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DEVELOPMENT OF AN INTELLIGENT MODEL FOR MANAGEMENT OF THE REQUIREMENTS OF MARKETING PROJECTS OF THE PHARMACEUTICAL INDUSTRY

The object of research is the processes of managing the requirements of the marketing project using means of intelligent data analysis and artificial intelligence systems. Marketing projects include a large number of projects of various types, formats and scales. The work considers projects that are initiated at an existing pharmaceutical enterprise that produces drugs for the local market. Over a period of time, the company needs to introduce new dosage forms to the market. It is not about the development of new innovative drugs. Usually, these are new mixtures of known components, but according to the results of global research, adding new components to the formulation gives a new, additional effect. Also, it can be a new form, for example, a spray or syrup for children, etc. Nevertheless, in order to produce such a new product and bring it to the market, to make a profit, it is necessary to conduct a study of the local market in order to find analogues, consumer expectations and predict future cash flows from sales of new drugs. In order to form requirements for the project of creating and manufacturing a new medicinal form, the company initiates marketing projects. Such marketing projects are the subject of research.

As a result of the marketing project of the analysis of the drug market, it is necessary to form the contours of a new product and the requirements for the project of creating this product – a new medicinal product. Collecting and forming requirements is not a trivial task. Therefore, in the work, it is proposed to apply means of intelligent data analysis, which will be implemented on artificial intelligence systems. As a result, an intelligent model for managing the requirements of marketing projects of the pharmaceutical industry was developed. The non-triviality of the task of requirements formation is based on the fact that it is multi-criteria. The desired requirements and, accordingly, the future product of the project depend on: the lack of a similar dosage form on the local market, the presence of theoretical and practical pharmacological developments in this direction, the technical and financial capabilities of the enterprise, the expectations of stakeholders and consumers of the product. The use of intelligent tools will allow to avoid a conflict of requirements and to develop a medicine that will not only meet the expectations of all participants of the local pharmaceutical market, but also provide profit to the developing company.

Keywords: *marketing project, pharmaceutical industry, product requirements, requirements management, intelligent model.*

How to cite

1. Introduction

Formation of requirements for marketing projects of the pharmaceutical industry is a non-trivial task. It should be divided into two parts. The first is the formation of requirements for the development projects of a new medicinal product, and the second is the collection and formation of requirements for the promotion of this medicinal product to the market [1].

According to the system approach, requirements should be characterized as conditions to which the "project" system [2] must comply, so as not to contradict: contracts, standards, specifications and other regulatory and legal documents.

Then, requirements management is the process of documenting, tracking, and managing requirements throughout the entire project development life cycle.

In [3], it is noted that this is the process of processing the specified requirements throughout the entire life cycle of the project, from initial planning to final delivery and maintenance.

Requirements management is a continuous process during the project life cycle [4].

Drug development and promotion projects always have three parties [5, 6]: drug manufacturer; pharmacies and medical institutions as intermediaries in promotion; the end users of medicines are patients.

The interaction of the parties in the formation of requirements is manifested through the defense of their interests. This interaction creates some problems. The first and obvious problem is a conflict of interests, at the same time, the requirements for the medicinal product must be formed on time and in full. There is still no universal solution to this problem [7]. In various professional literature, various recommendations are given for smoothing the conflict of interests: from strict formalization of the requirements and duties of each party to the assignment of the role of an arbitrator who will decide whether the requirement should be fulfilled and be responsible for this decision.

In practice, decision-making often rests with the developer of the medicinal product, while the interests of other participants will not be taken into account. The absence of allowed "limits" of responsibility for decision-making leads to another problem of requirement's management – non-compliance with drug development deadlines or their delay. The development team sometimes tries to attract experts to objectively evaluate the requirements, since the implementation of part of the requirements can have a slight effect on the relatively high development cost. Sometimes the customer, putting forward its requirements to the development team, may not notice that it goes beyond the "framework" of the legislation or ethical medical norms [8]. Of course, the project manager must take these features into account.

Another problem in claims management is the complexity of their collection and consolidation. This problem is more subjective than all previous problems.

Therefore, it is possible to conclude that there are key problems of requirements management in marketing projects [9]:
– conflict of interests;
– non-acceptance of responsibility;
– subjectivity of assessment of requirements;
– violation of development terms;
– complexity of collection and consolidation.

The list of all requirements management problems does not end here and can be continued. At the same time, in the theory and practice of management, there are a number of ways to solve the above problems. The main mission of requirements management is to approve changes, not to avoid them [7]. Expected results from requirements management can be considered:
– increasing the efficiency of project management and increasing the accuracy of project control;
– increasing and maintaining the ability to track the project at all stages;
– increasing the efficiency of reuse of the developed project products;
– improving the awareness of project stakeholders.

