

UDC 330.341.1

DOI: 10.15587/2519-4852.2024.303060

DIRECTIONS OF IMPROVING MANAGEMENT OF INNOVATIVE ACTIVITIES IN PHARMACEUTICAL COMPANIES

Sanjay Kumar Nayak, Olga Posilkina, Olena Litvinova

The purpose of the work is to substantiate theoretical provisions and practical recommendations for improving the management of innovative activities of pharmaceutical companies (PC) for the implementation of strategic tasks regarding innovative development and increasing competitiveness.

Materials and methods. To achieve the goal of the study, scientific sources on innovation management and intellectual property management and the peculiarities of the organization of innovation processes in pharmacy were analyzed. When conducting research, methods of information search, systematization, comparison, and generalization were used, as well as the method of expert evaluations, taxonomic analysis, and a graphic method to increase the clarity of the presentation of the material.

The results. The main directions and features of innovative activity in pharmacy have been studied. A generalized algorithm for managing innovative activities in pharmaceutical companies is given. The relevance of evaluating and managing the innovative potential of PC to achieve a synergistic effect from the use of resources involved in innovative activities is substantiated. A structural model of the innovative potential of PC is proposed, which considers the peculiarities of the flow of innovative processes in pharmacy, related to the development and introduction of new pharmaceuticals to the market. A methodical toolkit for quantitative and qualitative evaluation of the innovative potential of PC has been defined. To improve the management of the PC's innovative activity, a methodology for determining the range of management decisions is proposed based on the results obtained in the framework of creating a report on the patent landscape.

Conclusions. In order to achieve the provision of effective and safe domestic drugs to the population of Ukraine, it is necessary to intensify research in the direction of the formation of an effective system of management of the innovative activity of pharmaceutical companies (PC), focused on their gradual transition to an innovative development model. The conducted analysis showed that despite a sufficiently large number of publications devoted to the problems of innovation management, issues related to the problem of forming an effective system of managing the innovative activity of PCs, as well as choosing an effective toolkit for evaluating and managing their innovative potential, taking into account the specifics of the flow of innovative processes in pharmacy, remain insufficiently disclosed and require further research. The proposed structural model of the innovative potential of the FC, a justified methodological toolkit for its assessment, as well as the construction of a cognitive map to determine the most appropriate key components and directions for further improvement and development of the innovative potential will contribute to increasing the efficiency of the innovative activities of enterprises and the implementation of the goals of the innovation strategy. The developed algorithm of preventive management of innovative activity of the PC, aimed at improving the quality of decisions made on innovation management thanks to the use of patent landscape tools, will also contribute to the faster entry into the market of domestically produced innovative medicinal products

Keywords: pharmaceutical industry, pharmaceutical enterprise, innovation activity, innovation process, innovation potential, assessment methods, patent strategy, toolkit of patent landscapes

How to cite:

Nayak, S. K., Posilkina, O., Litvinova, O. (2024). Directions of improving management of innovative activities in pharmaceutical companies. ScienceRise: Pharmaceutical Science, 2 (48), 90–102. doi: <http://doi.org/10.15587/2519-4852.2024.303060>

© The Author(s) 2024

This is an open access article under the Creative Commons CC BY license hydrate

1. Introduction

The pharmaceutical industry is the most high-tech and science-intensive industry in the world economy, with a share of research and development costs in total sales of more than 14 %. At the same time, the companies, the leaders of the world pharmaceutical market, plan to increase R&D expenditures by another 30 % by 2026 [1, 2].

Creation of innovations in pharmacy, especially in the treatment of non-infectious diseases, has a favourable effect on the health and quality of life of patients. How-

ever, the availability of innovative medicines is a serious problem worldwide in the context of the COVID-19 pandemic, the global economic crisis, the aging population, and the increase in the number of non-infectious diseases.

At the same time, according to foreign experts, the number of new drugs approved in the US every year has increased only marginally in recent decades, while research and development costs have become incomparably higher. It is noted that the cost of pharmaceutical innovation has reached gigantic proportions – bringing a

new drug to the market costs more than 1.3 billion US dollars (direct costs), and the amount of capitalized costs for one drug is more than 2.5 billion dollars. Since only one of the many drugs being created turns out to be successful, the final cost of one successful drug consists of the costs of all other studies [3–7].

Table 1
Spending on R&D of the world's leading PCs [1]

Company	Expenditures on R&D, billion US dollars	
	2019	2026
Roche (Switzerland)	10.3	12.9
Merck & Co (USA)	8.7	11.0
Johnson & Johnson (USA)	8.8	10.7
Novartis (Switzerland)	8.4	9.7
Pfizer (USA)	8.0	9.7
Bristol-Myers Squibb (USA)	5.9	9.4
GlaxoSmithKline (United Kingdom)	5.5	7.6
AstraZeneca (United Kingdom)	5.3	7.5
AbbVie (USA)	5.0	7.3
Eli Lilly (USA)	5.6	7.0
Total	71.5	92.8
Others	114.5	139.7
All in total	186.1	232.5

Among the main problems faced by innovative activity in pharmacy today, experts include the difficulty of predicting the final success of innovative projects, high regulatory requirements, shortening of the effective term of patenting, etc. Often, the process of drug development is interrupted at the final stage of clinical trials. Thus, out of 10,000 substances synthesized in laboratories, only 1–2 successfully pass all stages of testing and enter the pharmaceutical market in the form of ready-made drugs. And even if all phases of clinical trials have been successfully completed, the decisive decision to bring the final product to the market is beyond the competence and influence of the PC, which fundamentally distinguishes the life cycle of innovative drugs from the products of other science-intensive industries. In addition, the duration of the period of clinical trials and the terms of consideration of their results by regulatory bodies significantly reduced the effective term of patenting, when the drug already brought to the market is still under patent protection [5, 8].

Thus, even half a century ago, the 20-year patent period was significantly longer than the time necessary for companies to conduct clinical trials and reach agreements with regulators. Instead, now the market entry of one innovative pharmaceutical product is preceded by 12–13 years of research, due to which a significant part of the exclusivity period is lost, and therefore the profitability of the developed drug is reduced.

Scientists single out the following reasons for the decline in the effectiveness of pharmaceutical innovation: exhaustion of “low-hanging” fruits: the industry's successes led to the emergence of effective drugs for many common diseases, and further progress is aimed at very complex and often rare diseases. Moreover, the in-

crease in the cost of drugs does not always reflect their clinical benefits and negatively affects the availability of innovative pharmacotherapy for the population [8, 9].

The increasing role of biotechnological drugs, as well as orphan drugs, which are admitted to the market every year, should be attributed to the trends of innovative activity of PC and the specifics of pharmaceutical innovations. In addition, in recent years, the focus of PC has shifted towards the specialization of activities: there is a narrowing of the research profile, increased interaction with contract research organizations, small and medium-sized companies, and state research institutes [1, 10, 11].

According to pharmaceutical market experts, Ukrainian companies seeking to withstand competition and develop need to constantly invest in R&D, particularly in the following three main areas: product portfolio expansion, process automation and digitalization, and staff training [2, 12, 13].

Therefore, it can be argued that innovative activity in pharmacy differs from the development of innovations of a general nature in specific aspects, which requires adaptation of the general provisions of innovation management to the peculiarities of management of innovative processes in the pharmaceutical industry.

Therefore, in order to achieve the provision of the population of Ukraine with effective and safe domestic drugs, it is necessary to intensify research in the direction of the formation of an effective management system for the innovative activity of FC, focused on achieving the target indicators of innovative development, capable of levelling the influence of internal and external negative factors and which will meet the set tasks and target orientations of the innovation strategy companies

The study, understanding and analytical evaluation of the works of foreign and domestic authors allow us to draw a conclusion about the undeniable presence of scientific interest in the management of innovative activities of enterprises in the conditions of a market economy. At the same time, despite considerable research experience and considerable study of the problems of innovation management, it should be noted that the issues related to the formation of an effective system of management of innovative activity in the pharmaceutical industry, as well as the selection of an effective toolkit for evaluating and managing the innovative potential of PC require further developments.

