St. Petersburg University
Graduate School of Management

Master in Public Management Program

THE IMPACT OF GOVERNMENT REGULATIONS ON THE VALUE CHAIN OF PHARMACEUTICAL COMPANIES IN RUSSIAN FEDERATION

Master's Thesis by the 2nd year student
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ЗАЯВЛЕНИЕ О САМОСТОЯТЕЛЬНОМ ХАРАКТЕРЕ ВЫПОЛНЕНИЯ ВЫПУСКНОЙ КВАЛИФИКАЦИОННОЙ РАБОТЫ

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Описание цели, задач и основных результатов	Целью настоящего исследования является использование модели цепочки добавления стоимости Майкла Портера для разработки методики оценки регулирующего воздействия и ее применения для оценки регулирующего воздействия на фармацевтические компании в Российской Федерации. Задачи данной магистерской диссертации включают в себя детальный обзор государственного регулирования в фармацевтической отрасли; рассмотрение ключевых существующих регулятивных механизмов; анализ теоретической основы регулирования; Проведение оценки регулирующего воздействия; на основе проведенного практического исследования разработка конкретных рекомендаций для уполномоченных органов по вопросам улучшения процесса регулирования фармацевтической отрасли. Результаты данного исследования могут быть использованы представителями как федеральных, так и региональных органов власти для улучшения эффективности регулирования фармацевтической отрасли в РФ.
Ключевые слова	Государственное регулирование, фармацевтический рынок, цепочка формирования стоимости, оценка регулирующего воздействия

ABSTRACT

Master Student's Name	Bogochanova Anastasia
Master thesis title	The impact of government regulations on the value chain of the Russian pharmaceutical companies
Faculty	Graduate School of Management, Saint-Petersburg State University
Main field of study	38.04.04 «Public Management»
Year	2018
Academic Advisor	A.E. Ivanov, associate professor, candidate of science (Mathematics)
Description of the goal, tasks and main results	The purpose of this study is to develop a methodology of regulatory impact assessment, based on Michel Porter's value chain, and its application to assess the impact of regulations on pharmaceutical companies in the Russian Federation. The objectives of this master's thesis include a detailed review of existing state regulation in the pharmaceutical industry; consideration of key regulatory mechanisms; the analysis of theoretical bases of regulation; conducting regulatory impact assessment analysis; on the basis of practical research, the development of specific recommendations for government for improving the regulatory process. The results of this study can be used by representatives of federal and regional authorities to increase the efficiency of pharmaceutical industry regulation in the Russian Federation.
Key words	State regulation, value chain, pharmaceutical market, regulatory impact assessment, cost-benefits analysis

List of abbreviations

API Active pharmaceutical ingredient

CBA Cost-benefit analysis

GMP Good Manufactures Products

IP Intellectual Property

IAS Information-analytical system

NBE New biotech entity

NME New molecular entity

OECD Organization economic co-operation and development

PVC Pharmaceutical value chain

RD Research and development

RIA Regulatory Impact Assessment

UNRISD United Research Institute for Social Development

VED Vital and Essential Drugs List

VC Value chain

WTO World Trade Organization

WHO World Health Organization

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INTRODUCTION

The social and economic role of medicines in the Russian healthcare system is highly important. Last years, the pharmaceutical market is growing fast and it is expected to reach $36.61 billion by 2021. The high profitability and rapid development of the industry is correlated with government state supportive programs and strong state policies. But for further sustainable functioning, pharmaceutical market needs effective state regulation.

Nowadays, Russian government supports the pharmaceutical and medical industry by different types of active financial support: subsidies, reduces taxes and tax preferences, also, by stimulation the flow of new domestic and foreign investments, opening the new high-tech enterprises opening and the modernization of existing production facilities. But apart from the financial support, there is a strong need in state regulation. The main authorities goal is to ensure that drugs are available, safe, and effective for people.

This research paper is based on Michael Porter's value chain concept applied for regulatory impact assessment and a cost-benefits analysis regarding the Russian pharmaceutical market's value chain.

The main goal of this research is to provide a methodology for assessing the drug regulation for authorities at a regional or federal level and methodology application to assess the impact of regulations on pharmaceutical companies in the Russian Federation.

Research objectives of the case study are:

- Identify the specifics of M. Porter value chain concept applying it in the pharmaceutical industry;
- Identify key regulations and policies;
- Modify the regulatory impact analysis techniques assessing successively the impact of regulation tool on elements of value chain by Porter's approach;

In order to achieve the goal of research, the following objectives had been set:

- Identify key regulations and policies in the pharmaceuticals
- Consider key legal aspects of pharmaceuticals
- Analyze theoretical foundations of value chain concept
- Provide metrology to enhance understanding of the fundamentals of drug regulation, which policy-makers may use in designing drug regulations
- Provide the cost and benefit analysis to evaluate the regulations

- Complete the results of regulatory impact assessment
- Design policy recommendations and make suggestions about further industry regulations.

Moreover, this work is aimed at answering the following research questions:

- What are the main tools of the government influence on pharmaceuticals in Russia?
- How to assess the impact of the regulation?
- What are the positive and negative effects of regulation?
- Which measures are needed to be implemented to decrease regulation costs?

In order to achieve these objectives, theoretical basis was explored, the international practices, data from manufacturers, distributors, and main market players was gathered and analyzed. Moreover, data regarding the methodology of regulatory impact analysis according to which the policies and regulation can be evaluated, including quantitative and qualitative parts of analysis, was also collected and complete. The methodological basis of this research combines a multitude of complementary methods and RIA techniques.

This paper consists of three chapters. The first chapter gives the main definitions and theoretical approaches of the value chain concept and the regulatory impact assessment background. The second chapter is devoted to the overview of the Russian pharmaceutical industry and the description of the existing regulatory system, measures and methods of regulation.

The third chapter is aimed at explaining the particular case study and research process, based on created for assessing the methodology, consisting of different techniques of analysis. The research is based on the value chain concept. Also, this part of case study includes recommendations for authorities, for improvement some regulations for effectiveness of policies.

This paper is directed for Russian authorities on a federal and regional level and pharmaceutical market players. This research will provide an analysis on the regulation of the pharmaceutical value chain by the Russian government and the effects of regulation, as well as recommendations.

CHAPTER 1. THEORETICAL BACKGROUND AND LITERATURE REVIEW OF VALUE CHAIN CONCEPT AND REGULATORY IMPACT ASSESMENT METHOD

1.1 Introduction

In the first chapter, literature which is related to the research and consistent with the objectives of the study was comprehensively surveyed and reviewed. Important theoretical and practical problems were brought out. Relevant literature on the value chain concept theory and the regulatory impact assessment analysis was discussed.

1.2 Theoretical background of value chain concept

The modern manufacturing process is based on the value chain (VC) structure. This concept shows that the links of the value chain are not in competitive relations with each other, but in close cooperation they aim at achieving one common goal. In each link of the chain an enterprise adds its price to the final product or service. This product or service is only considered complete when it reaches the final stage of this chain.

The concept of the value chain was first developed by Michael Porter in 1985 in his book "Competitive Advantage: Creating and Sustaining Superior Performance". M. Porter defined the value chain as a set of activities which adds value at every single step in designing, producing, and delivering a quality product to the customer and is used to evaluate the activities within and around the organization and relating to its ability to provide value for money, goods, and services. The total concept of the value chain is based on the idea of showing the process of manufacturing as a system made up of subsystems (each with inputs, transformation processes and outputs). Inputs, transformation processes, and outputs involve the acquisition and consumption of resources, such as money, materials, equipment, buildings, land, administration and management [Porter, 1985].

The value chain consists of three groups of business processes:

1) *Supporting activities - the processes that create the conditions for a more efficient operation of the company.*

Procurement – This is what the organization does to get the resources it needs to operate. This includes finding vendors and negotiating best prices.

Human resource management – This is how well a company recruits, hires, trains, motivates, rewards, and retains its workers. People are a significant source of value, so businesses can create a clear advantage with good HR practices.

Technological development – These activities relate to managing and processing information, as well as protecting a company's knowledge base. Minimizing information technology costs, staying up-to-date with technological advances, and maintaining technical excellence are sources of value creation.

Infrastructure – These are a company's support systems, and the functions that allow it to maintain daily operations. Accounting, legal, administrative, and general management are examples of necessary infrastructure that businesses can use to their advantage.

2) *The main activities are what the company does, excluding the process of directly creating value.*

The process starts from inbound logistic including the processes related to receiving, storing, and distributing inputs internally, where supplier relationships are the key factor in creating value.

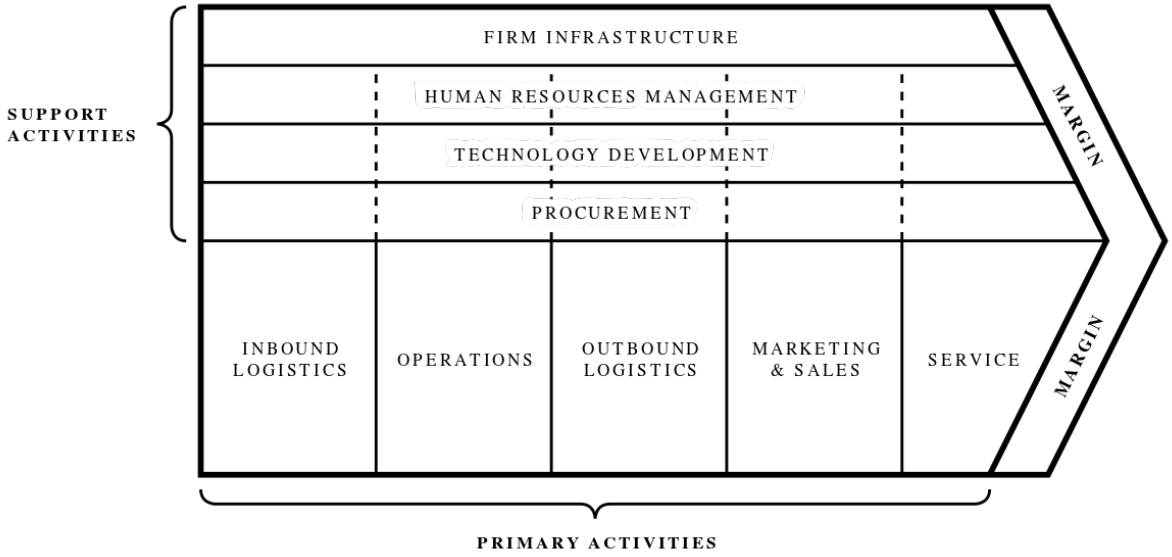
Operations are including the transformation activities that change inputs into outputs that are sold to customers.

Outbound logistics deliver product or service to customer. Process supports collection, storage, and distribution systems, and they may be internal or external to the organization.

Marketing and sales – These are the processes you use to persuade clients to purchase from you instead of your competitors. The benefits you offer, and how well you communicate them, are sources of value here.

Service part includes activities related to maintaining the value of product to customers, once it's been purchased.

3) *Stages of value creation are processes that directly create the final product and its value.*



Picture 1.1. Porter's Value chain concept

Source: M. Porter (1985) Competitive Advantage

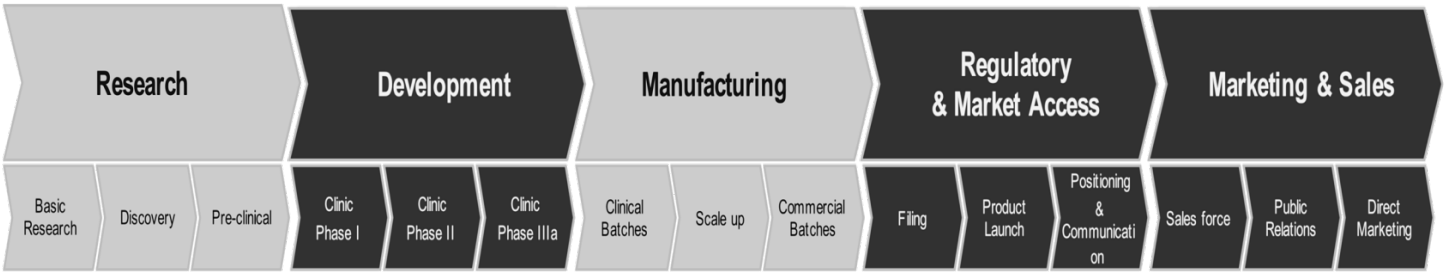
1.3 The specifics of concept applicable to the pharmaceutical industry

The pharmaceutical industry is an industrial activity whose main goal is the development, production, and marketing of drugs licensed for the use as medications. [McGuire, 2007].

