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Evaluation of Social Efficiency of the Project of Creation an Innovative Medicinal Product

The work examines the methods of evaluating efficiency of an innovative medicinal product, which should enable us to assess its social effect, using special software at the early stages of its design. The significance of the topic under question lies in the fact that due to the present-day increasing limitation of the financing, prioritization of projects on new innovative medication creation becomes of primary importance. The work recognizes that the choice of a project impacts both financial capabilities of an enterprise and economic conditions and wealth of the country as a whole.

resource management, innovation, innovative medicinal product, innovative project, efficiency, methodology, evaluation, software product

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Оценка социальной эффективности проекта по созданию инновационного лекарственного средства

В работе представлена методика оценки эффективности создания инновационного лекарственного средства, позволяющая рассчитать эффект с применением IT-технологий уже на стадии его проектирования. Обоснована необходимость исследования рассматриваемого вопроса, обусловленного тем, что в настоящее время возникает проблема выбора наиболее приоритетных проектов по созданию новых инновационных лекарственных средств. Показано, что выбор того или иного проекта по созданию новых инновационных лекарственных средств оказывает влияние на финансовые возможности предприятия и благосостояние людей.

управление ресурсами, инновации, инновационное лекарственное средство, инновационный проект, эффективность, методика, оценка, программный продукт

Statement of the Problem. The condition of the country's pharmaceutical industry is mainly defined by its ability to provide the population with safe, effective, and, what is also of high importance, affordable medications. Quick growth of the number of the original medicines and their numerous generics manufactured by pharmaceutical companies under various trade names is characteristic of the modern pharmaceutical market. On the one hand, wide selection of different groups of medicines resolves treatment needs in relation to any form of disease. On the other hand, in the modern market, fair competition between local and foreign manufacturers becomes especially significant.

Thus, state authorities put their efforts to increase the efficiency of local pharmaceutical companies' work, to consolidate such companies' material and technical base, and to render financial aid [12].

The global pharmaceutical industry is deservedly considered to be one of the most advanced in terms of technology and worthily plays an important role in the world economic system, stipulated by the social importance of the manufactured products, high level of governmental regulation of the pharmaceutical market, research intensity, and investment attractiveness [29]. The state-of-the-art technologies used in the sphere have a considerable multiplicative effect on other industries, especially agriculture, healthcare, and science [12].

At the same time, one of the key trends of the modern technologies development in relation to the whole pharmaceutical business evolution is the process of creation of decision-making systems. There are hardly any computer-aided tools designed for automation of the planning process in this field nowadays, while specialized software could enable management to make its process of strategic decision-making both easier and significantly faster.

Analysis of Recent Researches and Publications. Issues of assessing the effectiveness of investment and innovation projects, innovative design and evaluation of innovation efficiency, development of appropriate evaluation methods are given great attention in domestic and foreign literature. Thus, the theoretical and methodological aspects of the evaluation of the effectiveness of innovative projects were devoted the scientific works of A. Degtyar [11], L. Fedulova [16], V. Alexandrova [16], Yu. Bajal [16], L. Glinenko [8], A. Kuznetsova [3-5; 20] G. Vozniak [2-5], A. Savchuk [27], Zavlin P. [13], etc. The presence of these developments are the background of investigation of the problems of evaluating the effectiveness of the introduction of an innovative product for different industries, taking into account the specifics of different types of goods, works and services.

Particularly urgent now is the question of assessing the innovation of products in such a field as pharmaceutical, which are developed by domestic and foreign scientists. The general theoretical and practical questions of pharmaceutical innovation are presented in works of E. Volsky [6], M. Golovenko [9] and A. Kolbin [19]. The research of T. Delvig-Kamenskaya is devoted to the methodological problems of the classification of innovative medicines [10], and N. Klunko tested the matrix approach for the classification of innovations in pharmaceutical production [18]. Legal characteristics of innovative medicines and objects of intellectual property in the field of pharmaceuticals are considered in the works of I. Voronina [7] and I. Kirichenko [17]. A detailed study of the protection and protection of innovative medicinal product as an intellectual property is provided by Belarusian researchers [15]. Problems of development of innovative medicines the report of Zvonareva O.I. is devoted [14].