Thus, the complexity and multifacetedness of this problem, as well as its high practical significance for replenishing the assortment of innovative domestically produced pharmaceuticals, determined the choice of the research topic.

The aim of the work is to substantiate the theoretical provisions and practical recommendations for improving the management of innovative activities of pharmaceutical companies to implement the strategic tasks of their innovative development and increase competitiveness.

2. Research planning (methodology)

The following research plan has been developed:

– determination of the features of innovative activity in pharmacy and the specifics of innovative processes re-

lated to the development and introduction of pharmaceuticals to the market, and their further consideration in the process of developing scientific and practical principles for improving the management of innovative activity of PC;

- substantiation of the need to manage the innovative potential of FC on the basis of its objective assessment for choosing an appropriate innovative strategy and diagnosing promising directions for its development;

- analysis and generalization of theoretical and scientific-practical approaches to determining the structure and methods of evaluating the innovative potential of PC;

- formation of a system of local indicators based on the components of the innovative potential of FC, taking into account the features of innovative processes for the creation of new pharmaceuticals;

- development of an algorithm for calculating the complex and integral indicator of the PC's innovative potential;

- justification of the expediency of building a cognitive map based on the determination of correlations between indicators characterizing the innovative potential of PC, to determine the priority directions of its development and develop the map on the example of one of the investigated PC;

- development of an algorithm for preventive management of the innovative activity of PC with the application of patent landscape tools to improve the quality and validity of decisions on the management of pharmaceutical innovations.

3. Materials and methods

Research was conducted using databases on the Internet: the European Center for Information Systems Research, the European Medicines Agency, the State Statistics Service of Ukraine, scientific and metric databases – Scopus, Web of Science. The search was conducted using keywords: innovation activity, innovation process, innovation potential, assessment methods, patent strategy, toolkit of patent landscapes.

Following research methods were used: logical, systematic analysis, comparison, generalization, graphic, expert, and statistical methods and methods of taxonomic and correlational analysis.

When developing theoretical and scientific-practical approaches to determining the essence, structure, and methods of evaluating the innovative potential of PC, logical and systematic methods and the method of content analysis were used. Content analysis was also used in the justification of the system of local indicators for assessing the innovative potential of PC.

Methods of comparison and generalization were used to determine the features of innovative activity in the pharmaceutical industry.

The graphic method was used to visually present the research results.

The expert method was used to form a system of local indicators based on the components of the innovative potential of PC. The collection of information was carried out by the method of a standardized expert survey. The formation of the group of experts took place with the in-

volvement of representatives of the scientific field and practical pharmacy. The choice of the method of assessing the degree of competence of experts and the establishment of the minimum necessary number of the expert group were carried out using statistical research methods based on the methodology [14]. The level of agreement of expert assessments was determined using coefficients of variation and concordance. Pearson's test was used to assess the significance of the concordance coefficient.

The taxonomic method was used to calculate complex and integral indicators of PC innovation potential. Correlation analysis was used in the process of determining the indicators that have the most significant impact on the level of innovative potential of PC, to build a cognitive map.

4. Research results

Innovative activity in pharmacy differs from the development of innovations of a general nature by specific aspects of conducting preclinical and clinical research, strict regulatory frameworks, the presence of legal liability problems, high cost and high probability of risks and failures.

And, if for most industries, depending on the depth of the changes, innovations are divided into radical (basic), improving and modifying (partial). In pharmacy, most researchers, based on modern ideas developed in the world pharmaceutical industry, use the classification of pharmaceuticals in view of their innovativeness, according to which all drugs can be divided into 3 groups: original pharmaceuticals, generics, and other pharmaceuticals (phyto-, homeopathic drugs, combined drugs). In the composition of original drugs, the priority of which is determined by their patent protection, innovative drugs and analogue drugs are distinguished, the latter are divided into drugs with signs of innovation and pseudo-innovation (me-too). However, innovativeness is not a constant feature, and analogue drugs because of their use and disclosure of pharmacotherapeutic potential can receive the "title" of innovation either in the basic or in a new field of application. At the same time, medicinal products that were previously innovations are losing their positions and moving into the category of analogue drugs. The last statement is valid when it is necessary to clearly differentiate drugs that have grounds for priority registration consideration, priority appointment, inclusion in reimbursement programs, etc. [2, 15].

Implementation of PC innovation activities can take place in different directions (Fig. 1).

Therefore, in order to achieve the provision of effective and safe domestic drugs to the population of Ukraine, it is necessary to form an effective management system for the innovative activity of PC, considering its specifics, and which will be oriented towards achieving the target indicators of innovative development, capable of levelling the influence of internal and external negative factors, and which will meet the tasks and target orientations of the company's innovative strategy.

The management of innovative activities of the PC should involve the implementation of certain stages (Fig. 2).

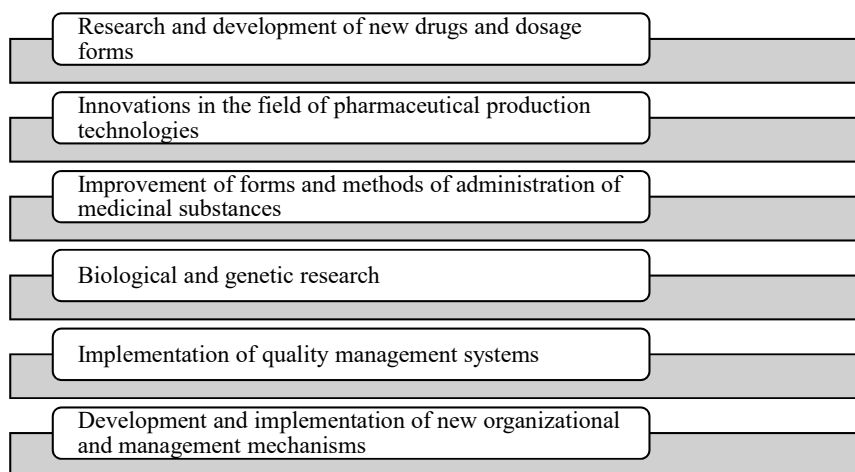


Fig. 1. The main areas of implementation of innovative activities of PC

As can be seen from the given algorithm, the first stage of managing the innovative activity of the PC should be the assessment of its innovative potential, that is, the determination of the level of innovative resources and opportunities, the analysis of the ability to use them effectively.

At the same time, an assessment of the favourable market situation should be carried out, because when developing both the general PC strategy and when choosing an innovative strategy, it is necessary to consider the threats and opportunities of the macro environment.

Based on the obtained evaluation results, the stage of the PC life cycle is determined, which is an important intermediate stage of management, because it makes it possible to choose the vector of further innovative development of the company based on the generation of the influence of internal and external environmental factors

The second stage – planning and forecasting, involves determining the long- and short-term goals of the innovative development of PC, forming an innovative strategy considering the stage of its life cycle.

The construction of these plans should consider the expected changes in the macro-environment of the enterprise; therefore it is

necessary at this stage to use modern economic-mathematical, statistical methods and models in order to construct accurate and reliable forecasts.

The organization stage involves the implementation of measures to achieve the goals of the selected innovation strategy. At the same time, it is necessary to constantly adjust the innovation strategy depending on changes in the external environment, which requires permanent monitoring of the market situation.

The final stage of the management of innovative activities of the PC is constant control over how successfully the innovative strategy is implemented and how effective the measures (projects) are aimed at achieving the goals of innovative development.

