

# PHARMACEUTICAL SCIENCES

## ОБГРУНТУВАННЯ НАУКОВО-ПРАКТИЧНИХ ПІДХОДІВ ДО ВИЗНАЧЕННЯ ДОЦІЛЬНОСТІ ТА ІНВЕСТИЦІЙНОЇ ПРИВАБЛИВОСТІ РОЗРОБКИ НОВИХ АНТИГІПЕРТЕНЗИВНИХ ЛІКАРСЬКИХ ЗАСОБІВ

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## A FOUNDATION OF SCIENTIFIC AND PRACTICAL APPROACHES TO DETERMINATION OF EXPEDIENCY AND INVESTMENT ATTRACTIVENESS OF THE NEW ANTIHYPERTENSIVE MEDICINES DEVELOPMENT

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### Анотація

Статтю присвячено дослідженню в області аналізу та формування системного підходу до технологічного процесу розробок нових лікарських засобів. Висвітлено необхідність комплексного дослідження та визначення доцільності, ефективності й інвестиційної привабливості проектів створення лікарських засобів. На прикладі антигіпертензивного препарату небіволол опрацьовано прогностичну частину показників для прийняття рішення та подальшого контролю за реалізацією проекту. Розрахунок основних маркетингових, економічних та інвестиційних показників підтверджує доцільність розробок таблеток небіволол 0,05 г та впровадження в медичну практику.

### Abstract

The article is devoted to the research in the sphere of analysis and formation of a systematic approach to the technological process of new medicines development. The necessity of complex research and determination of the expediency, efficiency and investment attractiveness of medicines development projects have been outlined. At the example of antihypertensive medicine Nebivolol a forecasted part of indicators for making decisions and further control of the project implementation has been worked out. The calculation of key marketing, economic and investment indicators proves the expediency of development of the pill Nebivolol 0,05 g and implementation in medical practice.

**Ключові слова:** привабливість, ефективність, доцільність, «дорожня карта», інвестиції, фармація, інновації, антигіпертензивні засоби, лікарські препарати.

**Keywords:** attractiveness, efficiency, expediency, "travelling map", investments, pharmacy, innovations, antihypertension facilities, medicinal preparations.

**Setting of the problem.** A significant prolongation of the duration and quality of human life is significantly ensured by the implementation of innovative medical technologies in practice and the use of more effective, safe and available medicines, which in turn, gave an opportunity to use new ways of treatment and increase effectiveness of heavy cured diseases treatment [8,13,14]. It was confirmed that the decrease of human mortality by 45% (1970-2000) was taking place at the expense of new medicines. However, even today

cardio-vascular diseases are the most widely-spread and threatening for the humanity as to the mortality and disability of people [1,2,5,16]. Cardio-vascular diseases are becoming "younger" in the world. In Ukraine from April 01, 2017 the effect of partial reimbursement based on the antihypertensive medicines has been prolonged as well as for treatment of bronchial asthma and diabetes of the 2<sup>nd</sup> type [13,14]. For the last years the product segment of antihypertensive medicines of Ukraine has been significantly replenished by various

medicines [1,5]. A significant expansion of their choice, which is characterized by a big range of manufactures, prices and qualitative characteristics of some medicines increase a possibility of an arsenal for doctors and a choice for patients.

A social importance of antihypertensive medicines, which significantly increase a quality of a human life, requires new motivated approaches as to the determination of perspective new medicines in medical technologies of treatment and prevention, as well as searching means and technologies as to the development and marketing of such medicines. Implementation of new innovative medicines requires large financial investments (\$2-3 and more milliard dollars for original and tens of millions US dollars for generic or hybrid medicines) in searching and development of new more effective and safe antihypertensive medicines, and too much time for the development (up to 10-12 and more years for original and three or more years for generic), big risks (because of insufficient clinical efficiency of suggested medicines, their significant toxicity, inappropriate safety profile, lack of necessary investments, false strategies and programs, insufficient projects supervision, management mistakes, low sales of the first two or three years, etc.) require a detailed forecasted processing of stages and types of work in coordination of stakeholder groups participants [4,7,8,15,17-20,25]. A significant role is given to the fulfillment of works based on the networking plans and algorithms taking into account crucial points of the project.

#### **Analysis of recent research and publications.**

Analysis of specialized literature in complex determination of expediency, efficiency and investment attractiveness of new medicines development proves a very small number of this problem investigations.

