

PHARMACEUTICAL SCIENCES

INNOVATIVE APPROACH IN THE SYSTEM OF MANAGEMENT OF ORGANIZATIONAL AND TECHNOLOGICAL PROCESS OF NEW MEDICINE DEVELOPMENT

Samborskyi O. S.,

Candidate of Pharmacy (Ph. D.), associate professor of the Department of Organization and Economics of Pharmacy and Drug Technology, Ivano-Frankivsk National Medical University, Ivano-Frankivsk, Ukraine

Slobodyanyuk M. M.,

Doctor of Pharmacy, Professor of the Department of Pharmaceutical Marketing and Management, National University of Pharmacy, Kharkov, Ukraine

Malyi V.V.,

Doctor of Pharmacy, Professor, Head of Department of Pharmaceutical Marketing and Management, National University of Pharmacy, city of Kharkiv, Ukraine.

Baygush Yu. V.,

Assistant of Department of Organization and Economy of Pharmacy and Technology of Drugs, Ivano-Frankivsk National Medical University, Ivano-Frankivsk, Ukraine

Abstract

The article is dedicated to the investigation of optimization of systematic approach in the management of organizational and technological process of new medicines development using innovative technologies. We have motivated the necessity of a complex approach to the process of marketing, economic, medical, pharmaceutical and financial components. Based on our own experience and available references, we have formed blocks of the process and its components, determined the sequence of events and their relationship. To accelerate the process and save the resources we have emphasized on the necessity to fulfill the work using network approach and critical points. Based on our own computer program, we have formed a road map of implementation of the module of previous forecasting of expediency, efficiency and attractiveness of the investment project, which allows managing the risks when developing a new medicine.

Keywords: medicines, attractiveness, efficiency, expediency, "a road map", management, risks, investments, pharmacy, innovations.

Setting of a problem. Searching and development of new medicines represent a difficult marketing, economic, technological, medical, pharmaceutical, financial complex of works and processes, which are subject to a target complex management in order to solve an important social problem of the development of more efficient, more qualitative, safer and more available medicines. The complexity of the problem is caused by the fact that segments of pharmaco-therapeutic groups of medicines are enough saturated by the range of products, in turn, they have changed the consumer demands as to their high quality, efficiency, safety, modern medical technologies in the whole by giving the doctors and patients more opportunities for treatment. And this together with the increase of requirements of public expertise to new medicines leads to more durable searching and development of new medicines, increase of the risks level, a significant increase of the cost of R&D investigations. Multi-billion (US dollars) budgets and a long-term durability (more than 10 years) of the developments of original medicines make health protection authorities direct their efforts on the wider use of generic (recreation) and hybrid medicines by increasing at the same time the requirements as to their quality. So, for example, the main regulatory requirement to the pharmaceutical development of generic medicine is to make the developed medicine pharmaceutically-equivalent (it must have the same qualitative and quantitative composition of active pharmaceutical ingredient in the same medical form) to the original medicine as the first

one having been implemented to the market and bioequivalent to the last one.

In the innovative process medicines represent a special product and goods, which require significant financial investments, they are characterized by a long durability, a scientific and work intensity, a peculiarity of stages of complex chemical, technological, pharmaceutical, medical, economic and other investigations, requires a project supervision.

The involvement of financial investments to the long-term projects with a significant uncertainty of results requires a motivated risks management as to their minimization, argumentative commercial and investment attractiveness for investors, by returning the invested financial resources as well as getting the invested income, taking into account average market income and further entrepreneurial profit.

Analysis of recent investigations and publications. The analysis of available publications confirms lack of scientific works of methodological motivation and complex analysis of stages, works and processes as a single project, which is fulfilled in case of the development of new medicines, projecting of management and investment decisions and analysis of risks according to the scenarios of events development [12,13,15]. Today we know the developments of some stages and works of such process [1,2,4,13]. Scientific and methodological developments with a previous motivation of efficiency and expediency of new medicines development and determination of methods of effective management of their implementation.