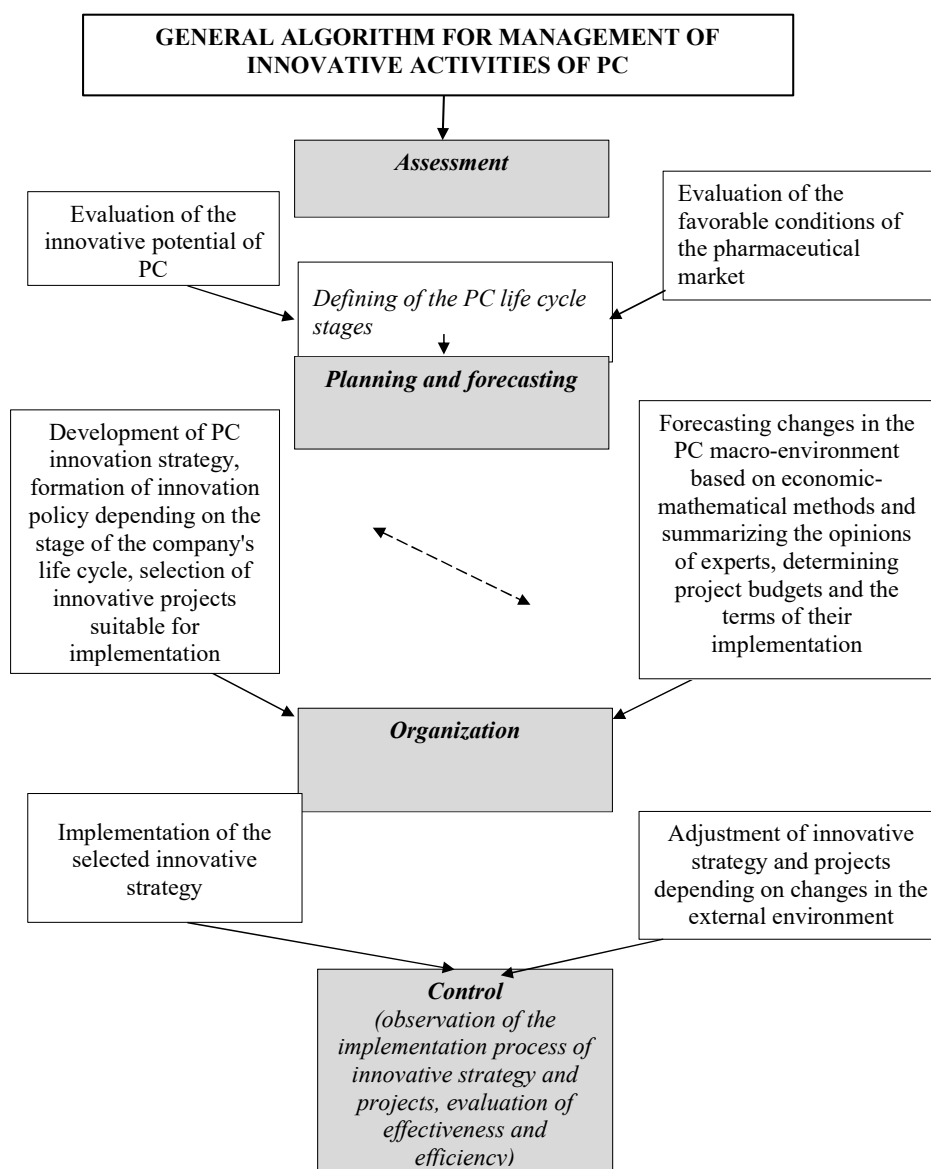


Fig. 2. Generalized algorithm for managing innovative activities of PC

Thus, it can be noted that the basis of effective innovative activity of any PC is its presence of sufficient innovative potential, which we consider as a set of knowledge, skills, technologies, equipment, organizational and management mechanisms, and other resources that can be used for development, production, and successful introduction of innovative pharmaceutical products to the market. It is the development and effective management of innovative potential that is a key condition for the creation of new, more effective, and safer pharmaceuticals.

Effective management of the PC's innovative potential involves its comprehensive assessment, which is due to several reasons:

- understanding the level of innovative potential of PC, the sufficiency of resources, strengths and weaknesses of the potential is the basis for forming a balanced innovative strategy and creating competitive advantages on the market;

- the results of the assessment and diagnosis of the innovative potential of PC significantly increase the flexibility of choosing innovative projects suitable for implementation from several available alternatives, choosing intellectual property objects created at the enterprise suitable for further commercialization;

- the presence of a strong innovative potential in PC is an important condition for increasing its investment attractiveness and attracting the necessary investments;

- on the basis of an objective assessment of the innovation potential existing in the PC, its opportunities for timely identification and prevention of certain risks related to the implementation of the innovation strategy are improved;

- the presence of appropriate innovation potential in the PC contributes to the development of partnership relations, increases the opportunities for participation in public-private partnership programs, the conclusion of effective partnerships with universities, research institutions and other stakeholders;

- the presence of appropriate innovative potential in PC and its skilful positioning significantly increases the market value of the company, its market capitalization.

In our opinion, the theoretical and methodological basis for evaluating the innovative potential of PC should be based on the main provisions of the theory of evaluation of economic systems [16], taking into account certain principles of evaluation (objectivity, complexity, systematicity, structuredness, continuity and flexibility, adaptability, effectiveness, determinism, comparison), the selection of adequate methods of potential assessment, which would take into account the specifics of innovative activity of PC, the justification of the appropriate structure (components) of the innovative potential of PC, the construction of a system of local indicators based on the components of innovative potential.

Based on the results of the analysis of existing approaches to the assessment of the innovative potential of enterprises, it was determined that scientists use various assessment methods, depending on the goals of the assessment, the sphere of activity of the enterprises, etc. (Table 2).

In our opinion, considering the multifaceted nature of innovative activity of PC, the innovative potential should be evaluated based on the principles of the system approach, when the synergistic interaction of the components of the innovative potential contributes to the emergence of new qualitative characteristics of the innovative PC system as a whole. The emergence of the synergistic effect of the innovation system is caused by the mechanism of combination, interaction, and intersection of various resources of the innovative potential of the PC. Considering the above, in our opinion, the most appropriate way to assess the level of innovative potential of PC is to use the method of integral assessment based on taxonomic analysis. The expediency of such a choice is due to the fact that the taxonomic analysis allows solving the problem of ordering the multidimensional system of local indicators in accordance with the normative vector-etalon and provides an opportunity to “collapse” the multidimensional statistical matrix in relation to local indicators that characterize the innovative potential of PC by various components, into a single quantitative characteristic that allows to obtain a summary assessment and contributes to increasing the efficiency of management of innovative activities.

The development of methodological approaches to the evaluation and management of the innovative potential of PC also requires the definition of its structure. As the analysis showed, as structural components of the innovative potential of companies, depending on the field of their activity, scientists single out [22–26]: material and technical; financial (financial and economic), marketing, organizational, organizational and managerial), personnel, information components.

But, in our opinion, for pharmacy, which has significant features regarding the organization of innovative activities and the nature of the flow of innovative processes, associated with the presence of certain specific stages (pre-clinical biological research of the active pharmaceutical ingredient (API); development of quality control methods (QCM) of API and other non-biological studies; preclinical biological study of the drug; clinical trials of the drug (I, II, III phases of clinical trials); choice of drug form and composition development; development of the QCM of medicines; study of drug stability; scaling of the production technology of drug products; preparation of documentation (registration file) and registration of medicinal substances and drugs; post-marketing clinical trials of drugs, etc.), on each of which scientific research is carried out (Fig. 3), the scientific research component should be an important component of the structure of the innovative potential of PC.

The proposed scheme of the structure of PC innovation potential is shown in Fig. 4. When justifying it, we proceeded, firstly, from the fact that the number of components should not be too large, which will complicate the evaluation process, secondly, the results of content analysis of publications of leading experts on the management of innovative activities in pharmacy were taken into account, as well as the opinions of industry experts regarding the importance of these components from the point of view of managing the innovation potential of PC itself.