Thus, in his work Maydannik V. [12] has generalized in detail only trends of more global tendencies of scientific research development in clinical medicine and showed deepening, price raising and acceleration of commercial technologies for new developments and use of medicines and medical technologies in medical practice. Among them there are the following: biopharmaceutical medicines, nanotechnologies, genetic therapy, pharmacogenomics, personalized medicine, etc.

Analysis of scientific articles shows that most domestic pharmaceutical enterprises do not have enough money for active innovative activity in new medicines development, and our country does not assist in the pharmaceutical industry development [8]. A very low part of expenses is given to scientific research. Analysis of financing investment activity of a leading pharmaceutical enterprise outlines the whole set of negative tendencies, which influence the financial state of the enterprise: decrease of current liquidity, a level of provision with own working capital and profitability in general [22]. Determination of the enterprise innovative activity under the conditions of economic instability is recommended to be replenished by the indicators of economic activity risks: risks of false innovative project choice, risks the project insufficient financing, risks of providing property right for the innovative project [23].

There have been found out some publications as to the expediency of new medicines development, which do not have a systematic approach to this problem [4,11].

Authors of publications state that all stages of innovative process are laborious, lengthy, require big investments and are accompanied with a large number of risks [7,8,10,17-20,24,26-28]. Financial investments to long-term projects with a significant uncertainty of results require reasonable risks management as to their minimization providing investors with commercial and investment attraction not only by returning the invested financial resources, but getting investment income, taking into account average market income and further entrepreneurial profit.

**Unsolved issues, which are part of general problem.** Some issues of the development process and taking to the market innovative medicines is not connected with general problem of forecasting expediency and effectiveness of innovative medicines development, processes modeling in order to reach quality and efficiency indicators to ensure complex management of stages and works, to accelerate and cheapen the developments and increase the results of the projects in general.

**The goal of our work** is to motivate scientific and practical approaches to methodological foundation of expediency determination, efficiency and investment attraction of new medicines development at the example of antihypertensive medicines.

The materials used in this work were the results of individual researches, available scientific publications, results of monitoring of the medicines market of the "Pharmastandard" system of the "Morion" company (Ukraine).

**Key results of research.** Social importance of antihypertensive medicines, high costs and a significant period of time for the development enforces to spend money for R&D research and regular searching ways of saving the finances. Effective use of material, labor and financial resources require detailed processing of forecasted determination of their demand, including by the types of work and stages. Using modeling of scenarios, it is important to choose the most realistic way of "the road map" for the fulfillment of such works. Intensity of works sometimes depends on time and full financing, which is possible in case of openness and interest of investors and guaranties of investments further return and getting a desirable profit. The finances invested for a long time depreciate in a certain period of time, and the cost of desirable income increases. A commercial part, which depends on the preparation of a target audience and markets for the new medicine, active marketing sale activity, commercial operations as well as a certain pathological disease, a degree of its complexity, an amount of costs for treatment, a therapy course duration, etc. is very important. Scientific researches prove that even 2 or 3 successful medicines in big volume of sale cover not only the payback of ten "failing", but they get desirable profits for investors and strong reasons for further investments in R&D research. Thus, the formation of an optimal logical chain in technological process of medicine development using a network approach and critical way can

significantly accelerate the medicine development. An important tool is “the road map”, which gives a chance to coordinate and control the fulfillment of works regarding the project in the determined time and to save significantly financial resources. It is worth mentioning that the use of “the road map” is especially actual in case of simultaneous availability in the development of a few medicines (“an innovative portfolio”), where it is necessary to coordinate many types and stages of work of various medicines simultaneously, to pay for the work done, raw material and materials in time, to form the order and turn of implementation of such new medicines with a chance for self-financing and optimal reinvestment of the income gained in the development of new medicines.

Investment and innovative, production, trading and commercial activity of the company under the conditions of a significant competition must be MTM (minimal time-to-market) oriented – a medicine should come to the market when it is necessary, otherwise – it may be forced out by the competitors.

Based on the analysis of Ukrainian Legislature requirements as to the development, expertise and producing new medicines, an informative and jurisdictional approaches to the technological fulfillment of works have been worked out.

To provide appropriate medicines, prevent monopolization and form healthy competition, foreign specialists of pharmaceutical market recommend no less than

4-5 manufacturers of medicines analogues. Therefore, we continued researching the expediency of expanding manufacturers of antihypertensive medicines.

At the example of the Nebivolol pills 5 mg development as a generic innovative medicine of new generation, we have suggested some reasons of scientific and methodical approaches to forecasting social and medical expediency, economic and commercial efficiency as well as investment attraction of new medicine.