Formulation the goals of the article. Comprehensive summary of methodological techniques, complex assessment of the components of the previous stage of organizational and technological complex approach of new medicine development based on innovative approach.

Unsolved issues, which are part of general problem. Traditional approaches in practice as to the implementation of new medicines development today do not meet the requirements of the market, investigators, manufacturers and investors. Therefore, the existing problems in this sphere require more profound scientific research, analysis, summary and methodical recommendations in innovative positions and requirements of the up-to-date world.

The goal of our research is to motivate innovative approach in the system of management of organizational and technological process of new medicine development.

Basic results of the research. A significant increase of the demand of the humanity for using more effective, qualitative, safer and more available medicines, especially socially-oriented, leads to strengthening searching and developments of such medicines as well as to the increase of requirements of public regulatory authorities regarding the new medicines. Big scientific and budget volume of such scientific and research works force the researchers and investors to searching and using up-to-date innovative approaches, to the organization of the process of new medicines development [3,5,7]. Here a special attention is given to works and processes in the forecasted part of projects, which give an opportunity to get as much objective information as possible regarding social and medical activity, economic efficiency, commercial capability and investment attractiveness of further works. According to general approaches, indicators and numbers of expectations from the project, an important place at the previous stage is given to primary complex, informational, marketing, pharmaceutical and economic investigations, which must then accompany the whole process of the project implementation. Head of the Department of Researches and Development of the leading innovative Ukrainian manufacturers of medicines of PSC "Pharmac" A.Goy emphasizes urgent necessity of preliminary marketing research of the expediency of new medicines development [9]. Innovative activity of

the company under the conditions of a significant competition must be MTM-oriented (minimal time-to-market) – a medicine must appear at the market when it is necessary, otherwise – it can be forced out by the competitors. Involvement of financial investments to the long-term projects with a high degree of uncertainty requires motivated management of risks as to their minimization, argumentative commercial and investment attractiveness for investors, by returning the invested financial resources as well as getting the invested income taking into account average market income and further entrepreneurial profit [5,6,8,10,11,13,17]. We should mention that investments become more expensive over time and it is possible to return them, even generic medicines, by starting active commercial use of medicine (approximately in 3.6 years). The complete return of discounted investments depends not only on the level of profitability of the medicine, it depends on active sales from the first series of its manufacturing [7,14,16].

The profound studying of the components of the procedures and types of work regarding the development of new medicines gave us an opportunity to form a logical sequence of their fulfillment, to determine a relation with other types and stages of work in general organizational and technological process. At the same time we have analyzed unified requirements as to the procedures of the process of development of new medicines, their control and expertise. The main regulatory requirement to pharmaceutical development of generic medicine is to make the developed medicine pharmaceutically equivalent (it must have the same qualitative and quantitative composition of pharmaceutical ingredient in a medical form) to the original medicine as the first one having been implemented to the market and bioequivalent to the last one [2].

In the process of detailed investigation of the works required during the previous analysis of the block of forecasting, expediency and efficiency of developments we have determined the sequence of events and critical points to work them out in the network flow. On the example of our own investigation, results of questionnaire of the researchers we have determined general needs of time expenditures (days), finances (UAH) and the required number of performers (labor costs) for each investigation (Table 1).

Table 1. Components of informational patented and marketing investigations when providing motivation of efficiency and attractiveness of new medicine development