Table 2

Methodical approaches to the assessment of innovation potential (summarized according to the data [17–21])

Method name	Calculation mechanism
Integration of partial indicators of the innovative potential of the enterprise into a complex indicator by applying weighting coefficients of partial indicators	$P_{LIP} = U_{CE} * K_{10} + G_p + K_{11} + K_{12},$ <p>where P_{LIP} – the level of innovative potential; U_{CE} – a general indicator of the frequency and effectiveness of innovation implementation by enterprises; G_p – an indicator of the readiness of the company’s employees for changes; K_{10} – the coefficient of weight of the generalized indicator of the frequency and effectiveness of the enterprise’s implementation of innovations; K_{11} – the weighting factor of the indicator that characterizes the innovative potential of the enterprise; K_{12} – the weighting factor of the indicator of the readiness of the company’s employees for changes</p>
The methodology is based on the determination of the annual specific weight of the enterprise in the areas of innovative activity, including financing and implementation of innovative products because of innovative activity and production	$K_{ec.ret.} = \frac{Q_{s.innov.pr.}}{Q_{in.act.fin}},$ <p>where $K_{ec.ret.}$ – coefficient of economic return of financing innovative activities of the region; $Q_{s.innov.pr.}$ – volumes of sold innovative products, UAH; $Q_{in.act.fin}$ – volumes of innovative activity financing, UAH This ratio shows how many hryvnias of innovative products sold per hryvnia of innovative activity financing</p>
Harrington desirability function	<p>The constituent parts of the enterprise’s innovative potential are translated into a dimensionless scale according to the gradation of Harrington’s desirability function. For a group of indicators with a one-sided restriction, the desirability function is determined using the equation:</p> $d(y) = e^{(-e^{-y})},$ <p>where $d(y)$ is a desirability function; e is the root of the natural logarithm equal to 2.7182; y is the coded argument of the desirability function. The formula is used to determine the generalized desirability coefficient:</p> $D = \sqrt[n]{d_1 \times d_2 \times \dots \times d_n},$ <p>where d_1-d_n – the values of the desirability functions for the given factors, determined according to the Harrington desirability scale</p>
The method of functional cost analysis (FCA) makes it possible to calculate and settle on the most competitive alternative innovation, which has the lowest value of the vector wT.E. and wBi and does not need improvement.	<p>The primary stage includes: structuring the task in the form of a hierarchy with levels: goals – criteria – alternatives; construction of matrices of paired comparisons of elements of each level, which allow expressing the relative superiority of one object over another according to their common feature; determination of priority criteria and alternatives for each of them. The next stage is the calculation of the integral priority vector wT.E. alternatives according to the target criterion of technical efficiency. Next, the determination of factor costs for each alternative is provided using the priority vector wBi. The last stage is the calculation of the ratio of vectors wT.E. and wBi and selection by the smallest value of the given vector:</p> $\mathbf{wT.E.} / 3 = \{wT.E. / wB, wT.E. / wB...wT.E. / wB...wT.E. / wB\}^T,$ $i, i1, i1, i2, i2, ij, ij, in, in,$ <p>where i is the factor of the proposed cost reduction; $j=1, n$ is the serial number of the alternative; n is the number of alternatives of the i-th factor; $wT.E.$ and wBi are the values of the corresponding vectors wT.E. and wBi</p>
Multifactor model of production of new products of the enterprise	$Q = f(A, T, M, I_{ns}, O, I_{nf}),$ <p>where Q – this is a new product created by the system at the expense of the enterprise’s resource potential; $A, T, M, I_{ns}, O, I_{nf}$ – components of potential, respectively: human (A), technical (T), material (M), institutional (I_{ns}), organizational (O) and informational (I_{nf})</p>

When conducting the content analysis, we first examined scientific sources on the issues of management of innovative activity and evaluation of innovative potential, prepared by pharmacy specialists who are well versed in the specifics of the innovative activity of the industry. In addition, during the expert survey, experts with considerable experience in the field expressed their recommendations.

When forming a system of local indicators based on the components of the innovative potential of PC, the features of innovative processes related to the creation of medicines were also considered. As already mentioned, investments in the development of new drugs are high-risk – newly created molecules in most cases do not reach the end users for reasons of efficiency and safety. In this

regard, it makes sense to evaluate not only the indicators characterizing the results of the innovative activity of the PC manufacturer – the number of innovative drugs brought to the market, their share in the company’s sales volume, the renewability of the company’s products (the coefficient of renewal of the range of manufactured drugs), as well as the number of received patents for medicinal products. It is also important to consider the indicators that characterize the process of innovation activity – costs for the development of new drugs and their share in the total amount of company costs, the share of researchers in the company’s staff, as well as the specific weight of special experimental equipment involved in the innovation process. An important indicator, from our point of view, is also the total number of clinical studies of all stages conducted by the company to bring new drugs to the market, including successful and unsuccessful studies, as well as their ratio. It follows from this that the evaluation of the innovative activity of pharmaceutical manufacturers should not be reduced exclusively to indicators of the effectiveness and efficiency of innovative activity but is intended to characterize the intensity of all processes related to the innovative activity of PC.

The final stage of selection of local indicators for evaluating the innovative potential of PC was carried out by us with the involvement of experts based on a previously developed questionnaire. More than 30 specialists who had more than five years of experience in the pharmaceutical industry in the areas of innovative and scientific activity and the field of pharmaceutical development participated in the expert survey. The degree of agreement of experts’ conclusions, which was measured using the concordance coefficient ($W=0.897$), can be recognized as high. The significance of the concordance coefficient was assessed by calculating the Pearson test (χ^2) and comparing it with the tabular value for degrees of freedom $n-1$. Since the calculated value of χ^2 significantly exceeds the tabular value, this confirms that the agreement of the experts’ conclusions is not a coincidence.

According to the proposed algorithm for evaluating the innovative potential of PC, which is shown in Fig. 5, the relevant complex indicators are first calculated by the components of the potential based on the use of the taxonomic analysis method. When constructing taxonomic indicators, a data matrix consisting of standardized implementations of features is used. Standardization

allows you to get rid of units of measurement, both natural and valuable. At the same time, dispersion is equalized [27].

In the future, in order to carry out a generalized quantitative assessment of the innovative potential of PC, on the basis of previously calculated complex taxonomic indicators, the corresponding integral indicator (*Iip*) is calculated for each component. The value of the integral indicator is in the range from 0 to 1: the higher the level of innovative potential of PC, the closer the value of *Iip* is to 1.

The scale proposed in [28] can be used to assess the qualitative zone (level) of the innovative potential of PC.

- high level of innovation potential – $0.75 \leq Iip < 1$ (high supply of PC with innovative resources, implementation of the strategy of active innovative development, leadership in updating technologies and the range of manufactured medicines, active patenting of R&D results);

- satisfactory level of innovative potential – $0.5 \leq Iip < 0.75$ (satisfactory level of provision of PC with innovative resources; for the introduction of new technologies, partial use of loan funds is necessary; PC-follower in the development of new or improving technologies; systematic updating of the range of manufactured drugs, moderate policy of patenting R&D results);

- the level of innovative potential is below average – $0.35 \leq Iip < 0.5$ (a low level of supply of PC with innovative resources; for the introduction of new technologies, a sig-