Despite a significant number of studies of innovations in the field of pharmaceutical activity, issues of evaluation of the effectiveness of projects of the creation of new medicinal product for various components, including social ones, remain relevant.

Statement of the Objective. The primary purpose of work consists in the development of a methodology for evaluating the effectiveness of the creation of innovative medicines and creation of software product for the estimation of efficiency of project of creation of innovative medicinal means.

For the achievement of the aim it was decided to consider next tasks: (1) to conduct the analysis of information necessary for the estimation of innovative project; (2) to choose the method of estimation of social efficiency of project; (3) to work out methodology of estimation of efficiency of innovative project; (4) to give an integral estimation to the economic and financial information that reflects accordance of results and expenses of project to the aims and interests of his participants, here corresponds to interests of population.

The Main Material. *Overall approach to defining social efficiency of project on creation of innovative medicinal means and basic method of his estimation.*

Feasibility study for projects on scientific research or experimental technology works dealing with separate tasks or scientific programs in general determines advisability of governmental support rendered to production teams in their technical work and enables to evaluate such team's work in the field of innovations. With all the difficulties in forecasting the results from development and introduction of new products, especially at earlier stages of the lifecycle, the scientific team and other specialists have to make rational managerial decisions that are aimed at mitigating any faults and minimizing deviation of the actual results from the planned ones. To make such decisions, they need to have full information and

methodological basis for a feasibility study and scientific assessment of the choices they make in the field of innovations, while developing new innovative medications in particular.

They also need to pay special attention to the methods of evaluation of efficiency of an innovative analysis, the concept of which is generation of full information on each alternative option. For example, evaluation with approved numerical descriptions of each innovation project (expenditures, financing, revenues, etc.) [12].

Outputs of research activities of a pharmaceutical company are work results presented in the form of a report, test prototype, its technical documentation obtained during contract labor in accordance with the defined technical assignment. Rights emerging for such work results are also included in the output. A combination of research work reports related to physical, chemical, pharmaceutical, biomedical, and other studies make up a consistent mechanism of medication creation, being a combination of new knowledge stored on a specific information carrier [12].

Scientific and technical information created as a result of such intellectual activity becomes intellectual property. Since the legal status of scientific and technical information is regulated by the Civil Code and other legislative acts, we suggest identifying the combination of such information in taxation and bookkeeping as a company's innovational asset, being part of its intangible assets.

Therewith, innovational asset should be regarded as the company's intangible property inalienable from its carrier, created as a result of innovative activity and conducive to future economic and (or) other profit in case of its prolonged use [21].

Information about a medication (innovational asset) planned for development is gathered in an assignment draft. It provides evaluation of the economic effectiveness of the scientific development project, which is one of the important stages of pre-innovational studies.

The draft also contains a feasibility study of the development, with relevance and characteristics of the future medication as well as general calculations and financing sources. Elaboration of a draft becomes a matter of special importance as the choice of the assignment directly impacts the economic outcomes in the future [12].

Implementation of an innovational asset can be presented as two interrelated, successive processes:

- the process of medication scientific development;
- the process of profit acquisition from the committed facilities [12].

This is the reason why an effective draft must include a detailed analysis and integral evaluation of all gathered and processed technical, economic, and financial information. Likewise, such draft must reflect the correspondence between the results and expenditures on the project and its aims, with consideration of its participants' interests and goals pursued by the government and the population. The project overall efficiency is assessed with the aim of determining its potential attractiveness for various participants and finding sources of financing.

Efficiency of project is estimated with the purpose of determination of the attractiveness for various participants and search of sourcing. Efficiency of project includes in itself:

- project social efficiency – reflects the level of improvement of people's health in general or of separate groups (mean life expectancy, decrease in the rates of sickness, disability, mortality, etc.) as well as the level of the population's satisfaction with the medications available;
- project economic efficiency – considers financial consequences of the implemented innovational project for all participants against expenditures needed for its achievement [12].