Item #	Name	Document	Scenario of events development						Number of performers
			Basic		Optimistic		Pessimistic		
			duration, month	cost, UAH	duration, month	cost, UAH	duration, month	cost, UAH	
1.	Assessment of pharmaco-epidemiological situation in the country	report	0,50	7 800,0	0,25	5 200,0	1,00	13 000,0	2
2.	Determination of perspective of medicine market segment	report	0,15	1 040,0	0,05	520,0	0,30	1 300,0	1
3.	Informational research as to the perspective of use of medicine	report	0,40	910,0	0,20	650,0	0,60	1 560,0	2
4.	Marketing research as to the product segment of medicine	report	0,30	7 800,0	0,20	3 900,0	0,50	10 400,0	3
5	Sales of medicines in the country for the last years. Tendencies for the last 3 years.	report	0,20	520,0	0,10	390,0	0,40	1 170,0	1
6	Determination of forecasted demand for medicines	report	0,40	1 820,0	0,20	1 040,0	0,60	2 340,0	2
7	Determination of perspectives of the development of domestic medicine in a specific medical form, techno+technological possibilities of production	report	0,20	520,0	0,10	390,0	0,30	780,0	1
8	Making a decision as to further developments	Decision	0,10	130,0	0,10	78,0	0,20	520,0	2
9	Forecasting of the volume of the product segment of the medicines market for the 3 or 5 years	report	0,40	1 560,0	0,30	1 040,0	0,60	2 080,0	1
10.	Influence of active communicative means on the sales of medicines	report	0,50	2 340,0	0,30	1 300,0	0,60	2 600,0	1
	Promotion campaigns	report							
	Loyalty programs	report							
	Marketing partnership programs	report							
	Other events	report							
11.	Forecasting of the market share of medicines for a new manufacturer	report	0,30	390,0	0,20	260,0	0,50	780,0	1

	With the use of active promotion campaigns	report							
12.	Primary informational searching	report	0,50	520,0	0,30	390,0	0,70	780,0	1
13.	Primary patent searching	report	0,80	1 170,0	0,70	910,0	1,10	1 820,0	1
14.	Analysis of data about the composition of original and available generic medicines	report	0,20	260,0	0,10	130,0	0,30	390,0	1
15.	Preliminary determination of patent purity and patentability of new medicine	report	0,20	260,0	0,10	156,0	0,30	650,0	1
16.	Determination of a medicine trade name		0,10	78,0	0,10	52,0	0,20	130,0	1
17.	Making a solution as to further works	Decision	0,10	130,0	0,10	78,0	0,20	182,0	2
18.	Searching and choosing of suppliers of active pharmaceutical ingredient or medical plant raw material	report	0,70	208,0	0,40	130,0	0,90	312,0	1
19.	Getting from a manufacturer of active pharmaceutical ingredient the required documents: certificate of quality and a certificate of origin	report	0,30	20,8	0,10	7,8	0,50	364,0	1
20.	Analysis of samples of active pharmaceutical ingredient or medical plant raw material	report	0,20	2 730,0	0,10	2 236,0	0,30	3 120,0	3
21.	Making a decision as to further works	report							
22.	Motivation of social medical appropriateness of medicines development	report	0,40	728,0	0,20	338,0	0,50	988,0	1
23.	Forecasted calculation of the cost price of medicines, manufacturer's price, profitability	report	0,10	208,0	0,10	130,0	0,20	312,0	1
24.	Sub-block "calculation of the product cost price"	Table							
25.	Forecasted determination of the volume of medicines production and techno-technological possibility of manufacturing	report	0,10	130,0	0,10	78,0	0,40	936,0	2
26.	Forecasted determination of total volume of investment	report	0,20	468,0	0,10	312,0	0,40	1 092,0	1
	Sub-block "Main characteristics of investments"	Table							
27.	Forecasted determination of the alternation of demands of investments in time	Table	0,40	2 080,0	0,30	1 690,0	0,60	2 444,0	1

28.	Assessment of the cost of investments in time during the period of medicine development, public expertise, registration and production	Table	0,20	260,0	0,10	156,0	0,30	572,0	1
29.	Making a decision as to further works	Decision							
30.	Forecasting of medicine sales volume (scenarios of development)	Report	0,20	182,0	0,10	78,0	0,40	234,0	1
31.	Forecasting of income, revenue	report	0,20	182,0	0,10	52,0	0,30	182,0	1
32.	Sub-block "Key characteristics of operating activity" (scenarios of development)	Table							
31.	Forecasting of break-even production	report	0,20	78,0	0,10	52,0	0,30	104,0	1
	Sub-block "Modeling of break-even point" (scenarios of development)	Model							
32.	Forecasting of the flow of income, revenue and return of investment	report	0,20	104,0	0,10	52,0	0,30	130,0	1
	Sub-block "Model of cash flows according to the project" (scenarios of development)	Model							
33.	Summary of data and general assessment of risks as to the appropriateness of the project	Scheme	0,30	312,0	0,20	234,0	0,50	728,0	1
34.	Sub-block "General block-scheme of the road map"	Scheme							
35.	Discussion of the investment project attractiveness	report	0,10	78,0	0,10	78,0	0,20	104,0	
36.	Indicators map	Map							
37.	Making a decision as to further works	Decision							
Total			10	35 016,8	6	22 107,8	15	52 104,0	