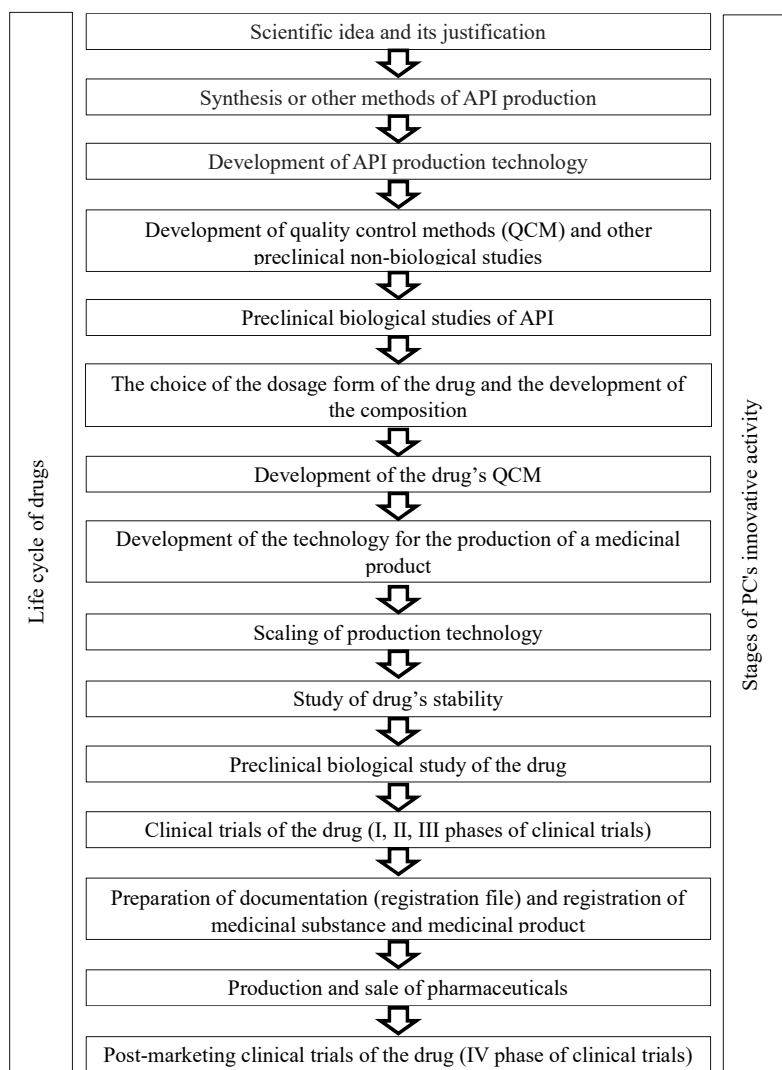


Fig. 3. Stages of innovative activity of PC

nificant use of loan funds is necessary, a follower in the development of improving technologies; updating the assortment due to the development of known generic medicines);

– low level of innovation potential – $Iip \leq 0.35$ (practical lack of resources for innovative activities in PC).

Considering the multifaceted innovative potential of PC in the future, it is advisable to develop measures aimed at increasing those indicators that have the most significant impact on its level and maintain stable positive dynamics in recent years.

For this purpose, it is advisable to apply a correlation analysis between local indicators for all structural components and an integral indicator of the innovative potential of the PC. Further, on the basis of the obtained correlation matrix, statistically significant relationships (at the significance level of $p < 0.01$ and $p < 0.05$) are established between the studied indicators. Establishing the existence of a strong direct correlation between the studied indicators (as evidenced by the pairwise correlation coefficient above 0.8) allows us to determine the key factors in the development of the innovative potential of PC, which should be developed and improved. Provided that the pairwise correlation coefficient between the local and integral indicator is less than 0.5, the indicator is excluded from the next study.

To visualize the relationships between local indicators of various structural components, it is advisable to use a cognitive map of the state of innovation potential [29]. An example of building such a map for one of the domestic PCs is shown in Fig. 6. On this map, arrows show the relationships and influence of each of the indicators. The following regularity was also observed: a high level of the indicator has a positive effect on the interrelated indicators, while at the same time indicators with an average and low level have a negative effect on the level of the interrelated indicators.

To ensure the effective innovative development of PC, it is also necessary to identify promising technologies and developments that will allow creating effective and safe domestic medicines and improving the quality of life of the country’s population. Patent information contained in the databases of national patent offices is a reliable source of data on promising and current technological trends. Expanding the scope of patent analytics is an important factor that creates conditions for the innovative development of key industries of the national economy [30, 31].

To improve the management of innovative activities of PC, we have proposed a methodology for determining the range of management decisions based on the results obtained as part of creating a report on the patent landscape.

Conducting a patent landscape analysis has a number of advantages that are necessary for successful PC innovation. Thus, the analysis of the patent landscape provides an opportunity to learn about commercially valuable solutions in a certain industry and the level of technology in the researched direction, allows you to make informed decisions about the development of pharmaceutical products and helps companies adapt to changes in the industry. In addition, such studies provide an opportunity to identify the main markets and competitors, directions of commercialization of drugs. A careful analysis of the patent landscape helps to avoid intellectual property infringement and reduce the risks of lawsuits. By analyzing the patent landscape, it is possible to identify potential partners for cooperation or technology licensing, which contributes to the faster introduction of new drugs. At the same time, the identification of gaps in the patent landscape indicates new opportunities for the development and implementation of innovative projects.