The aim of research is to identify the influence of the external environment of the marketing project on its requirements and to develop an intelligent model for managing the requirements of the marketing project of the pharmaceutical industry. This will make it possible to collect and form such requirements for the product of the project of creating a new medicinal product, which will satisfy the expectations of all interested parties of the project of creating such a product.

2. Materials and Methods

"Intelligent management model" emphasizes that the model itself is intelligent or uses intelligent methods and elements of artificial intelligence, analytics, machine learning to make decisions or optimize management processes.

In [10], the intelligent model was applied in the control system of a high-speed moving object using a wandering diagnostic core to determine failures and inaccuracies in the knowledge base.

The authors of the paper [11] described the use of intelligent models in enterprise management systems. Intelligent models are needed to make high-quality innovative decisions in tasks when the management situation is problematic, while the decisions must be thorough and effective.

The analyzed sources [10–13] showed the relevance of the intelligent model in increasing the efficiency of management of complex systems.

Next, let's present the results of designing an intelligent model.

An intelligent management model is a complex system that ensures effective decision-making and optimization of processes in the organization. It consists of entities, attributes, connections, processes, interactive and intelligent components, an evaluation and improvement module.

Entities include: management object, data, data models, decision-making models, analytical tools, stakeholders, etc.

Attributes include: management goal, key performance indicators (KPI), limitations.

Connections. These are usually connections between data, between data models and decision-making models, between the management object and stakeholders, between analytical tools and data models.

The processes of the intelligent model can include: data collection, data processing and storage, data analysis, decision-making procedure, monitoring and control.

Interactive components of the intelligent model are user interfaces and feedback.

Intelligent components include: machine learning and other artificial intelligence systems, expert systems, decision support systems.

By the evaluation and improvement module let's understand the periodic verification of the achievement of goals and the effectiveness of the decisions made.

For a pharmaceutical company planning the development of new drugs, the intelligent model of requirements management of marketing projects will include specific elements and tools that will help to analyze the local drug market and form requirements for the project of creating new drugs. Below is a *detailed structure of the model with specific tools and facilities for each element.*

The essence of the model:
– object of management – marketing projects aimed at the development of new medicinal products;
– data – information about the local drug market, competition, consumer needs, regulatory requirements, etc.;
– data models – drug market database, patterns of consumer behavior, ontologies of pharmaceutical products;
– decision-making models – algorithms for market opportunity assessment, risk analysis, demand forecasting;
– analytical tools – programs for data collection and analysis, artificial intelligence systems, machine learning programs;
– stakeholders – company management, marketers, researchers, regulatory bodies, end consumers (doctors, patients, pharmacies).

Model attributes:
– the goal of management is to create competitive medicines that meet the needs of the market;

– key performance indicators (KPI) – market share, level of consumer satisfaction, sales volume, compliance with regulatory requirements;

– limitations – financial framework, development terms, technological limitations, regulatory requirements.

Connections: between data; between data models and decision-making models; between the object of management and stakeholders; between analytical tools and data models.

Model processes:

– data collection – use of web scraping tools to collect data on the drug market;

– data processing and storage – use of cloud solutions for data storage and processing;

– data analysis – application of data analysis tools such as Python and R for statistical analysis;

– decision-making;

– monitoring and control of project implementation.

Interactive components: user interfaces; feedback – provision of mechanisms for feedback from stakeholders.

Intelligent components: machine learning and artificial intelligence – the use of machine learning algorithms to predict the demand for new drugs, neural networks for analyzing big data; expert systems; decision support systems based on big data.

Assessment and improvement of the model: performance assessment – regular assessment of KPIs using analytical tools to monitor project performance; model improvement – constant updating and adaptation of management models based on feedback and new data.

So, *the object of research* is the processes of managing the requirements of the marketing project using means of intelligent data analysis and artificial intelligence systems.

3. Results and Discussion

The structure of the intelligent model of requirements management of marketing projects contains modules or blocks that perform certain functions, provide integrity and a comprehensive approach to requirements management. The following structure of the intelligent model is proposed in the paper (Fig. 1).

Let's note that not all logical connections between blocks are indicated on the structural diagram in order not to clutter up the figure.

There are two types of components in the model. The first type are structural elements that do not perform any function, but reflect the state of the system or its components. The second type is blocks in which certain processes or functions are performed to obtain the planned result. All the components of the scheme have end-to-end numbering.