Social analysis of the project efficiency offers measures aimed at ensuring that the project results correspond to the interests of various social groups. Analysis enables to define a specific scope of measures that on the one hand guarantees the project support by the population and on the other hand contributes to achievement of the project goals by stimulating changes in public imagery and behavior. If such social analysis of the project is neglected, sociocultural attitude of the project developers can have stronger influence on the scope of the project than social values of potential consumers.

Social analysis of an innovational project usually focuses on the following factors and aspects:

- social and demographic characteristics of the population affected by the project (size and composition of the population, differential mortality statistics, primary and general illness rate per each class, group, and various diseases);
- project acceptability from the point of view of the local culture, its ability to lead necessary changes in people's needs and behaviors (dynamics of real available income of the population, rates of economic differentiation of the population);
- interest and involvement of the government on all stages of the project development (healthcare expenses, including expenditures on medications, sponsored by budgets of all levels, and foundations).

Social effect is defined with statistical and sociological indicators. The quality aspects of the achieved social goals are defined by the indicators that lie in the basis of the innovational project design and implementation: emergence of new innovative medications on the market, increase in the number of domestically produced medications, reduction of prices, improvement of the sickness rate, increase in the birth rate, and decrease in the mortality rate.

The main method used for evaluation of social efficiency of the project is the expert method. Expertise of social effectiveness of an innovational project on a new medication is more reasonable if conducted in the form of a group survey of high-quality specialists (experts) in the pharmaceutical and medical spheres.

At the innovative medication design stage, evidence of a future social impact can be a significant argument in favor of the project, while results of an evaluation of social and medical efficacy can be indicative of the fact that such innovations are aimed at increasing the population's life quality rather than affecting the corporate image only.

Therefore, in the present-day conditions of continuous development of the pharmaceutical industry and launch of import substitution programs, the criteria of medication innovativeness rise in importance in the process of definition of priorities and policies of governmental support of the pharmaceutical sphere.

Certain approaches were set forth for the estimation of innovativeness during realization of imported projects. They consider parameters that define the concept innovativeness from the therapeutic perspective, such as new production technology, means of delivery, formulation, impact on a new "target", and a new mechanism of the medication's action. The highest independent consultative body in the field of healthcare in France [23] Haute autorite de santé (HAS), also ranks major innovativeness criteria, but chooses a different classification feature – its relation to an additional therapeutic effect against the current methods of a specific disease treatment, from the greatest therapeutic effect to its absence [24]. The Swedish system proposed by the HTA agency, Dental and Pharmaceutical Benefits Agency TLA, evaluates the rate of economic efficiency by stimulating innovations from the social expectations perspective. Decisions are made on the basis of their value for a patient, necessity, social justice, and cost-based efficiency [25]. Italian Medical Agency L'Agencia Italiana del Farmaco (AIFA) evaluates innovativeness in relation to the severity of a disease, its prevalence rate, availability of the existing treatment methods, and the level of their therapeutic effect [22].

Thus, top specialists note that the list of parameters defining the value of such new technologies includes:

- on the one hand, the features of the medication itself (novelty of the molecule and production technology, alternatives of the disease treatment, clinical and economic efficiency);

- on the other hand, factors caused by the disease (its prevalence, hazard to life, patient's risk of becoming disabled, etc.).

At the same time, each of these parameters affects the innovational attractiveness of a medication, influencing the total value of the technology.

Results of researches.

The most rational solution of this issue is development of software that envisages a complex mechanism of bringing the specified parameters of social and other effects to a unified system of quantitative evaluation. In a table 1 the indexes of social efficiency of project are presented on development of new innovative medicinal means.

Table 1 – Indicators of social efficiency of the project on innovative medication creation