According to the results, to fulfill the above-mentioned works of the previous analysis of the project we need approximately 10 months (from 6 to 15 months) in appropriate scenarios of development of events and correspondingly 35 thousand UAH (from 22 to 52 thousand UAH).

When using innovative approach to the management of organizational and technological process of previous forecasting, we have determined the necessity of fulfillment of works and critical points (Figure 1).

At the block-scheme of the "road map" we have numbered types of works according to the ones shown in the table. As we can see in the figure, we recommend using five critical points during which we deliver management and investment analysis of indicators to make a rational decision as to the expediency of further works. We have determined period of time required for the fulfillment of works within a sub-block based on the longest term of fulfillment. Thus, at 1-5

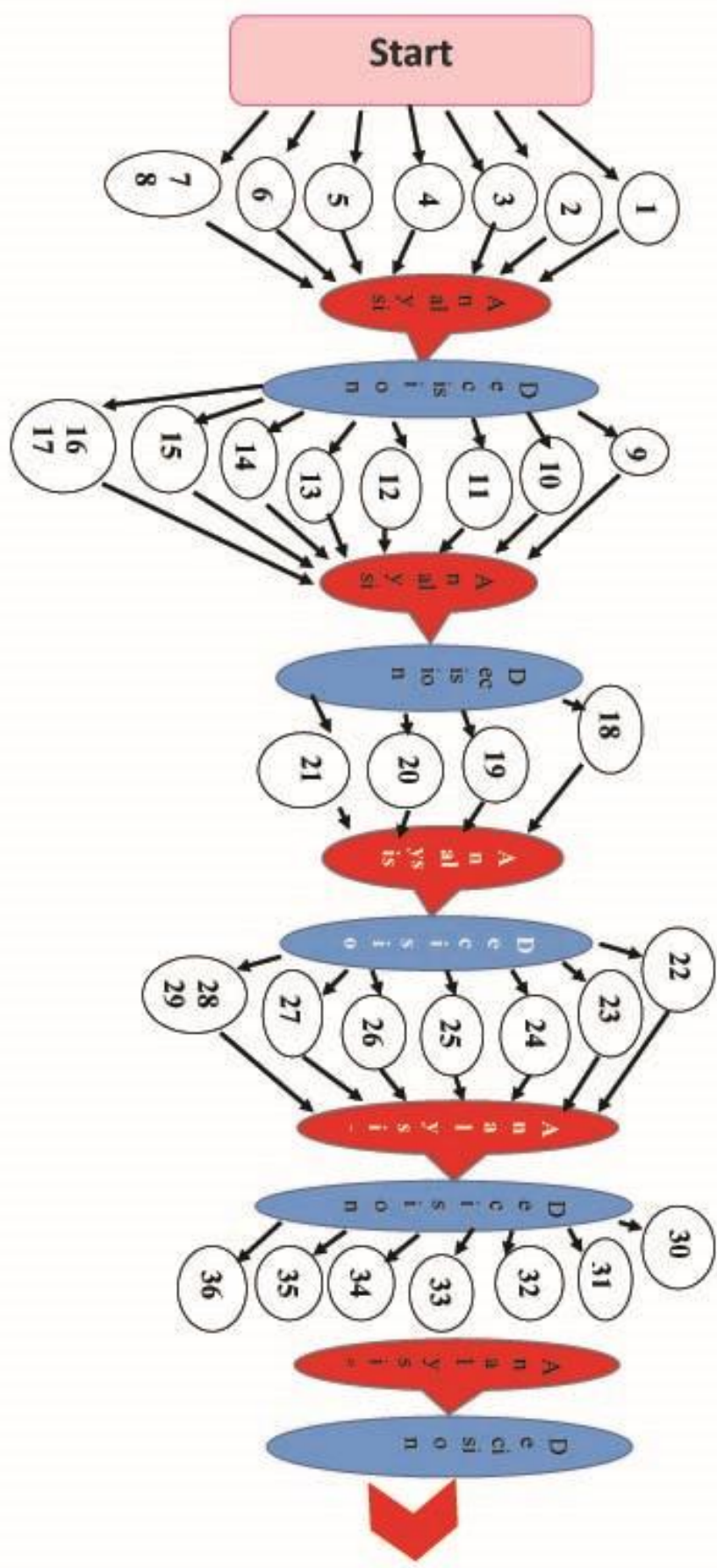


Figure 1. Block-scheme of “a road map” of management of organizational and technological process of new medicine development (author’s development)

Note: types of works are numbered according to the ones shown in the table

stages the longest terms amount to 0,5; 0,5; 0,7; 0,4 and 0,3 months (or 2,4 months total). In general, innovative approach of management focuses on the shortening the term of works forecasting when delivering complete investigation from 10 months to 2,4 months. Informational, marketing, economic and financial indicators obtained during this investigation should be used not only to motivate marketing decision, but to form a complex project, to determine budgets and their sequence of use, amount of investments, types of their allocation and sequence of demands.

Conclusions.

1. We have determined that the development of new medicines represents a unified complex of interrelated informational, marketing, technological, chemical, economic, medical, financial and commercial components. At each stage we see a high level of risks.

2. Increase of requirements as to the quality, efficiency, safety and availability of medicines, as well as regulatory authorities, leads to the significant increase of the cost of works and their duration. Transparency of investigations forces searching ways of saving time and money.