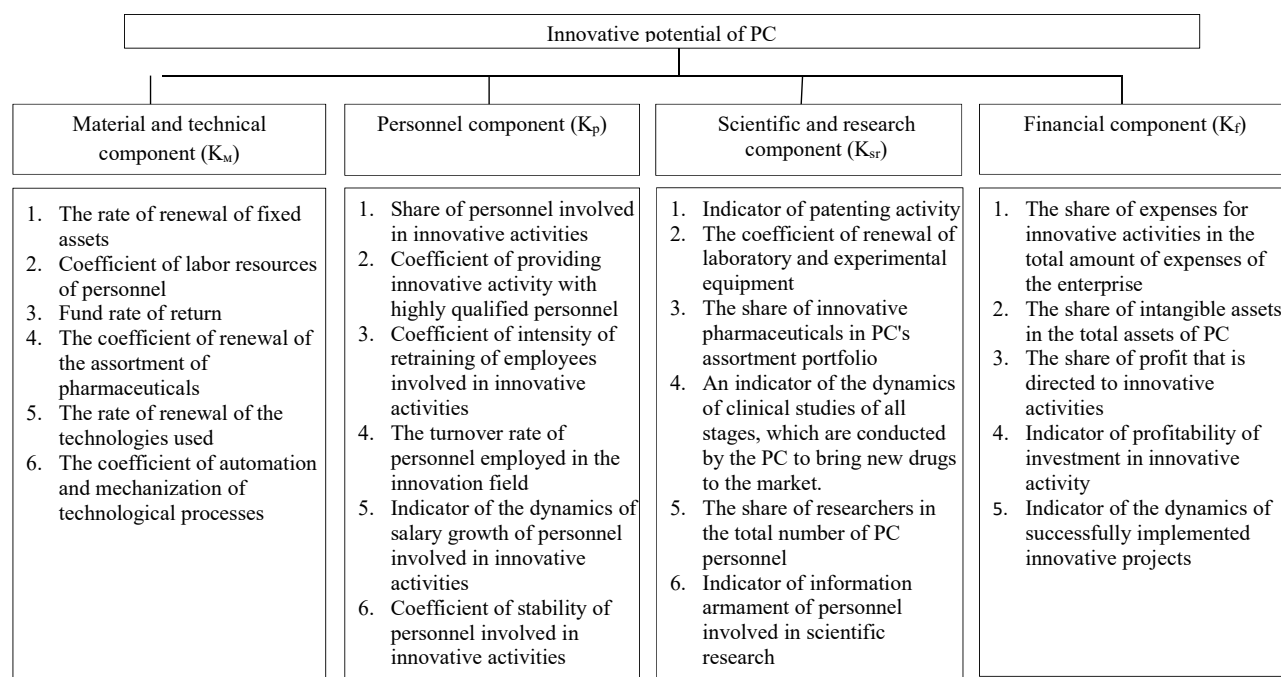


Fig. 4. The proposed structure of PC innovation potential

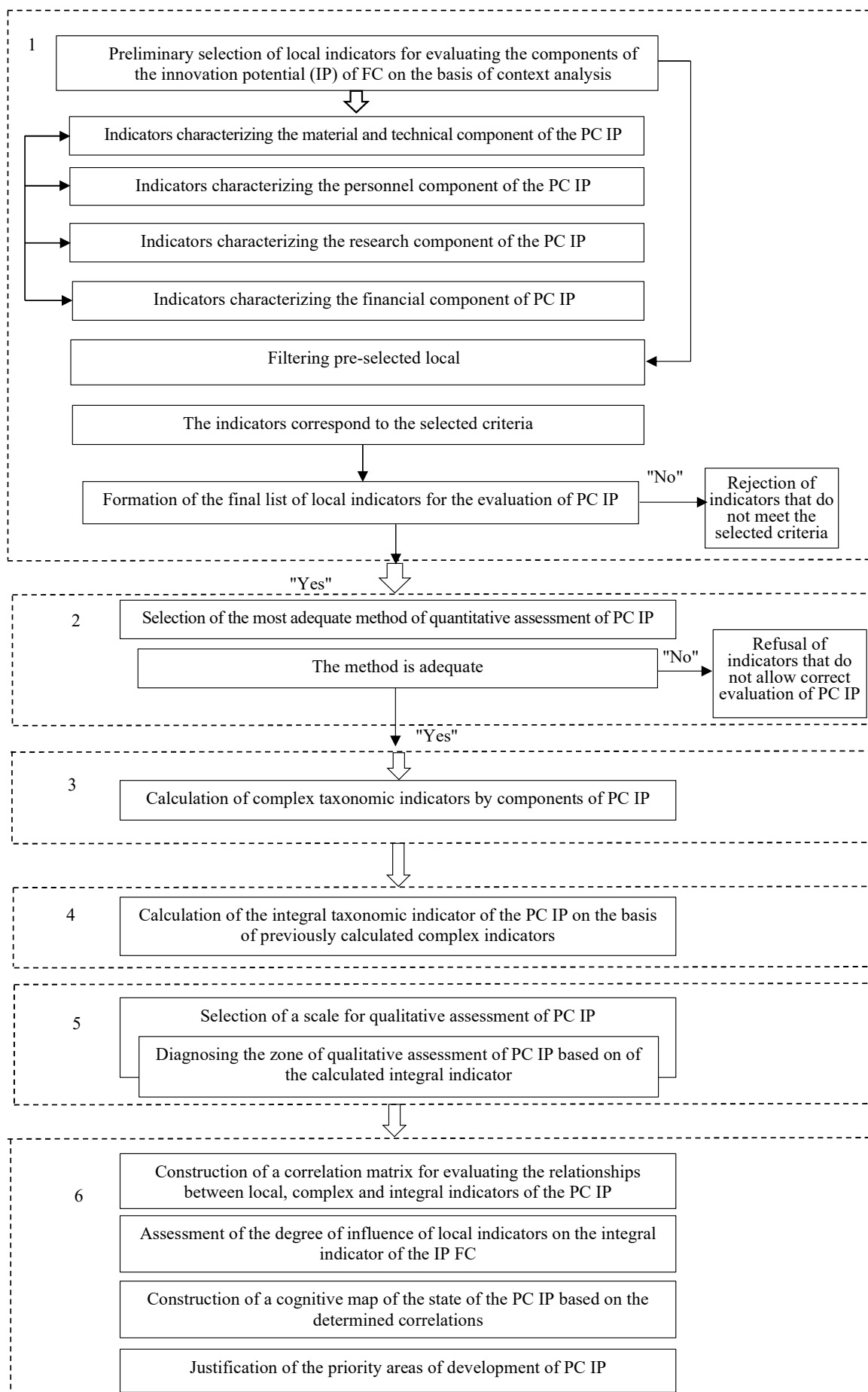


Fig. 5. Algorithm for evaluating the innovation potential of FC IP

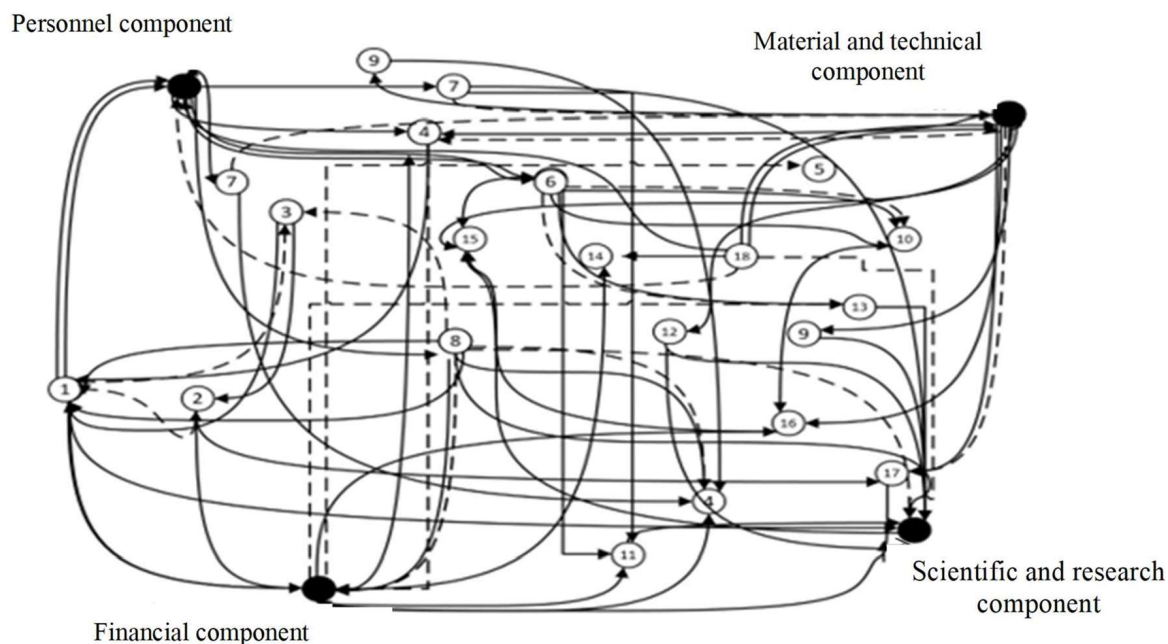


Fig. 6. An example of building a cognitive map of the innovative potential of PC: 1 – the share of profit that is directed to the innovative activity of PC; 2 – coefficient of renewal of PC fixed assets; 3 – coefficient of labour capital; 4 – fund return ratio; 5 – the share of expenses for PC innovation activities in the total amount of expenses; 6 – coefficient of provision of innovative activity of PC with highly qualified personnel; 7 – the share of personnel involved in innovative PC activities; 8 – indicator of the intensity of retraining of personnel involved in PC innovation activities; 9 – coefficient of stability of personnel involved in PC innovation activities; 10 – indicator of profitability of innovative activity; 11 – patenting activity indicator; 12 – factorization of the technologies used; 13 – indicator of information armament of personnel involved in scientific research; 14 – the share of intangible assets in the total assets of PC; 15 – coefficient of renewal of the assortment of pharmaceuticals; 16 – the share of innovative medicines in the assortment portfolio of PC; 17 – coefficient of renewal of laboratory and experimental equipment; 18 is an indicator of the dynamics of clinical studies of all stages, which are carried out by the PC for bringing new drugs to the market

All these factors make the analysis of the patent landscape an indispensable tool for PCs seeking to increase their competitiveness and successfully implement new medicines. The algorithm of preventive management of the PC's innovative activity using the toolkit of patent landscapes is shown in Fig. 7.

As can be seen from the above figure, at the first stage, the collection and analysis of patent information is carried out for the formation of the PC's innovative activity strategy. The subject of the search is determined, keywords and categories of patent classification are formed, and researchers and companies working in the relevant direction are identified. When determining the priority directions for the creation of the drug, it is advisable to also conduct a search in the scientific literature, which provides an idea of the work and achievements in a certain scientific direction and allows conducting a theoretical justification. A distinctive feature of the presented algorithm is the identification of information from non-patent sources (PubMed; the Administration for the Control of Medicines and Food Products, the European Medicines Agency, the State Expert Center, scientific and metric databases, etc.), which should be considered when creating a patent landscape and determining existing patent strategies of competitors. Searching in patent sources provides an opportunity to learn about commercially valuable solutions in a

certain field and the state of the art in the researched area. In the complex, these studies create a complete picture of the technical level in a certain direction of research with a simultaneous forecast of promising directions of research in the future. After that, the collected information is analyzed and the data is systematized in order to assess prospects and identify risks. This stage is crucial for the successful development and implementation of patent applications, since the effectiveness of innovative solutions and the possibility of preventing or minimizing risks depend on the correct analysis of the patent landscape.

At the second stage, the company's innovative development strategy is developed based on the results of the patent landscape analysis. Specific steps and resources necessary for the implementation of innovative projects are planned. Defining an innovative strategy allows the company to clearly define its goals and direction of development, which helps to ensure the successful introduction of pharmaceuticals to the market. Timely and adequate selection of an innovative PC strategy is of great importance in the conditions of fierce competition in the pharmaceutical market.