Indicator group	Indicator group significance	Indicator contents	Indicator value
<i>I. Productivity level (idea potential)</i>			
1. Innovational targeting (innovation characteristics)	0.1	New molecular formulation or chemical compound not registered or applied before	7
		Chemical derivant of an existing or previously approved medication	6
		New product form of a previously registered medication	5
		Combination of two or more medicinal substances of previously registered medications	4
		Reproduced medications	3
		New indications for registered drugs	2
		Circulating but not yet supervision-approved medications	1
2. Additional therapeutic effect (against existing methods used with a specific disease)	0.1	Most therapeutic progress	7
		Significant improvement	5
		Moderate or insignificant improvements	3
		no improvements	1
3. Completeness and quality of pre-clinical studies (evaluation of pre-clinical studies)	0.1	Therapeutic index of the drug under examination is higher than that of a compared drug during treatment of a specific disease or clinical condition	7
		Mechanism of action of the drug under examination was studied on the clinical condition/disease models	5
		Metabolism and safety of the drug under examination were studied	3
<i>II. Level of social targeting (technology potential)</i>			
4. Priority (correspondence of the investment project aims to the priorities, goals, and strategies of the	0.1	Corresponds	7
		Corresponds partially	3
		Does not correspond	1

Indicator group	Indicator group significance	Indicator contents	Indicator value
socioeconomic development of the state)			
5. Availability of analogs (the country's level of availability of medications with similar features prior to the launch of the drug provided by the investment project)	0.1	Below 50%	7
		50% to 75%	5
		75% to 100%	3
		100 %	1
6. Coverage by the project outcomes (percentage of the population that will use the results of the investment project implementation)	0.1	At least 30% of the population	7
		At least 25% of the population	6
		At least 20% of the population	5
		At least 15% of the population	4
		At least 10% of the population	3
		At least 5% of the population	2
7. Price of the medication (against prices set by the competitors)	0.1	Lower by at least 30%	7
		Lower by at least 15%	5
		Comparable prices	3
		Comparatively higher	1
<i>III. Feasibility rate (growth potential)</i>			
8. Financing support (the level of financial support provided by the budgetary funds)	0.1	At least 90%	7
		At least 50%	5
		At least 30%	3
		Below 30%	1
9. Patentability of the intellectual property (the level of novelty and exploitability of the innovative medical products)	0.1	Worldwide patents, satisfactory evidence of competitive capacity against analogs	7
		Nationwide patent value, satisfactory evidence of competitive capacity against analogs	3
		Reproduction of advanced products (lack of patent prospects with absence of risks of patent disputes)	1
10. Object completeness state (terms of the project implementation)	0.1	Works to be completed within the period of one to five years	7
		Works to continue for the period of five to ten years	5
		Works to continue for the period exceeding ten years	3
		other (suspended projects)	1
1 - minimum score; 7 - maximum score.			

Source: developed by the authors.

Indicator (meaningfulness) group significance can vary depending on its priority and importance. The one major task remaining in this regard is to make sure that the compared assignments are evaluated by the same indicator groups with the same significance, which should make their comparison substantial. Based on the values of social efficiency indicator as per the mentioned groups and their significance, we can calculate the indicator of social efficiency (I_{se}) using the following formula:

$$I_{se} = \sum_{i=1}^n P_{se_i} \cdot Sg_{se} , \quad (1)$$

where P_{se} is the value of the indicator of social efficiency of the project on new innovative medication development for a specific group (level of productivity, social targeting, feasibility); Sg_{se} is the significance (importance) of the indicator of social efficiency of the project on new innovative medication development for a specific group.

The practicality coefficient (C_p) envisages adjustment of the indicator of social efficiency [26]. This coefficient defines not the actual number of diseased people but the dynamics and tendencies of the sickness rate. This allows both to increase the importance of the projects where the number of the disease-affected population is rising, and to decrease the importance of the projects where the dynamics of the sickness rate is reducing due to the positive effect of the current and existing medications present on the market. To compare the values of the sickness rate, it is advisable to calculate the coefficient for 100K people in the country's population, using the following formula [1; 28]:

$$C_p = \frac{\left(\frac{P_i^v}{P_i^{total}} * 100000 \right)}{\left(\frac{P_{i-1}^v}{P_{i-1}^{total}} * 100000 \right)} \quad (2)$$

where P^v is the value of the population sickness rate for a specific period; P^{total} is the country's population for a specific period; i is the period of time.