Traditional pharmaceutical companies are dominating in the industry for decades. Meanwhile, the competitive advantage of biotechnology firms depends on advanced technological knowledge and research and development activities.

The process of describing the pharmaceutical value chain needs the identification of each participant from manufacturer to end consumer of medicines and moreover their interaction. Basically, the manufacturer's selling price represents just a small part of the retail price of medicine. More than half of the end user price results from insurance, extra charges, import tariffs, importer margin and taxes, it is the reason why pharmaceutical value chain is highly correlated with government regulations.

The goal of the pharmaceutical industry value chain is to identify each component from the manufacturer to the end consumer of medicines. The below figure explains the pharmaceutical value chain.



Picture 1.2. Pharmaceutical value chain

Source: made by Arthur Dr. Little

Research

The first step in the pharmaceutical value chain (PVC) is the process of research activities which involves the identification and validation of new targets. Those are a naturally existing cellular or molecular structure that the drug in development is meant to act on. This is followed by further identification and optimization of a lead drug candidate which could be a new chemical entity (NCE), which are typically called "molecules".

Development

It includes preclinical experimentation of the new molecular entity (NME) in live cells, tissues, or animal models to demonstrate and to prove its safety and effectiveness. Following this experimentation, the future drug is clinically tested to demonstrate its safety and efficacity on humans. The development process is divided in three phases:

- Phase I: clinical trials are done with a small number of people; typically between ten and one hundred healthy volunteers to examine the drug's safety.
- Phase II: trials are done with a larger number of patients; between fifty and five hundred to further examine its safety and determine effective drug doses.
- Phase III: trials are undertaken using a very large number of patients; up to thousands of patients in many different sites to explore its long-term safety and efficacy [Pisano, 2006].

In order to produce a medicine, a number of steps are involved. From the initial research and development phase up to gaining regulatory approval which allows a medicine to be produced. The specific steps and requirements will differ between the types of medicine, manufacturers, and countries.

The figure below as a good example which shows the R&D process in one of the biggest

manufacturers in Russia BIOCAD. They are using the universal platform to develop original medicinal products, which is named “BonMab”.

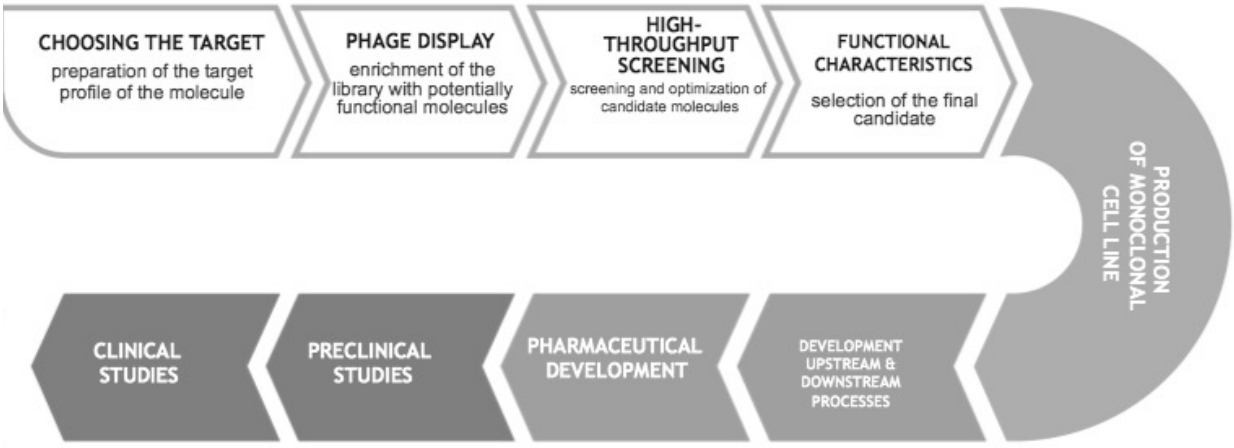


Figure 1.3 The R&D process in BIOCAD example
Source: BIOCAD

Market Access

The new molecular entity (NME) which successfully passes through all these stages finally goes through the approval stage, where it comes under the lens of the regulatory boards of the place where it is to be manufactured and marketed. Such newly developed drugs are patented by the organizations to gain exclusive commercialization rights. Patent policies in the pharmaceutical industry take a long time for the firm to license-out the patented NME and maximize its derived revenues, facilitating the reimbursement of the cost of associated R&D. After this period, a drug can be commercialized as generic with no revenue for the original developer.

Marketing and Sales

The marketing activities of pharmaceutical manufacturers are developing in line with modern pharmaceutical marketing. This pharmaceutical activities’ organization and management system is focused on studying the consumers’ needs, in order to improve their quality of life and the welfare of the whole society.

1.4 Pharmaceutical value chain costs

Nowadays, innovation companies invest a lot of money in research and development in order to discover and bring new medicines to the market. Due to the large financial investment involved, these medicines receive a period of market exclusivity. At the point this expires, generic manufacturers are able to manufacture and bring to market generic versions of the original brand

molecule which contain the same active substance, but cheaper, produce the same therapeutic effect and are manufactured to the same quality as the original product.

For originators, the largest costs are connected with drug research, which identifies new chemical or biologic entities that have the potential to advance the current standard of disease treatment, the costs of subjecting potential drug candidates to rigorous testing through clinical trials, which many will fail to complete.

Additional costs are incurred in the submission of applications to regulatory agencies, and once approved, costs are incurred by manufacturers to promote and educate key stakeholders about the product and the benefits it can bring to patients. It is difficult to put an exact figure on the cost involved in bringing a medicine to market, as this will differ between the type of drug, level of innovation and magnitude of risk involved. In contrast, generic manufacturers normally have relatively low development and manufacturing costs. Their main means of promotion is through trade incentives, offering larger discounts to secure volume sales.

The value added from the generation of a new medicine is first and foremost that which directly relates to patient treatment. Such advances may tackle a new disease or indication, improve health outcomes, treatment safety, tolerability and/or side effects and the ability to better treat specific patient sub-populations. In addition, there are wider benefits to the health system such as decreasing the burden on other health resources and overall societal benefits such as enabling people to return to work.

The added value from generics manufacturing is that of introducing competition into the market, which in an efficient market can help payers achieve savings on older treatments in order to invest in new ones or offer lower cost alternatives to patients in out-of-pocket markets.

	Manufacturing of drug	**Distribution**	**Dispensing**
Cost incurred	• R&D • Manufacturing costs • Import duties and taxes • Promotion and education	• Medicine acquisition • Handling and delivery • Obsolescence costs • Capital costs • Promotion and education	• Medicine acquisition • Labour, facilities, equipment • Medical wastage • Capital costs • Education

Value added	• Innovation • Regulatory documentation • Quality assured manufacturing • Education	• Ensuring continuous medicine supply • Waste management • Order processing • Education	• Medicine availability • Pharmacist advice • Patient convenience • Additional health services • Education

Picture 1.4. Costs incurred and value added in components of the pharmaceutical value chain. Source: MS Institute for Healthcare Informatics.

1.5 Theoretical background and definition of the regulation

The regulation theories research started by Averch and Johnson [1962], Caves [1962], Meyer et al. [1959], and Stigler and Friedland [1962] and represented a watershed in the study of economic regulation by administrative agencies.

Studies of regulation, whether theoretical or empirical, normally fall into areas of price and entry regulation in industries with competitive market structures, price and entry regulation in monopolistic industries, and "qualitative" regulation, which attempts to cope with various kinds of market-failure problems that are only indirectly linked to prices, profits, and market structure. In the third category are environmental, health, occupational-safety, and product quality regulation [Paul L. Joskow, Roger G. Noll, 1981].

The term regulation can be defined as rules or norms created by government and backed up by some threat of consequences, usually negative ones in the form of penalties. Given their variety, regulations can be described using many different labels: constitutions, statutes, legislation, standards, rules, and so forth. Regulation seeks to make such improvement by changing individual or organizational behavior in ways that generate positive impacts in terms of solving societal and economic problems. [Coglianese; OCED, 2012].

Even a well-defined, individual regulation will often comprise a complex chain of interventions, interactions, and impacts. The regulation works when it solves, or at least reduces or ameliorates, the problem or problems that prompted government to adopt it in the first place [Treasury Board Canada Secretariat, 2009].

1.6 Regulatory policy

The organizational and environmental characteristics that make up the regulatory institution will be general ones, rather than rules, procedures, or practices specifically directed at regulatory decision making and behavior. All the various rules, procedures, and practices related to regulation will, for simplicity, be referred as regulatory policy. They are also sometimes referred to as regulatory management systems [OECD, 2009] or more simply as policies, tools, and processes related to regulation [Jacobzone, 2007].

Regulatory policy includes transparency and consultation rules, such as requirements for public notice of proposed regulations, public access to key meetings, or disclosure of relevant information relied upon by governmental decision makers. Regulatory policy also includes processes for certain types of planning and analysis to be conducted prior to a regulatory decision, such as regulatory impact analysis, cost-benefit analysis, impacts on small businesses or local governments, or paperwork burden analysis.

1.7 Regulatory impact assessment (RIA) method

The use of RIA as a tool of public sector management and decision making is widespread, and the majority of OECD countries have adopted formalized RIA arrangements. In March 1995, the Council of the OECD adopted a Recommendation on Improving the Quality of Government Regulation, which made reference to the use of RIA [OECD, 1995].

Regulatory impact assessment is the core component for regulatory reform. According to Colin Kirkpatric and David Parker work, the RIA a method of policy analysis, which is intended to assist policy-makers in the design, implementation and monitoring of improvements of regulatory systems, by providing a methodology for assessing the consequences of proposed and existing regulations.

According to RIA guidelines [OECD, 2004] it is the process of identifying the problems and objectives of regulation, selecting alternatives to achieve these goals, with the aim of avoiding unnecessary and rash regulation, and, using scientific and verifiable techniques applied to all available information available, and taking into account the different the views received during the consultation, the analysis of costs and benefits of selected alternatives. Also, a mechanism to systematically identify the main problems and objectives of the proposed regulations, identify and assess the main alternatives to achieve the objectives for making managerial decisions.

In Russia, the assessment of the regulatory impact is an independent type of examination of regulatory legal acts, state regulation projects and draft normative legal acts having a special subject of research, the tasks of which cannot be resolved through the application of other types of expertise of regulatory legal acts.

RIA is considered a prerequisite for the existence of a regulatory policy in the state (the so-called "smart or qualitative" regulation), being a generally accepted tool in developed countries;

RIA started to be permanent rather than episodic - with schedules, targets and evaluation mechanisms;

Lack of a single RIA model in different countries. The introduction of RIA took into account the political, constitutional and administrative environment, as well as the social, cultural and legal characteristics of a country;

RIA develops in breadth, encompassing more and more areas of use. The breadth of use of RIA differs from country to country. For example, there are countries (Australia, Japan, N. Zeeland, Norway, United Kingdom, USA), where there are similar systems of impact analysis, including quality control, economic efficiency and impact on competition and market openness;

The trend towards greater openness and transparency in the implementation of RIA (including considerable attention in the conduct of RIA is given to public hearings and public consultations in developing the solution).

Emphasis on the transfer of knowledge on RIA, by training civil servants, cultivating among them technical skills and a cultural perception of the use of RIA as a means of policy.