The stage of conducting scientific research is a key stage in the development of pharmaceuticals, as it provides a scientific basis for the further development of innovations. When working on module 3 of the reg-

istration dossier, it is possible to identify the following patenting objects: active pharmaceutical ingredient, pharmaceutical composition, new dosage form, method of obtaining, process optimization, stability improvement, etc. According to the results of preclinical and clinical studies (modules 4 and 5 of the registration dossier), it is possible to identify the following objects of invention: active pharmaceutical ingredient, pharmaceutical composition, new dosage form, method of treatment, etc. At this stage, legal protection of the development is provided, namely the acquisition of exclusive property rights to inventions, utility models, industrial designs, and trademarks.

At the fourth stage, a registration file is created and the drug is submitted for registration. At the same time, a risk management program (pharmacovigilance plan) is presented to continuously collect safety data after the drug is released to the market. This stage is mandatory for obtaining the necessary permits and legal introduction of drugs on the market. During the implementation of medicine in production, there is commercialization of intellectual property objects, possible transfer of technologies, conclusion of license agreements, monitoring of illegal use by third parties of the invention, which is protected by the PC's patent. At the same time, it is necessary to systematically update the patent portfolio of PC on medicines.

It should be noted that information about scientific development is first submitted as part of the registration dossier when the drug is registered, and then updated when new knowledge is obtained during the life cycle of the drug. Thus, the creation of an object of intellectual property is possible even after the registration of the drug. Therefore, the development and implementation of innovative pharmaceuticals require step-by-step qualified patent support. The introduction of innovations completes the cycle of the innovation process and allows you to make a profit from new drugs.

The proposed algorithm allows pharmaceutical companies to effectively manage innovative activities, starting with the analysis of the patent landscape and ending with the introduction of new pharmaceuticals to the market. Each stage is important because it contributes to the successful completion of the following tasks and to the minimization of innovation risks.

Practical meaning. The proposed scientific and practical developments create a methodical basis for further improvement of the management of the innovative activity of PC and will contribute to the appearance on the market of new drugs of domestic production.

Study limitations. Issues related to the improvement of scientific and practical approaches to the justification and selection of an innovative PC strategy are not considered in the work.

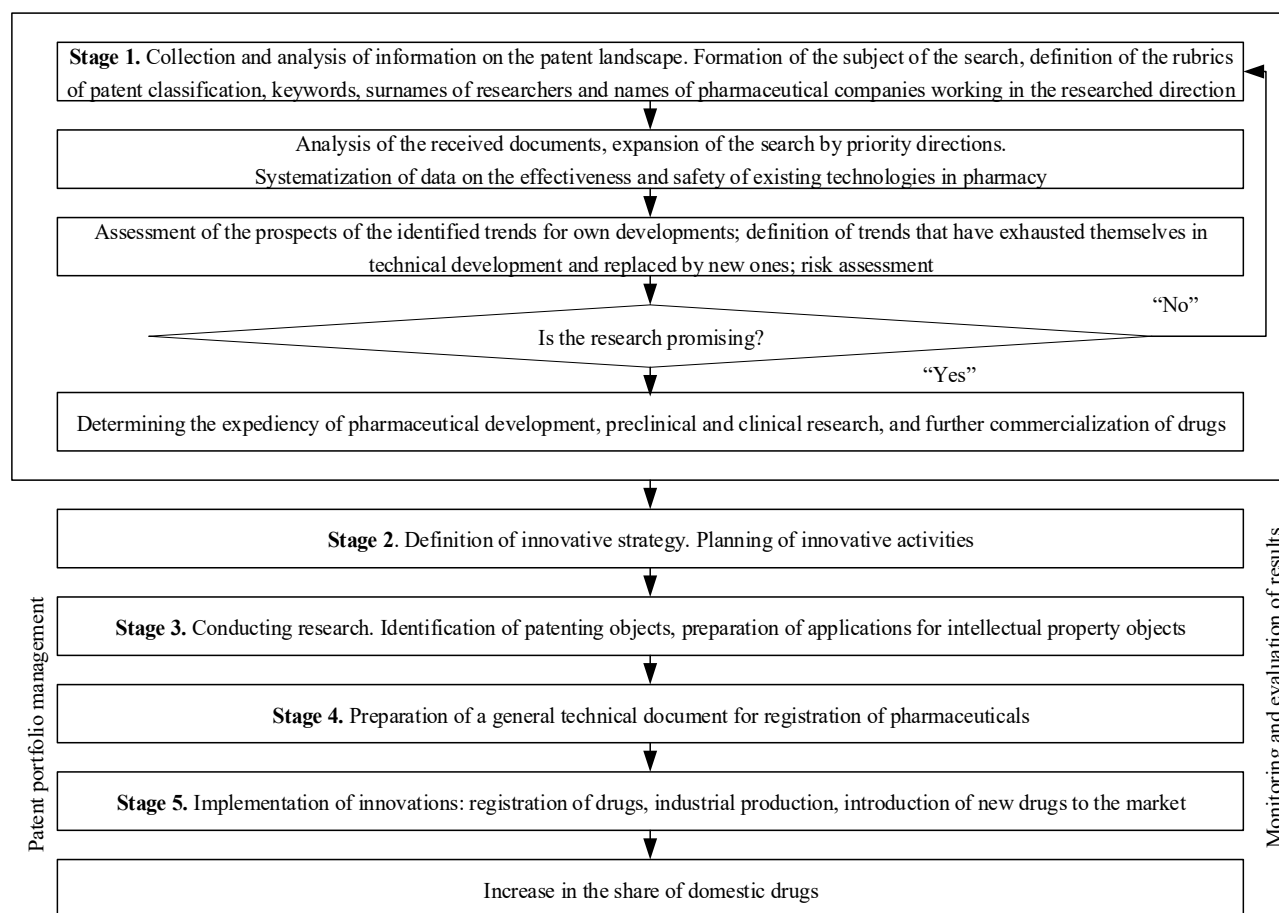


Fig. 7. Algorithm of preventive management of innovative activity of the PC with the application of the toolkit of patent landscapes

Prospects for further research. Prospects for further research are related to the elaboration of the proposed methodological approaches on the example of PC, which belong to different zones according to the level of the integral indicator of innovation potential, and the comparison of cognitive maps constructed for them, as well as the justification of recommendations for choosing an appropriate innovative strategy for PC, based on qualitative the zone (level) of the company's innovative potential and the results of the patent landscape analysis.

5. Conclusions

An important condition for the competitiveness and stable economic development of the domestic pharmaceutical industry and ensuring the social and economic security of our country is the effective innovative activity of PC. In this regard, the problem of developing scientific and practical approaches to improving the system of managing the innovative activity of PC is being updated, which will contribute to more effective use of innovative resources and acceleration of the introduction into production and market release of new domestically produced medicines. For this purpose, a structural model of the innovative potential of PC was built, adapted to the specifics of the flow of innovation processes in pharmacy, and a methodological toolkit for evaluating the innovative potential of FC

was proposed, which will allow to determine the priority directions more reasonably for its further improvement and development for the implementation of the goals of the innovation strategy. The developed algorithm of preventive management of innovative activity of PC, aimed at improving the quality of decision-making in the management of pharmaceutical innovations thanks to the use of the toolkit of patent landscapes, which will contribute to the faster introduction into production and market introduction of innovative drugs of domestic production.

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.

Funding

This study received no funding.

Availability of data

The manuscript has no associated data.

Use of artificial intelligence

The authors confirm that they did not use artificial intelligence technologies during article creation.