Thus, in our previous works we have provided the results of the antihypertensive medicines market segment research, we have offered data as to the consumption and demand [1,2,16], determined influence of emotional and rational factors on the choice and consumption of such medicines [6], assessed qualitative and quantitative brand indicators [3,21], developed scientific reasons of strategic and tactful approaches as to the increase of market potential of medicines at the example of antihypertensive medicines [3,6,16], singled out perspective medicines, among which is Nebivolol.

We have delivered the basic characteristics analysis and competitive advantages of Nebivolol pills available at the country market. We have determined market activity of 9 analogues of Nebivolol, among them 8 are produced abroad (Table 1).

Table 1 Market characteristics of Nebivolol medicines in product segment (2016)

Item №	Name of medicine and form of production	Manufacturer	Sales (PRT) and availability in pharmacies, %		Market share (%)	
			IPT	Penetration	Packaging	UAH
1.	NEBIVAL pills 5 mg blister, №20	PSC Kyiv Vitaminous Plant (Ukraine)	90,36	90,94	53,28	31,26
2.	NEBIVOLOL ORION pills 5 mg blister, №30	Orion (Finland)	19,55	21,77	0,99	0,41
3.	NEBIVOLOL SANDOZ® pills 5 mg blister, №30	Sandoz (Switzerland)	57,52	59,37	7,15	6,18
4.	NEBOVILOL SANDOZ® pills 5 mg blister, №60	Sandoz (Switzerland)	12,69	14,54	0,43	0,70
5.	NEBIVOLOL SANDOZ® pills 5 mg blister, №90	Sandoz (Switzerland)	29,88	32,17	1,97	4,19
6.	NEBIVOLOL-TEVA pills 5 mg blister, №28	Teva (Israel)	24,03	28,37	1,05	0,33
7.	NEBICARD pills 5 mg blister, №50	Torrent (India)	2,20	2,74	0,02	0,06
8.	NEBILET®, pills 5 mg blister, №14	Berlin-Chemie (Germany)	43,58	48,18	8,91	9,76
9.	NEBILET®, pills 5 mg blister, №28	Berlin-Chemie (Germany)	79,37	80,47	21,34	43,28
10.	NEBILONG pills 5 mg blister, №30	Micro Labs (India)	27,03	29,99	2,01	1,64
11.	NEBITENS pills. 5 mg blister, №30	Propharma International (Malta)	30,77	33,12	1,91	1,41
12.	NEBITREND pills 5mg blister, №28	Teva (Israel)	20,86	21,66	0,94	0,78
13.	NEBITREND pills 5 mg blister, №30	Teva (Israel)	0,03	0,03	0	0

At the same time, Nebivolol pills 5 mg №20 (Kyiv Vitaminous Plant, city of Kyiv) is one of the leaders, which uses it in medical practice (53,28% and 31,26% of product segment correspondingly in natural and monetary units). The appearance at the market of some medicine foreign manufacturers for the last 2-3 years shows its attractiveness, a big demand and perceptiveness. At the same time, a very low participation in this segment of domestic manufacturers of Nebivolol medicines proves insufficient activity of its managers and marketing specialists.

We have summarized Nebivolol characteristics and registered on its basis medicines using SWOT-analysis, which gave a chance to single out and asses advantages and disadvantages, perspectives and threats. Results of specialists polling (doctors and pharmacists) as to the innovation and perspective of further use of this medicine in medical practice have been used at the following research stages.

We have determined the components of the first forecasted block of works, which includes informational,

patent and marketing research, by the results of which we can single out basic marketing and project economic indicators. Among them there is the forecasted capacity of the product segment of the medicines market, an actual use of medicines, production volume forecasts, investments amount, sales and forecasted income and profit. As criteria indicators, we have determined a discounted term of returning the investments, a pure modern value of cash flow (NPV), an internal norm of the project profitability (IRR), which together characterize further economic expediency of development of this medicine.

We have formed modules as steps of works regarding the development of generic antihypertensive medicines of Nebivolol in the form of pills. At the first stage, we have determined the modules components and works required. We have outlined and worked out innovative, investment, scientific, research, production, trade, medical and commercial blocks (Figure).



Figure. Block-scheme of “the road map” modules of calculating the expediency, efficiency and investment attractiveness of this new medicine development and using (individual development)

We have included to the algorithm a forecasted part of the research, including marketing and economic, modeling the cash flow process and determining their price change in time as well as sale (actual). Together

with specialists of plant-manufacturer we have determined a forecasted demand for medicine and a desirable share of the market product segment for new manufacturer. Calculation of new medicine cost price proved its high production profitability (Table 2).