CHAPTER 2. GOVERNMENT REGULATIONS AND RUSSIAN PHARMACEUTICAL MARKET OVERVIEW

2.1 Introduction

In this chapter, there is an overview and main trends in the pharmaceutical industry nowadays in Russia. Also, the description of current governmental methods of regulations, prerequisites and consequences of regulation.

Pharmaceuticals are a key input into health care and cover a large, and for many countries a growing share of the health budget. They are a high tech, high value input to achieve and maintain health outcomes for a population.

In its extreme, access to drugs can mean the difference between life and death in many circumstances, especially for the poor and vulnerable populations. Furthermore, in case of the factor of demand, there are some social factors that are also having an influence:

The decision to purchase medicines is often not depends on the consumer, since the drug is prescribed by a doctor or recommended by a pharmacist, and treating doctors when prescribing drugs tend to recommend in the first-place drugs that have, from their point of view, the greatest clinical efficacy, regardless of the level of their price (in case of corruption absence)

Pharmaceutical companies and pharmacies in conditions when the pharmacy revenue is determined by the value of sold drugs, are interested in selling whiter expensive drugs.

The consumer choosing a drug alone, a rule, does not have the necessary information to assess the comparative economic efficiency and the conformity of these properties to the price.

The desire to recover soon makes the consumer to purchase expensive drugs, because of the opinion more expensive and their opinion is more effective. Therefore, even with competition on the market, pharmaceutical companies are able to gradually raise the price level by offering the consumer new expensive drugs.

Ewept for the social and demand specific, this sector requires strong and effective regulation and governance practices in order to avoid unqualified management and avoid opportunities for corruption.

In order to achieve rules based system for pharmaceutical governance, it is important to ensure intergovernmental collaboration (health, law enforcement, customs, judiciary, etc.). Additionally,

the consumer increasingly also has an important role to play. As consumers are getting better informed, they will demand greater transparency in pharmaceutical systems and from their service providers.

Governments, have to establishing and provide the legal and regulatory framework should be involved in monitoring their pharmaceutical systems performance.

2.2 Overview and main features of the Russian pharmaceutical market

Russia's healthcare and pharmaceutical sector was badly affected by the 2015-2016 recession, which resulted in a sharp drop in government spending, while the weak ruble and high inflation cut into households' disposable incomes. Though healthcare spending continued to increase in local currency terms, it slumped to less than two-thirds of its 2014 level in terms of US dollars. Pharmaceutical sales declined for the third straight year in 2016. However, the government's protectionist policy helped boost domestic production of pharmaceuticals, with output growing at double-digit rates in both 2015 and 2016. [Source: EMIS report, Russian pharmaceuticals 2018-2019].

Entry Modes

Foreign companies face high entry barriers, because the government has been pursuing a policy aimed at supporting local producers as it seeks to reduce the pharmaceutical sector's import dependence. As in February 2015, the government has barred foreign suppliers from participating in tenders for imported medicines in the event that two or more local companies have applied to deliver similar products. Additionally, foreign producers of medical equipment face restrictions in state procurements. Industry specific features of the Russian pharmaceutical market are: high profitability associated with low marginal costs of production, the high level of investment costs in research and development, the high level of indirect costs - to product marketing and promotion, the high degree of state regulation of the market.

Segment Opportunities

The government's import substitution policy provides local drug makers with significant opportunities for growth, especially those engaged in the production of the high-value products that represent the bulk of imports. It also encourages foreign pharmaceutical groups to open production plants in the country by offering them tax incentives. The segment that offers strong growth potential is generic drug production, because low purchasing power and the government's

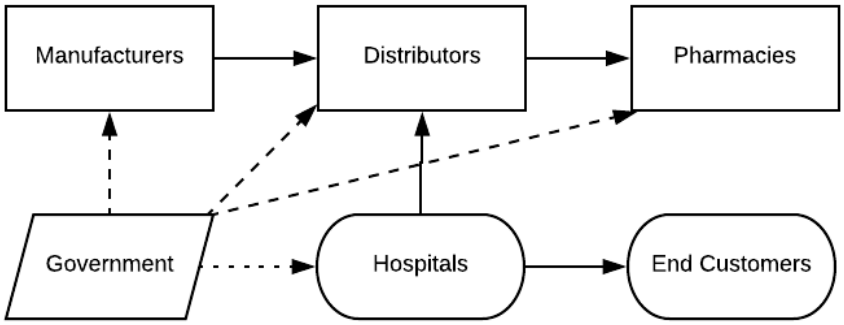
cost-cutting efforts will drive demand for such medicines. The formation of a single Eurasian Economic Union (EAEU) medicine market offers Russian producers the opportunity to boost exports to the Union's member countries.

The pharmaceutical industry in Russia has entered a new phase of development. Recently, the domestic pharmaceutical industry has radically changed its landscape - a critical mass of high-tech Russian pharmaceutical manufacturers has emerged. The pharmaceuticals have a significant long-term growth potential, not only the production of domestic medicines, but also for export.

The infrastructure consists of:

- retail: pharmacies, including pharmacy chains, drugstores, pharmacy corners, pharmacy stores;
- wholesale: producers (foreign, domestic);
- hospital segment (outpatient and inpatient type).

The activities on the pharmaceutical market in case of sales are between manufacturer and distributor, but some manufactures sometimes can play the role of manufacturer-distributor, they can directly work with medical organization.



Picture 2.1 Pharmaceutical market participants.

Source: made by author

The Russian healthcare and pharmaceutical sector was affected by the 2015-2016 recession, However, the government's protectionist policy helped boost domestic production of pharmaceuticals, with output growing at double-digit rates in both 2015 and 2016.

The volume of the pharmaceutical market in Russia in 2017 reached 1,629 billion rubles, which is 8% higher than a year ago. The volume of sales of medicines in physical terms increased by 6% and amounted to 6.3 billion packs. Positive dynamics in the packaging in 2017 testifies to an improvement in the purchasing power of the population and a decrease in the impact of financial and economic factors on the pharmaceutical market.

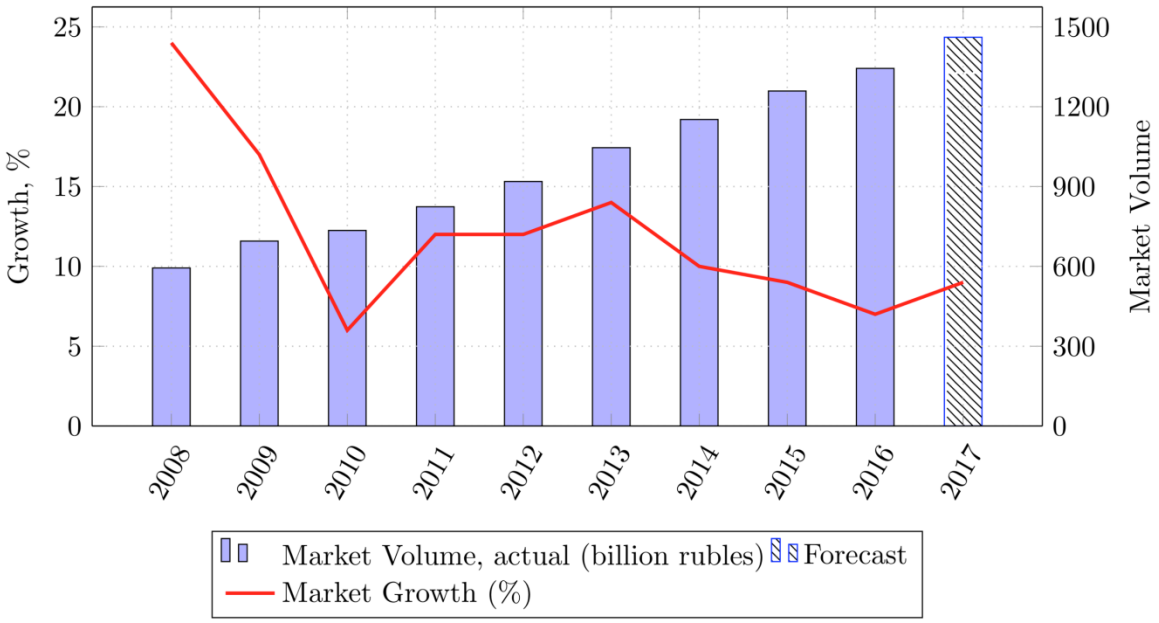
The main contribution to the growth of the market was made by the commercial segment of medicines. The dynamics of the retail market continued the positive trend of 2016 in packs. The market gain in rubles is lower than in 2016.

The main two trends in the consumption of drugs are an increase in the share of domestic drugs and the switching of the consumer to generics. But if the consumer switches mainly to branded generics, then in public procurements, volumes and generics realized by INN grow.

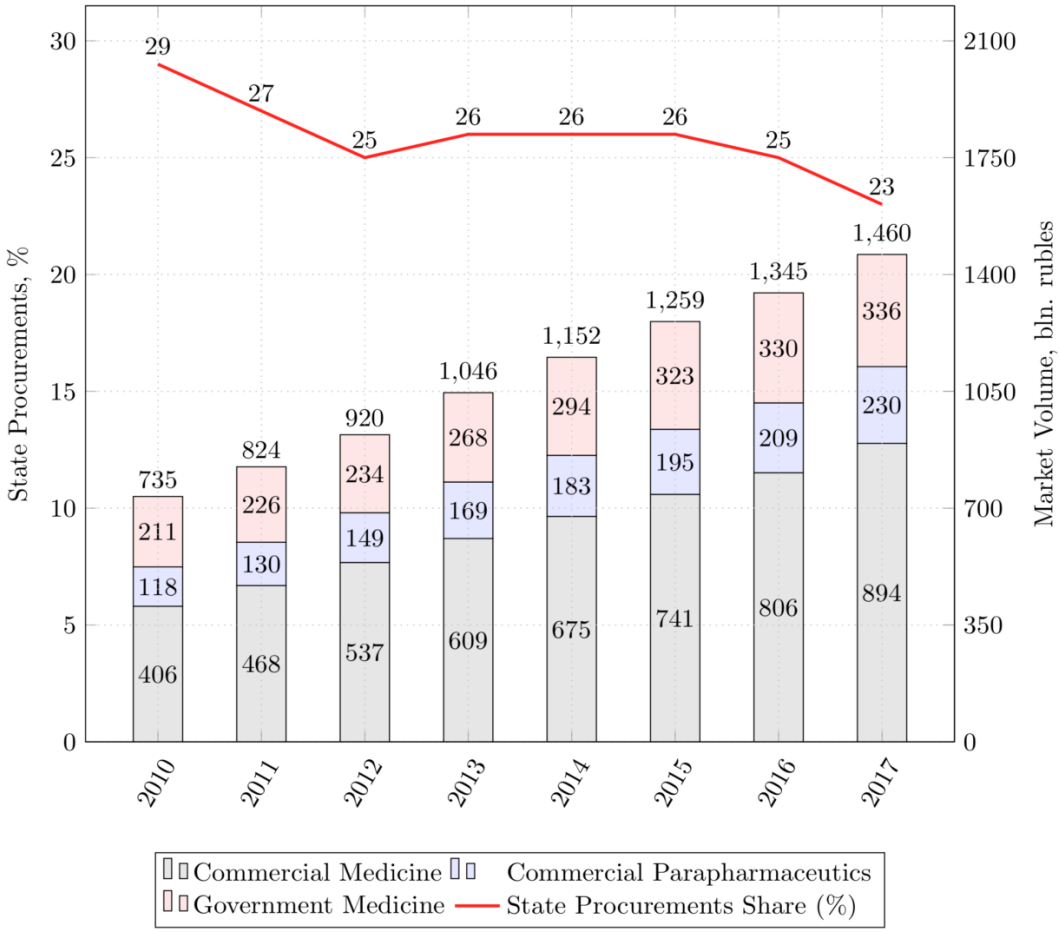
The share of imported drugs in the market as a whole in 2017 was 70% in money and 38% in packs. "Import substitution" mostly works in the state procurement segment + 2% to the share of 2016. In the commercial segment, the share of domestic drugs is growing at a slower rate + 0.5%. Therefore, the first places in the rating of manufacturers are occupied by foreign companies: Sanofi, Novartis, Bayer.