The input of the model (on the left) is a request for the creation of a new drug (shown in the diagram as structure element No. 4, E4), which comes from outside the project, from the local market of drugs and medical services E2 and from the national community E3, which needs new modern drugs means A request for the creation of a new medicinal product can be initiated by the pharmaceutical enterprise itself [14], taking into account the world's latest developments (E1).
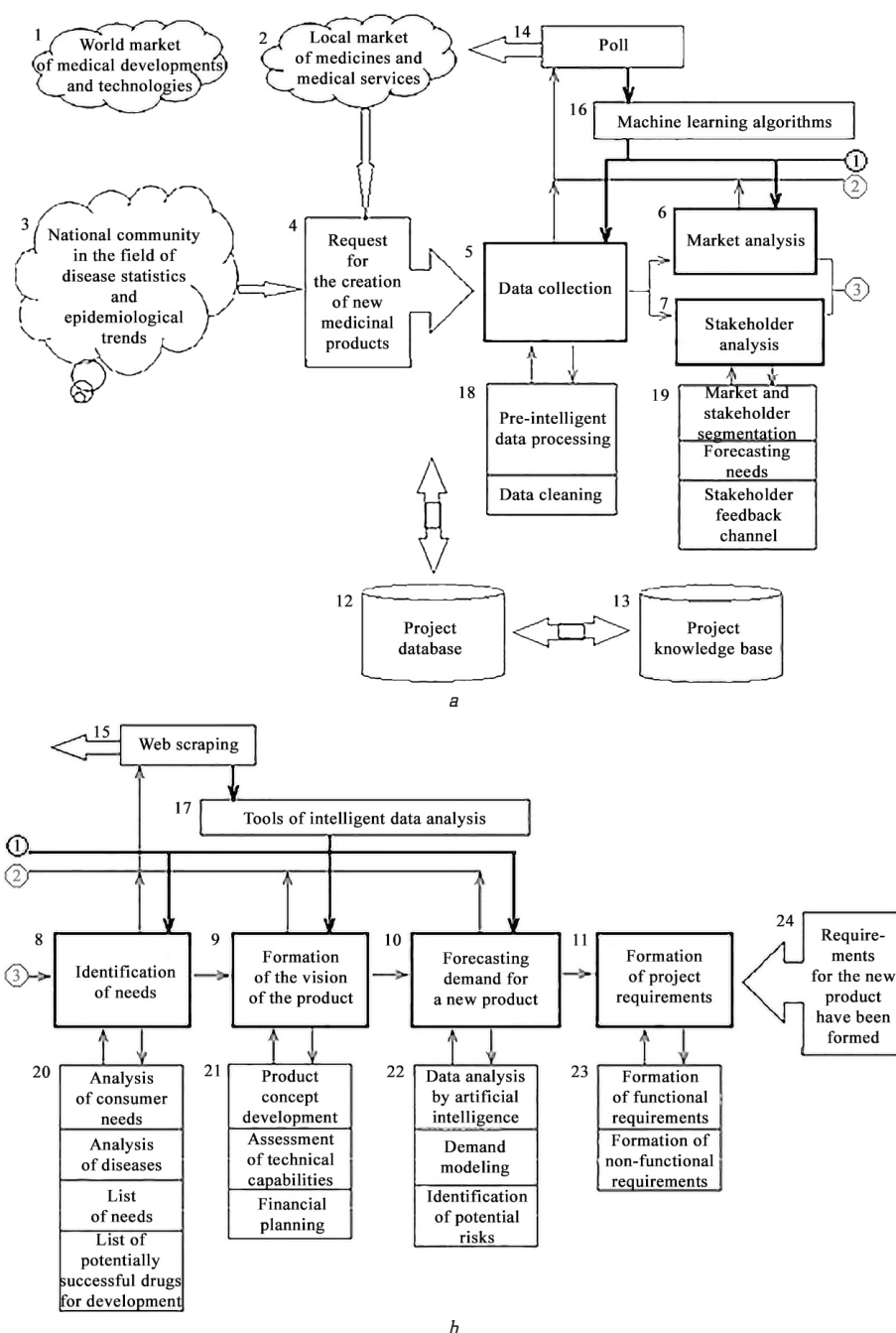

Fig. 1. An intelligent model for managing the requirements of marketing projects of the pharmaceutical industry: *a* – the beginning of the model; *b* – the end of the model

The output of the model (on the right) is the formed requirements for the new medicinal product and for the project (E24) thanks to intelligent tools and means. This project will be implemented at a pharmaceutical enterprise.

Blocks B6–B11, databases and knowledge of the marketing project B12, B13 will participate in the implementation of the end-to-end process from the request for the creation of requirements for a new medicinal product to the formed requirements for a new medicinal product and for the project. Blocks B14, B15 take part in auxiliary processes for analyzing the external environment in the form of a classic stakeholder survey [15]. And also, in the form of automated data collection and analysis on sites and social networks as auxiliary elements, machine learning algorithms and E16 and E17 data intelligence tools are added to them, respectively. Elements E18–E23 specify or clarify the tasks of the end-to-end process blocks.