Table 2 Basic marketing, economic and investment indicators of the project (Nebivolol pills 0,05 g)

Item №	Name of indicator	Unit	Value
1.	Actual consumption of medicine.	thous. UAH	118366
2.	Actual consumption of medicine.	thous. UAH	1258
3.	Forecasted demand for medicine.	thous. UAH	7800
4.	Forecasted production profitability.	%	2000
5.	Amount of investments to direct development and registration.	thous. UAH	275,8
6.	Total amount of investments.	thous. UAH	384,6
7.	Forecasted amount of sale of the 1 <sup>st</sup> year of implementation.	thous. UAH	128
8.	Forecasted amount of sale of the 2 <sup>nd</sup> year of implementation.	thous. UAH	448
9.	Forecasted destination of the product segment of the market of medicine.	%	4,3

We have determined the structure and total amount of investment to the project and basic characteristics of operational activity by the basic (the most optimistic), optimistic and pessimistic development scenarios (Table). To calculate this, we have determined that the developments term, public expertise, registration and implementation of medicine will take 2 years and 4 months, 7 months and 3 months, and the first cash income is possible in 4 months after commercial sale of medicine, or in 3 years and 6 months after the beginning of medicine development. High value of internal project profitability norm (IRR) proves efficiency and attractiveness of the proposed medicine. Investors will get 60% of income. Complete return of investments depending upon scenario is possible from 3 (optimistic scenario) up to 6 and more years (pessimistic scenario). We have determined cost change of investments during the project implementation. Modeling sale volume, price and discounts according to the cash flows scenarios proved the necessity to use active marketing program and a loyalty program in order to quickly master the product market segment, a significant increase of sale of preparation and getting a sufficient income to return the investments in time. The last steps will strengthen investment attractiveness of new medicines development and expands innovative and investment opportunities R&D of research, including optimal reinvestment of income gained to the new medicines development, business-angels involvement as people, who invest into perspective enterprises and business-projects, and provide them with their own network of contacts and experience. Among internal financing sources of innovations by the company – an experienced player we can single out unallotted income, existing assets, forecasted for another project, delay of payments [9,10,17,29,30]. In the process of projecting and management of marketing processes of innovations commercialization in industry we suggest using network planning, which increases achievement of consistency and determination in the implementation of the project, decreases its risks and partnership development with

customers. A mechanism of ‘breakpoints’ provides dynamics for the marketing project of innovations commercialization. Its functioning allows using basic management functions as a process (planning, decision making, formation of strategy, control). Breakpoints (planning, challenging and preventive) are focused on the processes development of commercialization at the most promising trends and determine transitional moments to strength management and at the same time they fulfill the indicative planning function, the implementation of which allows timely responding to the changes in marketing environment. With the help of breakpoints, we can build up a system of commercialization management, where the enterprise concentrates its resources on reaching strategies and goals.

#### Conclusions

1. It has been determined that innovative medicines significantly prolong the duration and increase quality of human life. Such medicines development requires significant finances; it is characterized by a long-term process duration of development and a high level of risks.

2. Difficulty and complexity of medicines development stimulate searching mechanisms as to monitoring the expenses and saving of finances for R&D research.

3. Publications analysis indicates practical lack of scientific works as to the systematic motivations and methodical approaches to technological process of innovative medicines development and implementation.

4. The motivated necessity of complex works as to the forecasting of expediency and efficiency of innovative medicines development.

5. We have demonstrated the importance of investment attractiveness motivation of new medicines development, interest in involving stakeholder groups to the implementation of innovative project.

6. At the example of generic antihypertensive medicines development, we have formed the key stages and modules of work. We have underlined the importance of previous predicted analysis of expediency,

economic efficiency and attractiveness of the whole project in some scenarios of development.

7. We have made basic calculations of economic indicators and required investments in the Nebivolol pills development. We have determined a high profitability of medicine production and big importance of internal norm of the project profitability (IRR). We have determined that the first cash income from the project is possible in 4 months after commercial medicine sale, or in 3 years and 6 months after the development beginning.

8. To use monitoring indicators of project forecasted model it is recommended to form "the road map" of medicines development, use network (circuit) approach, develop a marketing program and a loyalty program.

9. Extremely important is a previous forecasting and creation of "the road map" as to the determination of expediency, efficiency and investment attractiveness of the development and use of new medicine when setting the turn in the development composed by the innovative enterprise portfolio.

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