The process of "consolidation and unification" in the pharmacy market is gaining momentum, which leads to the enlargement of market players and increases their market share. The share of TOP-20 has doubled since 2014 and amounted to 51%. The share of independent pharmacies "ASNA", having occupied 13.8% of the market and representing 8 365 points of sales. Among the "traditional" networks, the pharmacy chain "36.6", 4.8% occupies the maximum share. With a small gap, the top three are Rigla with a share of 4.7%.

In 2017, the positive trend in the concentration in the distribution segment was replaced by a negative one. TOP-10 companies took about 72% (-8% to the indicator in 2016). Diversification and expansion of the business of distributors, rapid growth of companies from the "second ten", financial difficulties of market leaders - all this markedly changed the rating of pharmaceutical "wholesalers". In 2017, the first place was reserved by the distributor Protek, having occupied 18.1%. The second place belongs to the distributor Katren with a share of 17.6%. TOP-3 in 2017 closes the dispenser "Pulse" with a share of 12.4%.



Picture 2.2 The volume of Russian pharmaceutical market (billion rubles)
Source: DSM Group



Picture 2.3 The volume of pharmaceutical market by segments: commercial, government (billion rubles)
Source: DSM Group

The main feature of the market is leading amount of the foreign manufacturers: 78 % of the market. Main competitors for the moment are: Bayer, Sanofi, Takeda. After the implementation of the "Pharma Strategy 2020" which is aimed to boost domestic production of pharmaceutical and medical device products and includes limitations for foreign production companies, several multinational pharma giants such as Novartis, Takeda, Teva, Novo Nordisk and AstraZeneca have established their manufacturing facilities in Russia since 2011, and GlaxoSmithKline, Pfizer and Bayer have signed partnership agreements with domestic manufacturers.

Foreign companies face high entry barriers, because the government has been pursuing a policy aimed at supporting local producers as it seeks to reduce the pharmaceutical sector's import dependence. As of February 2015, the government has barred foreign suppliers from participating in tenders for imported medicines in the event that two or more local companies have applied to deliver similar products. Additionally, foreign producers of medical equipment face restrictions in state procurements. Under the 2015 rules, state orders for medical devices made from PVC are to be awarded only to suppliers that plan to set up or expand medical device production in the country.

December 2016	December 2017	Company-manufacturer
1	1	Bayer
3	2	Novartis
2	3	Sanofi
5	4	Takeda
8	5	Servier
4	6	Otispharm
6	7	Glaxosmithkline
9	8	TEVA
10	9	Berlin-Chemie
12	10	Gedeon Richter

Table 2.4 Top 10 manufacturing companies in Russian pharmaceutical market in 2017
Source: DSM group

Analyzing the market structure of the Russian pharmaceutical market, it can be concluded that it belongs to the type of monopolistic competition - there are several dozen producers on the market, many of which occupy strong positions in their segments, but no one has a decisive impact on the market as a whole. Thus, drug manufacturers have the opportunity to observe the actions of competitors and adjust their actions depending on other players.

The government's import substitution policy provides local drug makers with significant opportunities for growth, especially those engaged in the production of the high-value products that represent the bulk of imports. It also encourages foreign pharmaceutical groups to open production plants in the country by offering them tax incentives. The segment that offers strong growth potential is generic drug production, because low purchasing power and the government's cost-cutting efforts will drive demand for such medicines. The formation of a single Eurasian Economic Union (EAEU) medicine market offers Russian producers the opportunity to boost exports to the Union's member countries.

The sector is heavily regulated by the state, so government actions and policies define its development. Increasing state intervention regarding medicine registrations and tenders poses additional challenges to market players, especially foreign producers. In 2014, as a countermeasure to the Western sanctions imposed on Russia following the latter's annexation of Crimea, the government introduced an Import Substitution Policy whose ultimate goal is a full switch to domestically- produced drugs.

As the Russian economy entered its second year of recession in 2016, a record-high of 5,030 companies in the healthcare and social services sector were liquidated, while the number of new entrants declined by 7.3% y/y to 5,871. Overall, 85,900 companies were operating in the sector at end-2016. Nearly 70% of them were privately-owned [*Source: Statistics Office, CEIC]*.

Last main events in industry

Russia's leading vaccines producer, Nacimbio, said in November 2017 that it had plans to invest RUB 6bn in the construction of a plant for the production of vaccines in the city of Ufa. At the end of 2015, Nacimbio had signed an agreement with Indian Serum on the localisation of vaccines against pneumococcus, poliomyelitis and haemophilia in Russia.

In July 2017, Indian generic drug maker Hetero Labs announced plans to build a plant in Russia for the production of drugs for the treatment of cancer and AIDS. The new facility will be located in the Tula region, central Russia, and its estimated cost will be USD 30mn-40mn.

In June 2017, US pharma group Pfizer said that it was considering the construction of another manufacturing plant in Russia during the next few years. The announcement came just a month after Prizer had launched the construction of its first Russian plant in the Kaluga Vorsino tech park, a project developed in cooperation with its local partner NovaMedica.

In May 2017, Russia's Generium, owned by billionaire Viktor Kharitonin, set up a joint venture with Ireland-based Shire. The venture, SG Biotech, will focus on delivery of drugs for the treatment of haemophilia to the Russian market.

In March 2017, Swiss pharma group Roche signed an agreement with the I.M. Sechenov First Moscow State Medical University, pledging investments of RUB 5bn for R&D activities and the development of new drugs in Russia.

Indian pharmaceutical company Macleods Pharmaceuticals plans to open a plant in Belgorod in 2017. The plant will manufacture drugs for treatment of tuberculosis, HIV, hepatitis and other diseases.

The Russian biotech firm Biocad said in October 2017 that it was planning to build a EUR 25mn pharmaceutical plant in the Finnish city of Turku. The facility will specialise in the production of at least seven drugs that will be intended for the treatment of cancers and autoimmune diseases – including melanoma, breast cancer and stomach cancer.

France's Sanofi signed an agreement with Russian pharmaceutical company Nanolek to produce its Pentaxim vaccine at the company's plant in the Kirov region. The first batches of the vaccine packed at the Kirov plant went on sale in January 2017 [Source: EMIS].

2.3 Structure of drug regulatory authorities

Regulation of drugs encompasses a variety of functions. Key functions include licensing, inspection of manufacturing facilities and distribution channels, product assessment and registration, adverse drug reaction (ADR) monitoring, control of drug promotion and advertising, and control of clinical drug trials. Each of these functions targets a different aspect of pharmaceutical activity. All of these functions must act in concert for effective consumer protection. [WHO, 2002].

The table below provides the main regulation bodies in Russia and their responsibilities.

The Ministry of Healthcare	Responsible for drafting and implementing government policy and legal regulations in the areas of healthcare, mandatory health insurance, and the production and distribution of pharmaceuticals. The ministry coordinates and oversees the operation of its subordinated agencies, including the Federal Service for Supervision of Healthcare, the Federal Medical-Biological Agency and the Federal Mandatory Health Insurance Fund.
Federal Service for Supervision of Healthcare	Responsible for control and oversight of the healthcare system. It is the major authority for regulating the pharmaceutical manufacturing sector, including registration of pharmaceuticals, licensing of activities related to production and distribution of pharmaceuticals, state control over the production, preparation, quality, effectiveness and safety of pharmaceuticals, and state regulation of the prices of pharmaceuticals.
Ministry of Industry and Trade	Responsible for drafting and implementing government policy and legal regulation in the industrial and defence sectors, and in energy conservation and the improvement of energy efficiency in the movement of goods. As the ministry acts as the federal body responsible for technical regulation, it has a key role in the pharmaceutical and medical equipment segments, since it organises and oversees electronic tenders for public purchases.
Federal Mandatory Health Insurance Fund	State budget fund established in 1993 to finance medical services to Russian households. The major activities of the fund are: financing the program of mandatory health insurance; funding targeted programs under the mandatory health insurance scheme; control over the rational use of mandatory health insurance. FMHIF is financed mainly by payroll contributions from the working population.

Table 2.5 Key regulatory authorities
Source: made by author

2.3 State regulation methods in pharmaceutical industry in Russia

Due to its high social and economic importance of the sphere, the pharmaceutical industry is under the close supervision and control of the government. Russian government supports the domestic pharmaceutical and medical industry by the state programs, strategies, what is highly helps to stimulate the flow of new domestic and foreign investment, the opening of new high-tech enterprises, the modernization of existing production facilities.

The strategy for the development of the pharmaceutical industry in the Russian Federation for the period to 2020 (Pharma 2020), adopted by the Russian government in 2009. It has become one of the most successful state development program, it influenced on new pharmaceutical plants and production sites, new high-tech pharmaceutical enterprises equipped with the most modern equipment and corresponding to the international standards of GMP.

In recent years, there has been a significant increase in demand in Russia for quality medicines, health products and medical services. Moreover, it is expected that this trend will continue in the near future, despite the current decline in household incomes. According to analysts' forecasts, by 2020 the world pharmaceutical market will double and reach $ 1.8 trillion, which makes this sector especially attractive for all players in this market. [Deloitte report, 2017]

The government's protectionist policy creates high entry barriers for foreign companies. Recent law amendments protect domestic producers by not allowing foreign companies to participate in public tenders for the supply of medical goods if a similar domestically-made product is offered. Foreign companies, both pharmaceutical product and medical equipment suppliers, can enter the market via cooperation with domestic distributors, acquisition of existing businesses or localization of their production. The last of these options implies either the construction of the necessary infrastructure from scratch or cooperation with Russian manufacturers as well as transfer of technologies.

However, both Russian and international companies have to solve numerous complex problems that affect the business growth strategy both in the short and long term.

The main goals for the government to stimulate the production and development of the pharmaceuticals further:

1) Developing strategic goals and implementing timely solutions to achieve and maintain profitable and sustainable growth;

2) Compliance with the provisions of the "pharma-2020" program, adopted by the government of the russian federation;
3) Timely response to ongoing changes and identification of new trends and new opportunities in a dynamic market;
4) Improving financial performance and attracting additional funds for strategic business development;
5) Ensuring regulatory compliance in conditions of close scrutiny by regulatory bodies;
6) Achieving commercial goals by ensuring optimal tax consequences;
7) Transfer and protection of rights to intellectual property;
8) Involvement and retention of specialists able to achieve high performance;
9) Achieving the highest possible operating results by improving the efficiency of key business processes throughout the value chain;
10) Optimization of the sales function, including increasing the effectiveness of sales professionals;
11) Identify the most vulnerable places in the operating model of the company and assess and minimize the relevant risks;
12) Introduction of structural innovative business processes that will help the company stay one step ahead of its competitors.

2.3.1 Pharma Strategy 2020

To implement a unified state policy aimed at the development of the pharmaceutical industry by the Ministry of Industry and Trade, the Strategy for the Development of the Pharmaceutical Industry of the Russian Federation until 2020 (dated October 23, 2009 No 965) was approved. The Pharma-2020 strategy and the state program "Development of the pharmaceutical and medical industry for 2013-2020" have become one of the most successful among numerous industry programs in Russia. For a short time, there was a cluster of domestic pharmaceutical companies equipped with modern equipment and capable of producing innovative products.

The main goal of Pharma-2020 is to increase the share of domestic drugs produced in Russia by up to 50% by 2020. The main directions of the state policy are fixed in the federal target program "Development of the pharmaceutical and medical industry for the period until 2020 and beyond", which defines the following tasks "Development of the pharmaceutical and medical industry" for 2013-2020:

- technological re-equipment of pharmaceutical production;
- import substitution of medicines according to the nomenclature of VED;
- the launch of Russian innovative products;
- increasing the export potential of the pharmaceutical industry;
- personnel support of the industry with a view to transition to an innovative development model.

The "Pharma-2020" strategy confirms that the executive branch supports the development of its own innovative products independently from foreign companies.

