be noted that there may be unusual factors that can affect the effectiveness of the complaints-handling process, which were not taken into account when designing the process. The coronavirus pandemic, as one of the factors affecting the operation of companies, did not affect the effectiveness of the complaints-handling process in most medical device companies (nearly 67% of the surveyed companies).

7. Brainstorming, is a tool to identify potential root causes of reported problems. Through discussion, in a relatively quick and simple way, brainstorming members can put forward their ideas, which increases the chance of finding the root cause of the reported problem.

8. When analyzing the root cause of reported complaints, companies should consider first of all the possibility of production errors (operators, machines, tools), which are the most common cause of reported problems in medical device companies.

9. The most common corrective actions taken as a result of the complaint handling process include checking manufactured finished goods throughout the supply chain and separating non-conforming products found.

When taking corrective actions, companies should also consider taking the same type of action for products of a different type, manufactured on the same production line as the claimed product. Implementing appropriate preventive measures minimizes the possibility of a potential future complaint.

10. According to the survey, the most common corrective action taken is training for production workers. On this basis, it can be concluded that adequate training for production workers can minimize the risk of releasing a defective medical device on the market. Training is particularly important for operators who perform manual operations. Human labor (with no or partial use of machines) plays a key role there, so the possibility of mistakes by employees is high.

11. Evaluating the effectiveness of the complaint-handling process is a priority to confirm that the corrective and corrective actions introduced are effective. This is evidenced by the absence of complaints about the problem, due to the identified cause, in the future. To evaluate the effectiveness of the complaint-handling process, companies use indicators. According to the survey, the indicators used by most companies to monitor the complaint handling process are primarily the share of the number of repeat complaints (for the same problem) to the total number of complaints, and the timeliness indicator (the share of the number of complaints handled on time (according to the time for handling complaints specified by the company) to the number of all complaints received. The former is used to examine the effectiveness of the process.

The effectiveness of the complaint-handling process is crucial to ensuring the safety and performance of medical devices. According to the definition adopted, for the purpose of this dissertation, the process is considered effective when the problem reported in the complaint is eliminated and corrective action is taken to prevent the reported problem from occurring in the future (due to the identified cause). A review of the literature, as well as the author's own professional experience in this dissertation, allowed identifying determinants that can affect the effectiveness of the complaint-handling process in medical device companies. The most important determinants that should be taken into account by companies were identified based on the results of the survey. As a result, the main objective of the study, which was to identify and evaluate the factors affecting the effectiveness of the complaints-handling process in medical device companies in Poland, was achieved.

According to the results of the questionnaire survey, it can be noted that the most important factors influencing effectiveness may vary at different steps of the process. However, summarizing all the steps, it can be seen that effectiveness is influenced by several key categories of factors, among which are: knowledge of the product, proper description of the problem noticed by the customer, adequate staff (human resources) familiar with the complaint procedures and the atmosphere at work, the flow of information between different cells in the company on the complaint process and also effective audits (internal and external) in the medical device complaint process.

The second research hypothesis assuming that production errors (of operators, machines, tools) are the most common category of identified root causes of complaints was confirmed based on the scientific research conducted. According to the results of the survey, production errors are the most frequently identified root causes of reported complaints. To eliminate them, as well as to eliminate the identified root causes of complaints, companies take measures to improve the production process, among which are the inspection of manufactured finished goods throughout the supply chain and the separation of non-conforming products found, training for production workers. Accordingly, the third research hypothesis can be confirmed, which indicates that the most common corrective actions resulting from the complaint process are related to the improvement of the product manufacturing process.

The effectiveness of the measures introduced as well as the complaint-handling process is regularly monitored by companies. To determine effectiveness, companies use indicators.

According to the survey, the most frequently checked indicators are the share of the number of recurring complaints (for the same problem) to the total number of complaints, and the timeliness indicator (the share of the number of complaints handled on time (according to the time for handling complaints specified by the company) to the number of all complaints received.

The conclusions and recommendations presented in this dissertation can be a guideline for medical device companies that want to ensure the effectiveness of the complaint-handling process, thus affecting the assurance of the safety and performance of manufactured medical devices.

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