Next, the blocks of the end-to-end process are considered. Data collection and processing block B5 includes data collection from the local pharmaceutical market, their processing and cleaning for further analysis. For this, they use the blocks of auxiliary processes of surveying and web scraping B14 and B15 and cloud or local databases and knowledge bases B12, B13. Data cleaning and preparation, or ETL processes (Extract, Transform, Load), E18 are used to ensure data quality.

Market Analysis Block B6 is responsible for analyzing the collected data to identify trends, needs and gaps in the market. The main submodules include E19:

– analysis of competitors, study of their products and their positions on the market;

– analysis of supply and demand, identification of current and forecasted market needs;

– segmentation of the market, dividing it into segments according to various criteria (age, diseases, etc.).

Stakeholder Analysis Block B7 identifies key stakeholders and their expectations for new medicines. Submodules of the block include (E19): identification of stakeholders; analysis of their expectations, collection and analysis of their requirements; communication with stakeholders.

Identification of Needs Block B8 forms a list of drugs that are in short supply on the market and analyzes the needs of end users. It includes (E20): analysis of consumer needs through B14 and B15; analysis of disease statistics; formation of a list of needs, determination of drugs for development through B16 and B17.

Product Vision Formation Block B9 develops the concept of a new medicinal product, taking into account the collected requirements and capabilities of the enterprise [16]. It includes (E21): development of the product concept and its characteristics; assessment of the technical capabilities of the pharmaceutical enterprise; financial planning and project budget estimation.

New Product Prediction Block B10 uses artificial intelligence and machine learning to analyze data and predict the success of a new product, as shown in [17]. Its submodules include (E22): data analysis; forecasting demand for a new product; identification and analysis of potential risks.

Project Requirements Formation block B11 transforms all collected data and analysis results into project requirements for the creation of a new medicinal product. It includes (E23): definition of functional and non-functional requirements; their documentation, creation of technical documentation.

Thus, in Block 11, the end-to-end process of forming requirements is completed. The requirements for the project of creating a new medicinal product using the tools of intelligent analysis and artificial intelligence systems have been formed (E24).

For the practical application of the developed intelligent model of management of requirements of marketing projects of the pharmaceutical industry, it is necessary to develop an algorithm for the formation of requirements, or a method. Nevertheless, the resulting model can be used as a task statement for the formulation of requirements for project managers of marketing projects [18, 19] of the pharmaceutical industry.

A fairly narrow list of marketing projects can be considered a limitation of the research. The work considered only marketing projects implemented at an existing pharmaceutical enterprise when creating new drugs for the local market. For other groups and types of marketing projects, the obtained research results will not be effective.

The conditions of martial law in Ukraine, namely long blackouts and restrictions on the distribution of commercial and legal information, did not allow the full use of big data on the Ukrainian drug market in accordance with the feedback and expectations of drug users.

The perspective of further research is the development of a method of forming such requirements for marketing projects, taking into account all the patterns and relationships identified in the model, so that the project product created according to these requirements "sells itself" [20].

4. Conclusions

The work presents a developed intelligent model for managing the requirements of marketing projects of the pharmaceutical industry. Within the scope of the marketing projects considered in the work, it is necessary to analyze the local drug market and determine the list of drugs that are not available on it, taking into account the fact that the enterprise that initiates them was able to develop them. Based on this, it is necessary to formulate the requirements for the creation of such medicines. This task is multi-criteria and depends on many factors that may contradict each other. Therefore, the model assumes the use of tools for intelligent data analysis using artificial intelligence systems. The model is essentially an intelligent system for supporting project decision-making. The peculiarity of the model is that it uses artificial intelligence and intelligent data analysis to search for the necessary data, and on their basis conducts market and stakeholder analysis, based on the results of which options for new drugs are formed. A distinctive feature of the model is that it uses an end-to-end process to generate requirements, from identifying the needs of users of these drugs, through forming a vision for new drugs and forecasting demand for them in the local market. Due to the integration of these elements into a single process and the use of intelligent tools, changes can be made at any stage of requirements formation, taking into account all existing criteria and restrictions, while avoiding conflicts of interest.

Thanks to this, the model can cover the investigated problem completely, that is, form such requirements for the product – new drugs, so that they maximally satisfy the wishes and expectations of all project stakeholders. From a theoretical perspective, the research result can be

useful in the sense of expanding knowledge for intelligent management models.

On a practical level, the model can become an effective tool for managers of marketing projects aiming to research the market and the external environment of the project to form requirements for the next project in which the creation of a new medicinal product is planned.

Conflict of interest

The authors declare that they have no conflict of interest in relation to this study, including financial, personal, authorship, or any other, that could affect the study and its results presented in this article.

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Data availability

Data will be provided upon reasonable request.

Use of artificial intelligence

The authors confirm that they did not use artificial intelligence technologies when creating the presented work.

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