2.3.2 Pricing regulations

Pricing is the process of establishing, regulating prices and controlling the application of the procedure established by legislation for the formation of prices by legal entities, individual entrepreneurs, carrying out their activities without the formation of a legal entity, and other subjects of pricing.

The main factors of influence of pricing are the following:

- total cost of the course of treatment with the drug;
- rarity and severity of the disease;
- elasticity of demand for a drug at a price;
- the competition in this segment;
- presence or absence of state regulation;
- presence or absence of similar generic drugs;
- the presence or absence of requirements for the quality of the drug.

The government is obligatory to control the pricing of medicines because they have to provide their accessibility to the population is an integral part of social policy and health.

Responsible for that actions are the *Federal Tariff Service and the Ministry of Health*.

After the medicine has passed the procedure of state registration, experts determine its price. The price of imported drugs is determined on the basis of an analysis of weighted average prices for this drug in 21 countries. The Ministry of Health and the Federal Tariff Service compare an average price in other countries, and on the basis of these data a decision is made about the maximum allowable price for the drug in Russia.

In Russia, there is the mixed type of pricing, the government tried to stabilize and regulate the prices of certain drugs and created a list of vital and essential medicines (VED).

State regulation of prices for medicines from the VED list was introduced in April 2010 and provides control over the establishment by producers and importers of the maximum selling prices for medicines and control over the use of surcharges by sellers.

Prior to the introduction of regulation, prices grew unevenly and in 2009 showed significant growth: in the outpatient segment by 10.8%, in the hospital segment by 16.1%. For some regions, the price premium for medicines reached 200%, but according to the drug supply strategy for the Russian Federation, until 2025, approved by Order No.66 of the Ministry of Health of February 13, 2013, the annual increase in the price index for VED should be no more than 3 %.

The law "On the circulation of medicines" provides the state regulation of prices for vitally important and essential medicines (VED) from the special list created by goverment. A positive consequence of the adoption of this law was a virtually unnoticeable increase in vital medicines, but in a number of studies negative effects were also noted:

1. Producers tried to compensate for losses in other segments due to an increase in prices for drugs not included in VED (increased prices in adjacent segments).
2. Prices for some drugs were not agreed, as a result, these drugs disappeared from the market (supply reduction).

The process of ensuring state regulation of prices for VEDL includes the following stages:

1. Registration of prices for drugs on the list of essential and essential drugs (VED).
2. Establishment of a fixed price for medicines purchased at the expense of budget funds within the framework of targeted programs.
3. Establishment of the maximum levels of wholesale and retail mark-ups to the prices of VED (in accordance with Resolution of the Government of the Russian Federation No. 782 of 09.11.2001 "On state regulation of prices for medicines")

At the moment, positive results of state regulation for citizens are obvious and may be are easily estimated (absence of observable growth of prices for drugs included in the list of VED).

Prices for medicines from this list are regulated: the maximum allowable drug allowance for these drugs is determined (36% of which is produced only abroad), that is, in effect, interferes with the work of the commercial sector. In general, the pharmaceutical market is characterized by a

situation where the cost of the drug is virtually independent of the marginal costs of producing a unit of the drug. A much larger role is played by quasi-permanent costs (not depending on the volume of output) - the cost of research and development of the drug, the cost of patents, the cost of clinical trials, etc. Because of this, high prices for medicines appear to be speculative and unreasonable. Many drugs, including vital ones, are inaccessible to low-income groups of the population. The state, in turn, seeks to pursue a policy aimed at improving their accessibility.

1. Targeted provision of medicines to low-income population groups. In the Russian Federation, measures of this kind include the state program of additional drug provision (ADP, but in Russian is DLO).
2. Reimbursement or partial reimbursement of the cost of medicines. This policy is typical for the countries of Western Europe and is that after the purchase part of the costs of consumers for the purchase of medicines is reimbursed by the state, if the drugs were purchased under the prescription of a doctor.
3. Limit the price of the drug. Since 2010, in the Russian Federation, the legislation restricts the prices for the sale of drugs from the approved list of vital medicines (VED).

The establishment by the executive authorities of the subjects of the Russian Federation of the maximum sizes of wholesale and retail mark-ups to selling prices (according to the methodology approved by Order No. 442-a of the Federal Tariff Service of the Russian Federation of December 11, 2009 No. 442-a). Approval of positive (lists of medicines to be reimbursed) and negative reimbursement) of the lists. Preparations included in positive lists must comply with modern standards of quality, efficacy and safety, as evidenced by data from evidence-based medicine and pharmacogenomics, and are designed to treat the most common diseases.

2.3.3 Import substitution orientation

The problems of the pharmaceutical industry directly affect the problems of national security due to the high social importance of this sphere and the modern geopolitical design. In this connection, the directions of the state policy that allow increasing the social and economic efficiency of the Russian pharmaceutical sector are actualized. The basis of such a policy is import substitution, the formation of a sustainable domestic pharmaceutical sector.

At the moment, the problematic aspects for the development and establishment of domestic companies in the pharmaceutical market are:

- there are conditions for fierce competition in the market;

- there is a deterioration in the economic situation and a decline in the financial condition of domestic producers, caused by a slow transition to GMP standards. Either the absence of GMP certificates from a significant part of companies operating in the territory of the Russian Federation, while the conformity of production to the requirements of GMP is determinant in the world market of medicines. All manufacturers in Russia must pass to this standard from January 1, 2014;
- an administrative barrier to enter the market of medicines. When changes are made to the drug regulations after registration of the price for the drug, the manufacturer must repeatedly provide the full set of documents;
- a long process of drug registration, in connection with the Federal Law "On the circulation of medicines", according to which there is no feedback between the expert organization and the pharmaceutical company. It also requires improving tax incentives for the industry and unifying legislation within the WTO rules.

State regulation is one of the key factors determining the investment climate and macroeconomic indicators in general. Now, in many areas of small and medium-sized businesses, the entrepreneur himself can open a business under his own responsibility simply by notifying the relevant authority. As of November 1, 2014, more than 380,000 received such notifications. And this is only one of the results of the global reform of the state control system, which was carried out in the interests of the new economy and business. The point of contact between business and the state most often is either the situation of an entrepreneur's request for obtaining a variety of documents (permits, licenses, opinions, registrations, etc.) or checking his activities on the part of supervisory bodies. Therefore, the excessive powers of the authorities, the lack of necessary procedural regulations, the poorly prescribed responsibility of the entrepreneur and the official as participants in the process, the lack of a clear procedure for checking by the authority and the low awareness of businessmen of their rights - all this not only did not contribute to the effective development of entrepreneurship, but also served as a ground for systemic corruption. Recognition of the inadmissibility of the current situation and the conceptual definition of a new economic policy was the Decree of the President of the Russian Federation of 1998 "On Measures to Eliminate Administrative Barriers in the Development of Entrepreneurship". It was then that the development of entrepreneurship was defined as the most important factor in ensuring economic growth and employment of the population. Throughout the 2000s, the Government of the Russian Federation consistently set the task of simplifying and clearly regulating the procedure for creating business entities, as well as eliminating unreasonable restrictions that arise in the course of their economic activities. To solve these problems, a number of laws were adopted:

from August 8, 2001, No. 129-FZ "On state registration of legal entities", from May 04, 2011 No. 99-FZ "On licensing of certain types of activities" and dated December 26, 2008 No. 294 - FZ "On Protection of Rights of Legal Entities and Individual Entrepreneurs in the Conduct of State Control (Supervision)". An important system-wide measure of reform was the building of a process of technical regulation, including the unification of procedures for entry of entrepreneurs into the market. The entire accreditation system has been reformed, as well as the harmonization of accreditation rules and procedures with uniform international standards. To date, normative legal acts have been adopted in the field of accreditation, corresponding to generally recognized international standards, the process of joining the key international organizations in the field of accreditation - ILAC and IAF - has been initiated by the Rosacredit.

In addition to the systemic measures taken to find a balance between the state regulation of the economy and the liberalization of the market, without which long-term economic growth is impossible, it was important to find tools that cut off the appearance of excessive barriers to business at the stage of legislative initiative. Therefore, practical application in the law-making process in Russia first found an institution for assessing the regulatory impact, and the Decree of the President of the Russian Federation of May 7, 2012 No. 601 "On the main directions of improving the system of public administration" set the task of developing and practical implementation of new mechanisms aimed at improving the quality development of regulatory measures. All changes within the framework of the principles of public administration are working to reduce the scale of administrative influence on business participants, reduce their costs and increase economic activity. Therefore, along with other measures, control and supervisory and permissive functions in various sectors of the economy are being improved.

2.3.4 The drug registration

In Russian Federation, its obligatory to register original medicinal products, reproduced drugs, new combinations of previously registered drugs, medicines previously registered, but produced in other dosage forms, in a new dosage. Without this procedure, the developed medicine can’t be produced and be used for clinical research trial.

The drugs registration in Russia is regulated by chapter 6 of Federal Law No. 61 from April 12, 2010 "Concerning the circulation of medicinal products".

The registration procedure for medicines consists of several main stages:

- Stage I. Preparation of documents for the formation of a registration dossier, including the documents necessary to obtain a permit for conducting a clinical trial of a medicinal product, the submission of a registration dossier to the Ministry of Health of the Russian Federation.
- II stage. Obtaining permission to conduct a clinical trial (for drugs that are allowed for medical use in the Russian Federation for less than 20 years), conduct a clinical study.
- Stage III. Examination of the quality of the medicinal product and examination of the relationship between the expected benefit and the possible risk of drug use following a clinical study of the medicinal product:
  - quality control of the medicinal product at the authorized laboratory center and approval of the normative document;
  - examination of the relationship between the expected benefit and the possible risk of use and approval of the instruction on the medical use of the drug.
- IV stage. The adoption by the Ministry of Health of the Russian Federation of a decision to include a medicinal product in the state register of medicinal products and the registration of a registration certificate. Registered medicinal products and pharmaceutical substances are entered in the state register of medicines. The applicant is given a registration certificate of the medicinal product and a decision to include the pharmaceutical substance in the State Register.

The total period for completing the entire procedure is no more than 210 working days.

2.3.5 Procurements

Since 2008, regional authorities have been responsible for the procurement of medical equipment for the needs of state-owned hospitals and medical centres. This decentralisation was designed to simplify the public procurement process. According to a government resolution in force since August 2017, medical devices made from PVC plastics can only be procured from companies that implement projects to expand or localise medical device production in Russia over the 2017-2024 period.

In 2016, the total value of contracts for the supply of medical equipment awarded via state procurement tenders stood at RUB 346bn, an annual increase of 45.2%, according to data provided by research company MDpro. By type of product, in-vitro diagnostic equipment witnessed the strongest demand in public tenders, accounting for 32% of all contracts awarded in December. Medical equipment for general surgery followed with a share of 15%, ahead of intensive care devices (12%) and equipment for minimally invasive surgery (11%).

To stimulate the development of domestic production, the government introduced measures to restrict government purchases of imported medicines. In particular, we are talking about the following measures:

According to the draft "On the establishment of additional requirements for participants in placing orders when placing orders for the supply of medicines" from 2014, foreign medicines are not allowed to trade, provided that two or more of the same preparations of Russian production.

According to the project "On the criteria under which drugs produced in the territory of the Russian Federation using components of foreign origin," only those medicines whose finished form is produced on the territory of Russia, namely at full-cycle enterprises, will be considered as domestic medicines.

It should be noted that, in accordance with the agreements between Russia and the WTO, WTO principles are not taken into account to compensate for the cost of medicines and medical products included in the package provided by the system of state provision of citizens with free medical care. But, discrimination against foreign producers is not a violation of WTO rules in the framework of public procurement. Therefore, it can be assumed that measures to limit the access of foreign producers and medicines to the public procurement market continue.