3. Analysis of publications indicates practical lack of scientific works as to the systematic motivations and methodological innovative approaches, as to the preliminary motivation, efficiency of developments and implementation of medicines. According to the results of questionnaire and individual investigations we have motivated the components of the first forecasted stage of works. We have worked out the necessity of time and financial investments. According to the results, to fulfill the highlighted works of the previous analysis of the project we need approximately 10 months (from 6 to 15 months) in the appropriate scenarios of development of events and correspondingly 35 thousand UAH (from 22 to 52 thousand UAH).

4. We have developed a block-scheme of the "road map" algorithm of work regarding determination of critical points for decision making as to further works. General duration of work was determined by the biggest ways, which is 2,4 months.

5. The required data based on the suggested innovative approach are given for making a decision as to the expediency of further works and reducing of risks.

Results of this investigation may be used as a foundation of further scientific developments when forecasting the expediency and efficiency of making investment and management decisions as to the new projects, assessment of projects during their fulfillment, and the implemented projects in order to determine their efficiency.

References

1. Байгуш Ю.В. Обґрунтування економічної ефективності та комерційної доцільності впровадження нового антигіпертензивного препарату / Ю.В. Байгуш, М.М. Слободянюк, О.С. Самборський // Управління якістю в фармації: збірник наук. робіт X наук.-практ. конфер. з міжнародною участю (м. Харків, 20 травня 2016 р.) / ред. кол.: В.О.

Лебединець, Ю.В. Підпружников, Ю.І. Губін та ін. - Харків : НФаУ, 2016. – С. 18–20.

2. Демкин И.В. Оценка риска инвестиционных проектов фармацевтического предприятия / И.В. Демкин, А.В. Стрельцов, И.Д. Галетов // Управление риском. – 2004. – № 4. – С. 16–27.

3. Доровской А. В. Состояние и перспективы развития фармацевтического рынка Украины // Проблеми економіки. – 2014. – № 3. – С. 71–80.