References

1. Evaluate Pharma. World Preview 2020, Outlook to 2026. Available at: https://fondazionecerm.it/wp-content/uploads/2020/07/EvaluatePharma-World-Preview-2020_0.pdf
2. Ostashchenko, T., Lutska, A., Tomchuk, V., Koval, A., Solomennyi, A., Snizhynskyi, S. et al. (2023). Current Trends in the Development of the Pharmaceutical Market in Ukraine. *Pharmacophore*, 14 (4), 64–67. <https://doi.org/10.51847/ckmtd2lm8>
3. Kotvitska, A. A., Kutsenko, S. A. (2021). Farmatsevychna industriia ta naukovi doslidzhennia – skutii odnym lantsiuhom. *Apteka online*, 29 (1300). Available at: <https://www.apteka.ua/article/603663>
4. Işık, E., Orhangazi, Ö. (2022). Profitability and drug discovery. *Industrial and Corporate Change*, 31 (4), 891–904. <https://doi.org/10.1093/icc/dtac011>
5. Rennane, S., Baker, L., Mulcahy, A. (2021). Estimating the Cost of Industry Investment in Drug Research and Development: A Review of Methods and Results. *INQUIRY: The Journal of Health Care Organization, Provision, and Financing*, 58. <https://doi.org/10.1177/00469580211059731>
6. Schramm, M. E., Place, K. R., Laskin, A. V. (2022). Framing the strategic R&D paradigm shift in Big Pharma: a content analysis of pharmaceutical annual reports. *Journal of Communication Management*. <https://doi.org/10.1108/jcom-05-2021-0052>
7. Kermaniojarad, M. (2020). What is the impact of patient recruitment on offshoring of clinical trials? *Life Sciences, Society and Policy*, 16 (1). <https://doi.org/10.1186/s40504-020-00104-4>
8. Kinch, M. S., Kraft, Z., Schwartz, T. (2021). 2020 in review: FDA approvals of new medicines. *Drug Discovery Today*, 26 (12), 2794–2799. <https://doi.org/10.1016/j.drudis.2021.07.003>
9. The pharmaceutical industry in figures (2020). EFPIA. Available at: <http://www.efpia.eu/publications/downloads/efpia/2020-the-pharmaceutical-industry-in-figures>
10. Laermann-Nguyen, U., Backfisch, M. (2021). Innovation crisis in the pharmaceutical industry? A survey. *SN Business & Economics*, 1 (12). <https://doi.org/10.1007/s43546-021-00163-5>
11. Straw, M. (2015). Pharma Must Move Beyond Cooperation to True Collaboration. Available at: <https://www.pharmexec.com/view/pharma-must-move-beyond-cooperation-true-collaboratio> Last accessed: 05.04.2024
12. Moingeon, P., Garbay, C., Dahan, M., Fermont, I., Benmakhlouf, A., Gouyette, A. et al. (2024). L'intelligence artificielle, une révolution dans le développement des médicaments. *Médecine/Sciences*, 40 (4), 369–376. <https://doi.org/10.1051/medsci/2024028>
13. Yak vidbuvaetsia tsyfrova transformatsiia biznesu v kompanii «Farmak» – lidera farmatsevychnoho rynku Ukrainy (2021). Available at: farmak.ua/publication/yak-vidbuvaetsya-cyfrova-transformacziya-biznesu-v-kompaniyi-farmak-lidera-farmaczevtichnogo-rynku-ukrayini Last accessed: 05.04.2024
14. Kilkisni metody ekspertnoho otsiniuvannia (2009). Kyiv: NADU, 36.
15. Aronson, J. K., Green, A. R. (2020). Me-too pharmaceutical products: History, definitions, examples, and relevance to drug shortages and essential medicines lists. *British Journal of Clinical Pharmacology*, 86 (11), 2114–2122. <https://doi.org/10.1111/bcp.14327>

16. Shumpeter, Y. A. (2014). Teoriia ekonomichnoho rozvytku. Doslidzhennia prybutkiv, kapitalu, kredytu, vidsotka ta ekonomichnoho tsykladu. Kyiv: Vydavnychiy dim "KyievoMohylianska akademiia", 246.
17. Epifanova, I. Iu., Gladka, D. O. (2022). Methodological approaches to assessing the innovation potential of the enterprise. *Innovation and Sustainability*, 3, 152–158.
18. Yepifanova, I., Dzhedzhula, V. (2020). Methodology of evaluation of innovative potential of enterprises. *Agricultural and Resource Economics*, 6 (3), 171–190. <https://doi.org/10.51599/are.2020.06.03.10>
19. Stadnyk, V. V., Holovchuk, Yu. O. (2020). Upravlinnia innovatsiiny na osnovi rozvytku partnerskykh vidnosyn pidpriemstva. Kamianets-Podilskyi: TOV «Drukarnia «Ruta», 232.
20. Orlova-Kurylova, O. (2018). The modern methods of evaluation of innovative potential. *Visnyk Khmelnytskoho natsionalnoho universytetu*, 4, 143–146.
21. Piatnytska, H. T., Hryhorenko, O. M., Naidiuk, V. S. (2018). Methodical and practical approaches to the evaluation of innovative potential of the catering trade small enterprises. *Ahrosvit*, 4, 53–59.
22. Dzhedzhula, V., Yepifanova, I. (2020). Components of the innovation potential of industrial enterprises. *International Humanitarian University Herald. Economics and Management*, 42. <https://doi.org/10.32841/2413-2675/2020-42-2>
23. Marchenko, V. M., Tsvirkun, A. S. (2017). The system of management of innovative potential at industrial enterprises. *Economic bulletin of NTUU «KPI»*, 411–417.
24. Piletska, S., Tkachenko, Y. (2020). Enterprise Innovative Potential in the System of Anti-Crisis Management. *Accounting and Finance*, 1 (87), 178–184. [https://doi.org/10.33146/2307-9878-2020-1\(87\)-178-184](https://doi.org/10.33146/2307-9878-2020-1(87)-178-184)
25. Dovbush, V. I. (2022). Innovative potential as a tool for ensuring innovative development of an enterprise. *Market Relations Development in Ukraine*, 12 (247), 46–51. <https://doi.org/10.5281/ZENODO.6090038>
26. Krawczyk-Sokolowska, I., Pierscieniak, A., Caputa, W. (2019). The innovation potential of the enterprise in the context of the economy and the business model. *Review of Managerial Science*, 15 (1), 103–124. <https://doi.org/10.1007/s11846-019-00374-z>
27. Klebanova, T. S., Hurianova, L. S., Chahovets, L. O., Panasenko, O. V., Serhiienko, O. A. (2018). Biznes-analytika bahatovymirnykh protsesiv. Kharkiv: Vyd. KhNEU im. S. Kuznetsia, 272.
28. Posylkina, O. V. (2002). Innovatsiino-investytsiinyi rozvytokfarmatsevtichnoho vyrobnytstva: problemy finansovoho zabezpechennia. Kharkiv: Vyd-vo NFAU: Zoloti storinky, 528.
29. Kryvoruchko, O., Desiatko, A., Karpunin, I., Hnatchenko, D., Lakhno, M., Malikova, F., Turdaliev, A. (2023). Cognitive Modeling and Formation of the Knowledge Base of the Information System for Assessing the Rating of Enterprises. *International Journal of Electronics and Telecommunications*, 697–705. <https://doi.org/10.24425/ijet.2023.147690>
30. Litvinova, O., Klager, E., Tzvetkov, N. T., Kimberger, O., Kletecka-Pulker, M., Willschke, H., Atanasov, A. G. (2022). Digital Pills with Ingestible Sensors: Patent Landscape Analysis. *Pharmaceuticals*, 15 (8), 1025. <https://doi.org/10.3390/ph15081025>
31. Holgersson, M., Wallin, M. W. (2017). The patent management trichotomy: patenting, publishing, and secrecy. *Management Decision*, 55 (6), 1087–1099. <https://doi.org/10.1108/md-03-2016-0172>

Received date 23.01.2024

Accepted date 23.04.2024

Published date 30.04.2024

Sanjay Kumar Nayak, General Director, CEO, AmaroX Ukraine LTD, Sichovykh Striltsiv str., 77, Kyiv, Ukraine, 04053

Olga Posilkina*, Doctor of Pharmaceutical Sciences, Professor, Department of Management and Quality Assurance in Pharmacy, National University of Pharmacy, Pushkinska str., 53, Kharkiv, Ukraine, 61002

Olena Litvinova, Doctor of Pharmaceutical Sciences, Professor, Department of Management and Quality Assurance in Pharmacy, National University of Pharmacy, Pushkinska str., 53, Kharkiv, Ukraine, 61002

**Corresponding author: Olga Posilkina, e-mail: o.posilkina@gmail.com*