According to public procurement Federal law №44, there are special rules applicable to the procurement of medicines:

1. A private purchaser of a purchase must have a license to manufacture medicines and (or) to carry out pharmaceutical activities.
2. If the contract involves the purchase of narcotic or psychotropic medicinal products, the procurement participant must have a license to carry out activities related to the circulation of narcotic drugs, psychotropic substances and their precursors, and cultivation of narcotic plants.
3. The participant in the procurement of medicines, who has offered the price of the contract, which is 25 and more percent lower than the initial (maximum) price of the contract, is obliged to provide the customer with the justification for the proposed price of the contract. The justification can contain a letter of guarantee from the manufacturer, including the price and quantity of the delivered goods, other documents that confirm the ability to deliver goods at the proposed price. In case of failure to comply with this requirement or the recognition of the proposed price unreasonable,

the tender application is rejected, and during the auction its winner is deemed to have evaded the conclusion of the contract.

4. When purchasing a drug from the list of vital and essential medicines (ved), their value should not exceed the maximum selling prices established by the state. Otherwise, the application will be rejected (part 10, article 31 of law №44).

2.3.6 Information-analytical system

The Information and Analytical System (IAS) is a software package that allows real-time analysis of the health status of citizens and the healthcare system in the region with any level of detail.

The information-analytical system operating with primary data, which are consolidated in the data center in real time. The reports generated with the help of the IAS, as quickly as possible, reflect the processes taking place in the healthcare of the region.

Data processing in the information-analytical system is performed on the basis of OLAP-technologies (online analytical processing, analytical processing in real time), which allows you to get the result in a matter of seconds. Information in the IAS is structured in the form of so-called OLAP cubes that combine data.

Result: Such information processing technology provides dynamic construction of multidimensional reports in various sections, analysis of large amounts of data in real time, monitoring and forecasting of key performance indicators of participants in the health system. With the help of the IAS, health authorities receive a clear picture of the situation in the industry.

2.3.7 Approval for clinical research

The market of clinical trials of medicines in the Russian Federation has undergone significant changes in recent years in connection with the reform of state regulation of the circulation of medicines.

Since 2010, the conduct of clinical trials of drugs is regulated by the Department of State Regulation of Drug Administration of the *Ministry of Health of the Russian Federation*.

Conducting clinical trials of medicines is an integral and most important and responsible part in the procedure for registration of medicines in the Russian Federation. From July 1, 2015, a clinical trial is an independent step in the registration of a drug.

The applicant can file the registration dossier on the medicinal product only after completing the clinical study of the drug and preparing a full report for provision to the state regulator.

To obtain permission to conduct a clinical trial, the producer must submit to the Ministry of Health of Russia a dossier containing sections governed by federal legislation.

The procedure is quite long and complicated, includes documentary report. The most serious attention should be given to the preparation of such documents as:

- a report on laboratory tests and pre-clinical studies on animals;
- draft protocol of clinical research;
- researcher's brochure;
- an information sheet of a patient participating in clinical trials;
- resumes of researchers in relevant specialties, indicating their experience in conducting clinical trials;
- information on medical organizations accredited by the Ministry of Health of Russia in which a clinical trial is to be carried out.

Examination of the possibility of conducting clinical trials in the Russian Federation, in accordance with federal legislation, includes an examination of the scientific justification and documentation for each clinical study at the Scientific Center for Expertise of Medical Applications and an ethical review of the possibility of conducting a clinical trial of the drug by the Council on ethics.

In case of receiving positive expert opinions of the Ethics Council and Department of State Regulation of Drug Administration of the Ministry of Health issues a permit to conduct medical organizations (i. e hospitals, hospitals, clinical centers) in the Ministry of Health accredited by the Ministry of Health research. The main problematic issues in the regulation of the market for clinical trials of drugs.

2.3.8 Marking of medicines and implementation of monitoring system

In February 2017, based on a number of companies across the entire production and distribution chain - from producer to consumer - a pilot project was launched to introduce and test a traceability system for medicines, which according to government plans should be extended to all participants in the pharmaceutical market by January 1, 2019.

The system is designed, first and foremost, to protect the population from counterfeit medicines and promptly withdraw from counterfeit and substandard drugs. However, it will also allow the authorities to monitor and control the flow of goods. In particular, participation in the development and implementation of the project on the labeling of pharmaceutical products is reflected in the Comprehensive Development Program of the Federal Customs Service of Russia for the period until 2020.

In addition, since the Federal Tax Service of Russia is the operator of the traceability system, the data transferred to the system is likely to be used also in the course of tax control measures. In this regard, the introduction of a system of traceability of medicines should be carried out with the involvement of relevant financial, tax, customs and legal specialists.

Undoubtedly, the introduction of the system will lead to additional costs for the purchase of equipment for the imposition of control identification marks and their reading, the development and implementation of software, etc.

However, on the other hand, the introduction of the system will create great opportunities for manufacturers and distributors of drugs in the analysis of data reliability on the movement and sale of medicines in fact in real time. These data and the results of their analysis can be used by the business, in particular, when implementing a strategy to increase inventory turnover and more effective control over accounts receivable (which, as noted above, is the main direction of cost optimization for market participants).

In addition, a huge amount of data will be formed in the monitoring system, the analysis of which will increase the effectiveness of the promotion and advertising of medicines, which in turn can significantly change the current financial and legal nature of the relationship of producers/distributors with pharmacies, and reshape market as a whole. Those producers and importers who, before others, will be able to obtain data on the sales of their preparations from the traceability system (for example, by purchasing them from distributors and pharmacies) and to analyze "large data", will be able to obtain significant advantages by squeezing market leaders or by strengthening their own positions on it.

2.3.9 Good Manufacturing Practice

Good Manufacturing Practice is an international standard with unified rules for the production of quality medicines. The standard reflects a holistic approach to the production process, regulating and evaluating all parameters of production and laboratory testing. High-quality expensive

equipment, an internal quality control system at each stage of the producing process allows GMP to minimize the human factor in production. To standardize the quality of medical services and products, the population is used in conjunction with standards:

- GLP (Good laboratory practice);
- GCP (Good Clinical Practice);
- GDP (Good Distribution Practice).

This standard should contribute to increasing the competitiveness of domestic pharmaceutical production, and hence, production, reducing its import dependence. The introduction of this standard should promote the development of industry and facilitate the entry of Russia into new markets, as well as reduce export from other countries. In the modern realities of the Russian economy, not all enterprises of the Russian pharmaceutical industry are interested in implementing these quality standards. This can be explained by the lack of economic incentives to create quality systems. The implementation leads to an increase in the costs of the product production. This situation has a negative impact on the competitiveness of medicines that are produced in Russia. The introduction of the standard actually means the creation of new industries, which is an expensive operation. An important problem is that there are a large number of drugs on the Russian market that were produced in the Soviet times and unfortunately, they cannot meet standards in any way, that is, inexpensive products can eventually leave the market.

The GMP conformity assessment procedure is regulated in accordance with Order No. 1714 of the Ministry of Industry and Trade of the Russian Federation of 26.05.2016 "On approval of the Administrative Regulations of the Ministry of Industry and Trade of the Russian Federation for the provision of a public service for issuing conclusions on the compliance of manufacturers of medicines for medical use with the requirements of the Rules of the proper production practice ".

In February 1998, Russia entered into force a joint order of the Ministry of Health of Russia and the Ministry of Economics of Russia on the implementation of the industry standard OST 42-510-98 "Rules for the organization of production and quality control of medicines", which established that from July 1, 2000, operation of newly created and reconstructed manufacturing enterprises of pharmaceuticals and pharmaceutical substances, issuance of licenses for production, storage and distribution of these products to these enterprises only in case of implementing GMP standard.

The first version of the Russian GMP standard was prepared by the Association of pollution Control Engineers (ASINCOM) and in 2004 by the Decree of the State Standard of Russia dated

March 10, 2004 No. 160-st GOST R 52249-2004 "Rules for the Production and Quality Control of Medicines" with the rules of GMP (Good Manufacturing Practice for medicinal products) of the European Union.

Rules GMP - GOST R 52249 "Rules of production and quality control of medicines" - are analogous to the European GMP EC Rules in Russian. The GMP rules are a document that incorporates forty years of experience in GMP.

Result: the rules of good manufacturing practices were approved by order of the Ministry of Industry and Trade of Russia on June 14, 2013 N 916 (in the edition of Order No. 4148 of the Ministry of Industry and Trade of the Russian Federation of December 18, 2015).

Since GMP is a mandatory, not a voluntary set of rules, it is subject to state verification. In Russia, the Federal Budgetary Institution "The State Institute of Medicines and Good Practices" is authorized to inspect the manufacturers of medicines for medical use for compliance with the GMP standard.

Decree of the Government of the Russian Federation of December 3, 2015 No. 1314 approved the "Rules for the organization and conduct of inspection of drug manufacturers for compliance with the rules of good manufacturing practice, as well as issuing conclusions on the compliance of the manufacturer of medicines with these requirements."

2.3.10 Market accesses

In turn, the state controls access to the market, through measures aimed at reducing the share of imported drugs. It encourages foreign manufacturers to switch to the use of full cycle production by offering various benefits and preferences, including tax incentives, and not by imposing additional restrictions and prohibitions. Indexing of registered prices for VED at Russia, and the absence of such indexation (or indexation at a slower rate) for VED produced abroad.

- Further restrictions or prohibition on the participation of foreign (non-localized) producers in public procurement.
- Measures to combat corruption and increase competition.
- Guarantees of public procurement of medicines produced in the EAEC, including the possibility to participate in tenders as the sole supplier.
- Additional procedures for registration of drugs, approved and produced abroad.

2.3.9 Marketing and advertising regulation

In accordance with the concept of social and ethical marketing, pharmaceutical marketing involves an emphasis on pharmaceutical care. Its ultimate goal should be to meet the needs of the patient, not the manufacturer or the pharmacist. However, existing industry features characterized by specific and stringent requirements for products that are circulating in the pharmaceutical market, requirements for companies manufacturing and marketing them, special end-users (who have health problems and), the availability of intermediate consumers (doctors).

Medications are associated in patients with the disease, so their purchase is not associated with the prospect of pleasure, but with the need for an unpleasant treatment of the disease, from which there is a desire to distance themselves. This imposes significant limitations on the possibilities of building pharmaceutical brands. There is some contradiction between the effectiveness of the drug and its safety. In the perception of the consumer, the increase in the effectiveness of drugs correlates with a decrease in its safety, which causes distrust of patients and doctors when combining these properties in the implementation of positioning strategies.

Also, it is necessary to indicate the existence of a trend in the dependence of the end consumer on the behavior of pharmaceutical manufacturers and the professional medical environment, which is a consequence of unfavorable changes in the environment and the way of life of a person. These trends are potentiated by a decrease in the effectiveness of certain drugs. For example, the growth of the immunity of pathogenic bacteria to antimicrobial therapy of various groups leads to the need to develop and use newer means.

In this regard, changes in the production and marketing systems of pharmaceutical manufacturers have a significant impact on the entire market, which has repeatedly led to proceedings at the national and international levels. In particular, the overpriced prices for new medicines are traditionally criticized, however, pharma companies substantiate this situation with significant costs for their development and testing, as well as the need for further research to develop this process in the future. Therefore, in our opinion, the modern concept of pharmaceutical marketing retains a certain share of the concentration on the needs of pharmaceutical manufacturers.

Although, under the pressure of competition, modern pharmaceutical marketing has gained much more flexibility by integrating many of the tools of the client-oriented approach (relative to the initial period of its development - the 1950s-1960s). It should be noted that the lag in the degree

of pharmaceutical marketing from the marketing of consumer goods has the following positive consequences for the pharmaceutical industry:

- the ability to justify rising prices for pharmaceutical products by the growing cost of their creation and promotion;
- Reduction of risks due to their re-allocation to state regulatory bodies and the medical environment.