4. Коваленко Св. М. Обґрунтування соціально-медичної доцільності розробки та економічної ефективності таблеток «Гіотарін» / Св. М. Коваленко // Вісник фармації, 2015. – № 4(84). – С. 47 – 51.

5. Самборський О.С. Стейкхолдерська модель відносин у соціально орієнтованій асортиментній політиці фармацевтичних підприємств / О.С. Самборський, М.М. Слободянюк // Технологічні та біофармацевтичні аспекти створення лікарських препаратів різної направленості дії : матер. II Міжнар. наук.-практ. Інтернет-конфер., 12-13.XI.2015 р. – Харків, вид-во НФаУ, 2015. – С. 215–216.

6. Слободянюк М.М. Особливості фінансування розробок нових лікарських засобів як довгострокових інвестиційних проектів / М.М. Слободянюк, О.С. Самборський // Соціальна фармація: стан, проблеми та перспективи: матер. III міжн. наук.-практ. інтернет-конференції, 25-28 квітня 2017 р. / ред. кол.: А. А. Котвіцька та ін. – Х.: Вид-во НФаУ, 2017. – С. 180–183.

7. Слободянюк М.М. Особливості підходів до визначення вартості та фінансування розробок інноваційних лікарських засобів / М.М. Слободянюк, О.С. Самборський // Сучасні досягнення фармацевтичної технології та біотехнології: збірник наукових праць. За матер. V наук.-практ. Інтернет-конфер. з міжнар. участю (18.XI.2016 р.) – Х.: Вид-во НФаУ, 2016. – С. 557–560.

8. Слободянюк М.М. Логістичний ланцюг та мережевий підхід як засіб підвищення ефективності стейкхолдерської моделі створення нових лікарських засобів / М.М. Слободянюк, О.С. Самборський // Актуальні проблеми розвитку галузевої економіки та логістики: матер. V міжнарод. наук.-практ. конференції з міжнар. участю 20-21 квітня 2017 р. / ред. кол.: О.В. Посилкіна, О.В. Літвінова, Я.Г. Онищенко. – Х.: Вид-во НФаУ, 2017. – С. 291–294.

9. Соколова Е. Инновации доступны каждому // <http://gazeta.zn.ua/HEALTH/innovacii-dostupnye-kazhdomu-.html>

10. Хонл Т. А. Затраты на разработку инновационного лекарственного препарата // Проблемы учета и финансов. – 2013. – №2 (10). – с. 52–54.

11. Drug repositioning: bringing new life to shelved assets and existing drugs / edited by Michael J. Barratt, Donald E. Frail. Printed in the United States of America. – 2012. – 470 с.

12. Samborskyi, O. There is a question of risk and management of vagueness processes in the field of pharmaceutical / O. Samborskyi, M. Slobodyanyuk, O. Yevtushenko // The scientific heritage. (Budapest, Hungary) – 2017. – No 9 (9). – P. 26–35.

13. Samborskyi, O. A foundation of scientific and practical approaches to determination of expediency and investment attractiveness of the new antihypertensive medicines development / O. Samborskyi, M. Slobodyanyuk, Yu. Baygush // The scientific heritage. (Budapest, Hungary). – 2017. – No 14 (14), P.1. – P. 36 – 42.
14. Ding M., Eliashberg J., Stremersch St. Marketing in the Pharmaceutical Industry. Editors Emerging Practices, Research, and Policies. Chapter 3. Portfolio Management in New Drug Development. – New York. – 2014. – s. 83-117.
15. DiMasi J.A, Hansen R.W, Grabowski H.G, Lasagna L. Cost of innovation in the pharmaceutical industry. Journal of Health Economics. 1991,10 (2): 107–142.
16. DiMasi J.A, Hansen R.W, Grabowski H.G. The price of innovation: new estimates of drug development costs. Journal of Health Economics. 2003, 22(3): 141–185.
17. Scannell J., Blanckley A., Boldon H., Warrington B. Diagnosing the decline in pharmaceutical R&D efficiency. Nature Reviews. Drug Discovery. – Volume 11. – March 2012. – 191-200.