The practicality coefficient is defined on the basis of the official numbers provided by the Ministry of Health on the country's aggregate sickness rate and statistics per specific diseases (total registered cases per 100K people of a certain age in the population). We can calculate the mean value of the practicality coefficient for several periods:

$$\overline{C_p} = \sqrt[n]{\frac{P_1^{v100}}{P_0^{v100}} * \frac{P_2^{v100}}{P_1^{v100}} * \dots * \frac{P_n^{v100}}{P_{n-1}^{v100}}} \quad (3)$$

where P^{v100} is the sickness rate per 100K people in the population for a specific period; n is the number of periods.

Thus, to assess the price-based evaluation of the project effectiveness we propose to use social effect from implementation of the innovational project on a new innovative medication development (SE) calculated on the basis of the social efficiency and practicality coefficient indicator as the basic value:

$$SE = I_{se} \cdot C_p . \quad (4)$$

Conclusions and prospects for further researches. As a result of undertaken studies:

1. It is set that in the list of parameters, which allow to evaluate the value of new technology and innovative attractiveness of medicinal means it is necessary to include properties of medicinal preparation (novelty of technology of production, alternative of treatment of disease, clinical and economic efficiency) and factors that is determined by a disease (his prevalence, threat for life of and other).

2. It is suggested as a base index for settling of cost estimation of social efficiency of project to use the integral index of social effect from realization of innovative project on development of new innovative medicinal means, expected on the basis of indicator of social efficiency and coefficient of utility/

3. The software designed to evaluate effectiveness of the assignment project on innovative medication development will enable:

- calculate the most important indicators of social efficiency of a project on a new innovative medication development;
- accumulate full information about each alternative option;
- make evaluations with approved numerical descriptions of each project;
- consider the level of improvements in the health indicators of the population or its specific groups and the level of the population's satisfaction with the range of medications available;
- save time in the process of making important strategic decisions.

Further researches should be aimed at improving the presented methodology, taking into account the specifics of certain medicinal products and directions for their use.

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Оцінка соціальної ефективності проекту по створенню інноваційного лікарського засобу

Світова фармацевтична промисловість вважається однією з найбільш високотехнологічних і займає особливе місце в світовій економічній системі, що обумовлюється соціальною значимістю виробленої продукції, високим ступенем регулювання фармацевтичного ринку, наукоємкістю виробництва та інвестиційною привабливістю. В даному дослідженні були поставлені такі завдання: 1) провести аналіз інформації, необхідної для оцінки інноваційного проекту по створенню нового інноваційного лікарського засобу; 2) обґрунтувати методику оцінки соціальної ефективності проекту; 3) запропонувати інтегральну оцінку техніко-економічної і фінансової інформації, яка відображає відповідність результатів і витрат проекту цілям та інтересам його учасників, в тому числі і інтересам населення.

У роботі представлена методика оцінки соціальної ефективності створення інноваційного лікарського засобу, що дозволяє розрахувати ефект із застосуванням ІТ-технологій вже на стадії його проектування. Обґрунтовано необхідність дослідження даного питання, обумовленого тим, що в даний час виникає проблема вибору найбільш пріоритетних проектів по створенню нових інноваційних лікарських засобів. Встановлено, що до переліку параметрів, що визначають цінність нової технології та інноваційної привабливості лікарського засобу необхідно включати властивості лікарського препарату і фактори, які визначаються самим захворюванням. Запропоновано в якості базового показника для розрахунку вартісної оцінки соціальної ефективності проекту використовувати інтегральний показник соціального ефекту від реалізації інноваційного проекту по розробці нового інноваційного лікарського засобу, що розраховується на підставі індикатора соціальної ефективності та коефіцієнта корисності.

Обґрунтовано, що програмний продукт по оцінці соціальної ефективності проекту по створенню інноваційного лікарського засобу дозволить: 1) розрахувати найбільш значущі показники соціальної ефективності; 2) дати повну інформацію по кожному з альтернативних рішень; 3) провести оцінку проекту з розробки інноваційного лікарського засобу; 4) врахувати ступінь задоволеності населення асортиментом лікарських засобів, а також ступінь поліпшення показників здоров'я населення; 5) скоротити час на прийняття важливих стратегічних рішень.

управління ресурсами, інновації, інноваційний лікарський засіб, інноваційний проект, ефективність, методика, оцінка, програмний продукт

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