The specific features of the formation of commodity, communicative and price policies in pharmaceutical marketing are determined by the presence of two main approaches in the philosophy of the pharmaceutical business:

The formation of a product portfolio based on the development and production of innovative medicines, followed by their patronage and copying the development of products, lost in accordance with patent law. The first is characterized by a continuing increase in the cost of developing a fundamentally new drug formula

- high social responsibility of the pharmaceutical industry in comparison with other branches of the economy;
- Increased regulatory pressure on the production and promotion of medicines through the adoption of laws on the limitations of the marketing activities of pharmaceutical companies (for example, the activities of medical representatives) and toughening procedures for clinical trials of new medicines;
- a high degree of risk (out of every 12 innovative drug formulas that are at the stage of preclinical research, only one reaches the stage of commercialization) and a significant duration of developing innovative drugs (up to 14 years).

At the same time, sales of original drugs provide a high rate of return. The second approach, which is generic, is based on the price advantage of generics over original patented products. So, the primary copying of the original medicine discounts the brand price to 60% of the original, and as the new players enter the market, the price goes down further. The low cost of generics is determined by the low cost of companies to make copies and the absence of commercial risk from operations in connection with the introduction into an already formed segment and the absence of significant costs for marketing products.

Due to the lower price, generics are quickly introduced into the market and during the first year of generalization, they take on average 55-65% of the natural sales of the proprietary product,

by the end of the second year - up to 70-80%. Also, characteristic is the emergence of a first copy of the original product in the developing market, and only then of the original product, which is due to low solvency of the population. The determinant of the development of promotion tools in pharmaceutical marketing was a strong competitive pressure. Traditionally, the main modern tools for promotion of goods include advertising and personal sales, public relations and sales promotion. Features of pharmaceutical marketing are associated with a highly socially important pharmaceutical industry as a sphere of social production, as a result of which there is a significant level of its regulation by the government bodies of most countries (in Russia - the Ministry of Health of the Russian Federation). In this regard, the promotion of pharmaceutical products is carried out in conditions of significant restrictions.

The use of advertising as a means of communication in the pharmaceutical market is usually limited by the relevant laws. In Russia - the Federal Law "On Advertising" dated 13.03.2006 No. 38-FZ. Advertising Sanitary-epidemiological rules and standards SanPiN 2.3.2.1290-03 "Hygienic requirements for the organization of production and turnover of biologically active food additives (BAA)" approved by the decree of the Chief State Sanitary Doctor of the Russian Federation of April 17, 2003. The biggest restrictions are on advertising prescription drugs, according to the law, information on these pharmaceutical products can only be distributed in specialized publications designed for medical and pharmaceutical workers.

In Russia, advertising of biologically active additives has the same limitations as advertising of medicines. However, a ban is added to the statement that the natural composition of dietary supplements is a guarantee of drug safety. In addition, the advertising of dietary supplements should not undermine consumer confidence in the effectiveness of traditional medicines.

In the segment of prescription drugs, due to the prohibition of their open advertising in the media, the complex of marketing communications is directed, first of all, to the medical professional environment (since the decision to prescribe the medicine is taken only by the doctor). Therefore, its structure includes personal sales, the inclusion of pharmaceutical products in specialized reference books, the publication of scientific medical materials (clinical trial data, monographs), the participation of pharmaceutical companies in medical congresses and seminars.

In Russia, as the leading instruments of the promotion complex in the prescription drugs segment, it is possible to single out drug directories (primarily nosology reference books), visits by medical (trade) representatives of pharmaceutical organizations, and specialized medical publications. One of the most effective tools for the promotion of pharmaceutical products in most

countries is the visits of medical representatives, during which the employee of the pharmaceutical company carries out an oral presentation of specific medicines, the distribution of promotional materials.

However, in the context of the annual major incidents involving the imprisonment of the largest pharmaceutical companies in violation of the ethics of marketing in the promotion of their absence products (financial incentives for physicians to assign specific drugs, misleading information in the advertising of pharmaceutical products, concealing the facts of negative drug use results, etc.), in the EU countries and the United States, access restrictions have been imposed.

2.3.10. Special investment contracts (SPIC)

Special investment contracts (SPIC) have been introduced by the Federal Law "On Industrial Policy" as a non-financial tool to stimulate investments in the creation and modernization of industrial production, the introduction of the best available technologies, and the development of industrial production, which has no analogues in the Russian Federation. Decree of the Government of the Russian Federation No. 708 of July 16, 2015 approved the rules for the conclusion of the SPIC.

The SPIC is a two- (investor and federal authorities), three- participants an agreement designed to guarantee the stability of tax and regulatory conditions and implement incentive measures in priority industries.

The measure implies an investor's obligation to create or modernize and develop industrial production under the agreement provided by the agreement, provided that the state provides investment-stimulating measures of support in the form of tax preferences, special fixed rental rates for state-owned assets, as well as the right , but not the obligation of the state customer not to play tenders for public procurement, but to buy directly from the investor unique products for a fixed period at a fixed market price.

The criteria for classifying to industrial products that do not have analogues produced in the Russian Federation, are divided by the Resolution of the Government of the Russian Federation of July 17, 2015 No.719. The fixing of the price under a state contract can be for a period of one year. The term of the contract as such is established based on the project's expiry date for the operating profit with an increase of 5 years (but not more than 10 years in total). It is important to determine the amount of investment - at least 750 million rubles., That is, the projects should be sufficiently capital-intensive. Legislation does not mean specific incentive measures, but offers an

individual regime for an investor that can independently solicit support measures and coordinate them with the Minpromtorg. As of the end of the first quarter of 2016, no applications for the conclusion of a SPIC by pharmaceutical manufacturers were submitted to the Ministry of Industry and Trade, however, analogues of products on the territory of the Russian Federation. In May, there was information that the company BIOCAD filed 17 applications for referring a number of its preparations, not yet registered, to products that do not have Russian analogues.

One of the measures to stimulate the conclusion of the SPIC is to invest the investor as the sole supplier for the duration of the contract (predictably, the guaranteed purchases should amount to 30% of the production capacity). The corresponding draft amendment to the Federal Law "On the Contract System in the Sphere of Procurement of Goods, Works, and Services for Ensuring State and Municipal Needs" was adopted by the State Duma in the first reading. The SPIC as a measure of incentives for investment innovative and innovative activity is designed to lead to the creation of high-tech pharmaceutical manufactures and products that do not have analogues in the territory of the Russian Federation, as well as to ensure the payback of such investment projects. The SPIC as a tool to support the investor should minimize market risk and guarantee the sale of the investment product design.

But in the mechanism of using SPIC there are weak moments. The instability of the economic and market situation in the country may be negative on the investor's activity. The fixation of the price even for a short-term perspective, given the dependence of production on the import component, can lead to losses.

In addition, pharmaceuticals are a very dynamically developing industry: over the years, while production and the production of a new drug will be established, it may lose its uniqueness, and the investor will not receive the income that he expected. Since this mechanism implies the right, and not the duty of the customer to make purchases, there are no guarantees for the producer in this regard.

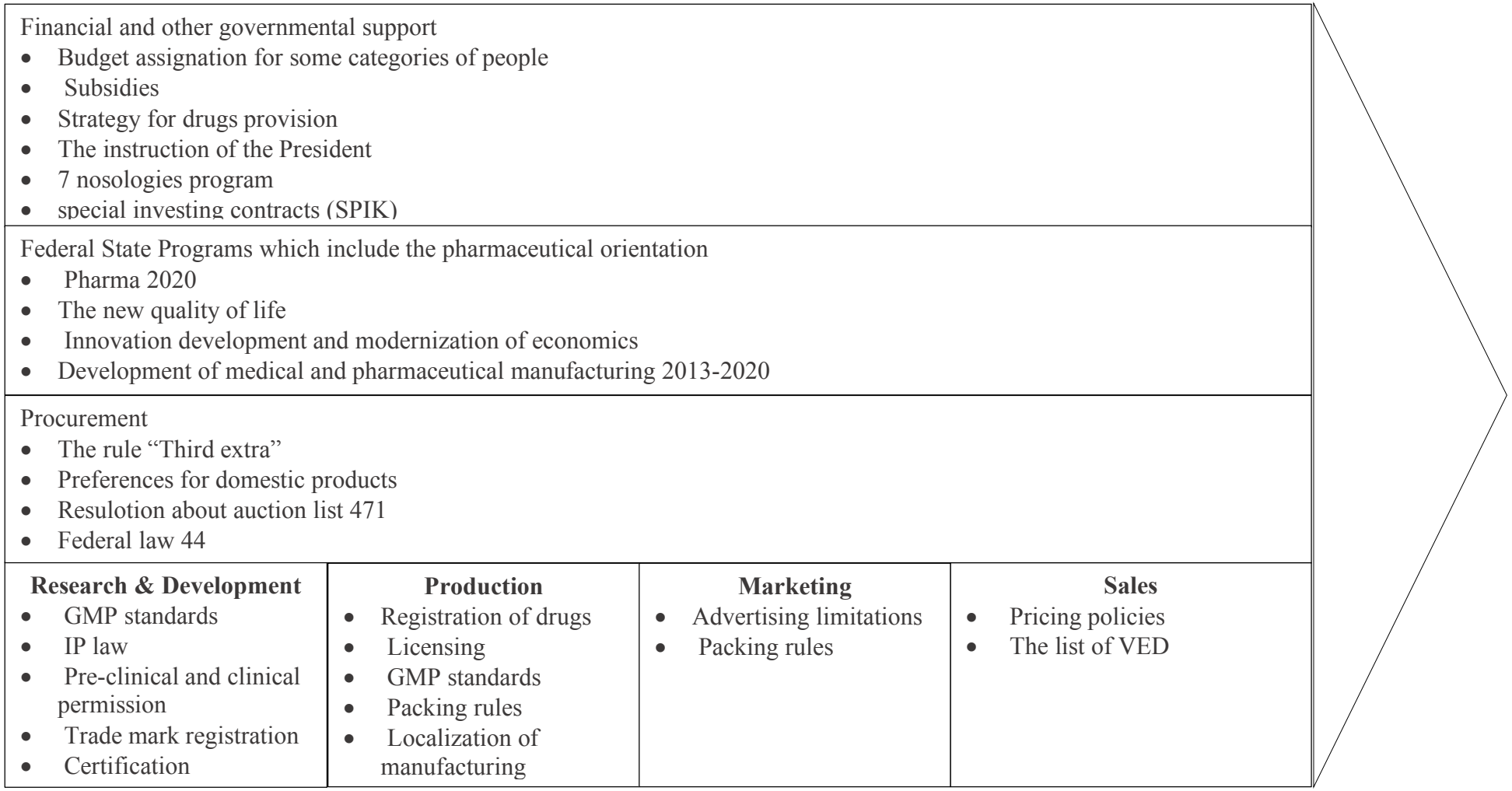
2.4 Summary

In the last few years the institute of state support of the industry has been actively developing. The changes are aimed at improving the initiatives to stimulate the development of the industry, including starting from a real economic situation. If initially only the programs specific to the industry were operating, then in the last two years universal support measures were implemented, implemented within the framework of the general program for priority sectors of the state program and aimed at reviving the investment processes in the economy.

Time has shown that the ongoing strategy for the development of the pharmaceutical and medical industry has become an effective tool for attracting investment in the industry. To achieve this goal, a number of measures have recently been adopted to stimulate investments in integrated investment projects and to obtain external project financing. Investments are also facilitated by the fact that pharmaceutics is one of the most marginal and profitable in terms of net profit of industries. The industry operates in a situation of fairly stable demand for medicinal products and the creation of priority market conditions for domestic products.

At the same time, the Russian economy currently represents a risk zone for both external market participants (investors) and domestic investors. This is due to political reasons, unstable legislative environment, undeveloped institutions, which not only does not contribute to investment processes in the economy, but, on the contrary, stimulates the outflow of capital from the country. The value chain template below shows the regulations distribution in Russia Federation.

Figure 2.6 Value chain concept by M. Porter with distributed regulations for Russian pharmaceutical market



CHAPTER 3. CASE STUDY: ASSESMENT PHARMACEUTICAL VALUE CHAIN REGULATION BY APPLYING RIA METHOD

3.1 Introduction

The third chapter summarizes the research process description and recommendations on the findings of the main objectives of the study which are created to establish the effect of government regulations of the value chain of the Russian pharmaceutical companies.

3.2 Problem statement and research gap

Regulation of the market is necessary for providing the available, safe and effective medicines. The fluctuation in prices caused not only discontent of the population, but also negatively affected to the socio-economic indicators and the level and quality of life.

A weak link in the current system is the insufficient regulation of the formation of producer prices for medicines. For economic and health impact reasons, sound pharmaceutical policies and regulations, minimum quality standards for drugs, transparent licensing, registration and procurement and evidence-based prescription practices are a concern for both consumers and policy makers. State regulation and absence of corrupt practices is important for the performance of health systems. The pharmaceutical market, production and marketing is highly monopolized.

3.3 Methodology of research

This part is dedicated to research process description. In the current case study, I'm using the methodology of regulatory impact assessment and particularly costs-benefits analysis to evaluate existing governmental policies dedicated to pharmaceutical value chain. Also, I will describe the process of collecting the relevant qualitative and quantitative information from the interested groups, the interview results and further recommendations.

The issues of assessing the regulatory impact in foreign countries and the prospects for its implementation in Russia were considered in the works of domestic and foreign scientists: V. Bulev, D. O. Derman, E. N. Kiseleva, P.V. Kryuchkovoy, A.E. Shastitko, D.B. Tsygankova, Colin Kirpatrick and David Parker.

As was already mentioned before, RIA is a systemic approach to critically assessing the positive and negative effects of proposed and existing regulations and non-regulatory alternatives [OECD].

The main role of RIA is the adoption of a balanced, deliberate decision at the state level and the screening of inefficient decisions at the stage of adoption of a regulatory act. Summarizing the general idea about the practice of conducting RIA, the procedure for conducting RIA in this research paper can be divided into several key stages:

1. Formulation and description of the problem of the proposal.
2. Description of possible options for achieving the goal (regulatory and non-regulatory).
3. Analysis and assessment of the presented alternatives (positive and negative factors, benefits and costs for business, consumers or other interest's groups).
4. Consultations with stakeholders and other interested parties.
5. Conclusions and results, presentation of the recommended option.
6. Realization of the chosen alternative, the subsequent monitoring.

Basically, RIA involves using its own set of methods for collecting and analyzing data. The main analytical methods used in conducting RIA are cost-benefit analysis and cost-effectiveness analysis. Both methods are used to consider the proposed regulatory alternatives (phase 3 of the RIA process).

In order to achieve the research paper goal, the following methods were applied: system analysis, classification, analysis of documentary sources, in-depth interviews, analysis of costs and costs.

Also, the theoretical basis of the study is including the international acts, normative legal acts, federal laws, resolutions of the Government of the Russian Federation, normative acts of the Ministry of Economic Development of the Russian Federation, normative legal acts of the subjects of the Russian Federation and the information from official sites and portals of the Russian Federation, authorities of the Russian Federation.

The practical information for research was collected with use of in-depth interviews from the participants of the value chain. In the interviews, I included questions that helped to get the information about the main aspects of the planned regulatory measure. The questionnaire for the survey of the target group, with people from companies, manufactures, market players and participants of pharmaceutical value chain is correctly compiled, the responses are a good basis for assessing compliance costs. At the same time, one should take a very close look at the following issues: Analysis of the experience of other countries in many cases, the regulatory norms that are planned to be introduced in your country have already been adopted in neighboring countries. In this regard, it may be very useful to seek advice from government officials or other

sources in these countries - this can be an effective way of obtaining information on the possible consequences of introducing the relevant rule.

One of the most cost-effective ways to obtain data for RIA is through consultations with representatives of stakeholders. In addition, such consultations contribute to the legitimacy of regulation, since they provide for the possibility of active participation of people in norm-setting activities at the stage preceding the implementation of regulatory standards.

3.4 Research relevance

Governmental authorities need a systematic approach that allows ensuring high quality of norm-setting activity, because inefficient regulation costs the society quite expensive. The poor quality of regulation entails higher costs of compliance with regulations for business and other stakeholders, unnecessarily complicates the process, introduces an element of unnecessary uncertainty with respect to related obligations and, ultimately, reduces the ability of the state to achieve its objectives.

RIA is one of the tools for improving the quality of regulation and, as a result, increasing the efficiency and effectiveness of the government. Also, RIA is a process of systematic identification and evaluation with the help of a sequential analytical method of possible effects that may result from the introduction of certain regulatory measures.

3.5 Research limitations

The main research limitation is obtaining reliable and qualitative data. To provide a deep RIA there is a need of additional analytical work, data collection, stakeholder consultation and analysis. Therefore, more time and resources should be allocated to provide more reliable results.

3.6 Research process

In this part of the case study applicable to practice case, on the basis of Michel Porter value chain concept and the regulatory impact method, there is the evaluation for regulations in Russian pharmaceutical industry.

In-depth interviews, consultations

First, the information and data for the research was collected over the course of in-depth interviews with main actors of the market and industry, but also with companies who are working alongside government and procurements entities. The main point was to have the information from

representatives of all value chain's blocks, in order to understand every stage and evaluate the existing problems in regulations and methods.

The table below describes the respondents of qualitative survey conducted during interviews.

Participants	1. The CEO of distributor company 2. The marketing department representative "Shtada" 3. Procurements department representative Protek 4. Pharmacists from local pharmacies 5. The head of pharmacies chain 6. CEO of a private medical hospital chain 7. An employee in the procurement department of a state hospital 8. An R&D department employee from BIOCAD 9. Not-direct interviews from the pharma journal and conferences - Pharmvestnik.ru - Vandecum - Medcom - Medvestnik - Medka - Medical newspaper - Expert.ru 10. Open lecture by Dmitrii Morozov (BIOCAD) 11. Arthur Antonovich Linneberg, Sotex 12. Anatoly A. Vaganov, Biocad 13. Victoria Sarycheva, Biocad

Interviews were conducted between February and April 2018 with employees of pharmaceutical companies and drugs distributors. Interviews lasted 30 minutes on average. They were recorded and transcribed, allowing an accurate representation of opinions.

The aim of these inquiries was to gather sufficient information to identify strengths and weaknesses of regulation in order to complete the regulatory impact analysis and cost-benefits analysis with the goal of creating recommendations for further development.

BIOCAD Biotechnology Company is an international innovative company that unites a world-class research and development center, cutting-edge pharmaceutical and biotechnological production, preclinical and international clinical studies corresponding to modern standards.

During the interview with Anatoly A. Vaganov, head of the strategic development department of the company BIOCAD, the following measures of state support which are used by this pharmaceutical company were mentioned:

First, BIOCAD company has special investment contracts (SPIC) with the Ministry of Industry and Trade, which fixes the investor's obligation to master the production of industrial products within the specified period, in return for the Russian Federation or its entity guarantee stability of tax and regulatory conditions and provide incentive and support measures. SPIC contracts are regulated by the Government of the Russian Federation from July 16, 2015 No708 "On special investment contracts for certain industries." Within the framework of the SPIC, the state supported subsidies for the construction of a complex of pharmaceutical production buildings in Strelna, for which 1/3 of the financing came from the Moscow region and the city of Pushkin.

However, by the present time the Russian Federation, represented by the Ministry of Industry and Trade of Russia, has concluded only 12 SPICs. Seven of them have been concluded with subsidiaries of transnational or foreign holdings. As many applications of large business groups for the conclusion of the SPIC are under consideration, many more companies are willing to use this tool to implement their development programs.

Also, the company has offset deals which are state contracts for the purchase of necessary goods, which provide for the reciprocal investment obligations of the supplier to create the production of these goods. If such a contract is concluded, the investor is included in the list of single suppliers, which allows state institutions to purchase goods from him without a tender offer. In other words, the company receives a guaranteed state order in exchange for setting up production.

Thirdly, the pharmaceutical company is actively involved in public procurement. One of the largest cases is the success of the company BIOCAD with the bio-analogue of rituximab of its own design in the tender for the purchase under the "Seven Nosologies" program in 2016 for 2.516 billion rubles. It was in this auction that the "third extra" order worked, which ensured the victory of BIOCAD.

Fourth, the expert noted that the company is actively using state support for enterprises participating in the special economic zone.

As for subsidizing, Victoria Sarycheva, head of the GR department of the company BIOCAD, noted that the size of the subsidies in the field of export is significant, in 2017, the company BIOCAD received subsidies totaling 112 million rubles.

Also, during the interview it was found out that most of the state support is related to the development stage, and that there is a problem being that all subsidies aim at compensating the part of costs incurred by the company in the production, development or registration of drugs. However, if the company does not have sufficient funds, then it becomes impossible to implement these processes.

In an interview, published by the website "Expert.ru", Dmitry Morozov, general director of the company "BIOCAD" noted: "We use all the benefits provided by the special economic zone, and I do not understand why others do not use this opportunity. Probably, the stagnation of thinking of managers does not allow us to make full use of the preferences that the state gives us.

First, it is a significant saving on taxes, secondly, we have been provided with a ready infrastructure, we use administrative buildings. To counter foreign giants, we must use any opportunities provided by the state. We are strongly supported by the Ministry of Industry and Trade. The issue of creating a number of preferences for Russian producers is being considered, and state funding for the development of original and reproduced drugs continues. "

The results of the state policy in the field of import substitution are the victory of BIOCAD in the competition for the supply of rituximab under the Seven Nosologies program. It was in this auction that the "third extra" order worked, which ensured the victory of the domestic pharmaceutical company. According to data obtained during the interview, it was found that the inflow of money from the supply of rituximab was directed to the development of the company's export projects. Thus, the result of the current state policy on import substitution is to support the development of export of pharmaceutical products.

In an interview with Arthur Antonovich Linneberg, head of the export development department of the pharmaceutical company Sotex, an assessment was also made of the effectiveness of state regulation measures in the sphere of pharmaceutical exports. "Sotex is one of the dynamically developing domestic developers, manufacturers and suppliers of high-quality

and affordable medicines that compete successfully with the products of well-known global pharmaceutical companies."

Talking about the impact of the Decision 1289 "On the restrictions and conditions of admission, originating in foreign countries of medicines on the list of essential medicines, for procurement purposes to ensure state and municipal needs, then, according to the expert, The decision "the third superfluous" strongly influences both activity of the given company, and on other participants of the pharmaceutical market of Russia.

The export direction of the company started in 2009, and today Sotex delivers its own products to 11 countries of the near and far abroad. On October 20, 2016 Sotex production received the European GMP certificate, which expanded the company's opportunities to enter global exports. October 11, 2017, Sotex received the first European registration certificate for its own medicinal product, allowing it to export to the European Union. In 7 countries, the process of registering a whole series of drugs is at different stages of completion. As the expert notes, the expansion of geographical borders of presence is one of the priority tasks of Sotex.

According to the data provided by the expert, the revenue from the export turnover for the last 3 years has doubled and continues to grow. This not only strengthens the company's position in the international pharmaceutical market, but also agrees with the objectives of the national strategy "Pharma-2020", which aims the domestic pharmaceutical industry for an eightfold increase in exports by 2020. And, as the trends in the pharmaceutical market, thanks to the system work and support measures of the Ministry of Industry and Trade of Russia, coincide with the trends of the market as a whole, the company can count on further strengthening its positions in the export direction. Arthur Anatolyevich Linneberg characterized the measures of state regulation in the sphere of export of pharmaceutical products as effective.

Thus, in the course of interviews with experts from the pharmaceutical industry, the effectiveness of measures for state regulation of the Russian pharmaceutical market was assessed. Despite some existing subsidizing problems, state support can be characterized as sufficient and effective, as the support of pharmaceutical companies is carried out at all stages of the production cycle and covers a wide range of measures. The above-mentioned cases of pharmaceutical companies BIOCAD and Sotex are a clear example of the effectiveness of the state policy of import substitution, which results in support in the development of export of Russian pharmaceutical products.

During this research, analytical reports from DSM group, IMS Health and reports from consulting firms, such as KPMG, Deloitte and PwC were used. They provided the quantitative information and data to complete the information gathered during in-depth interviews. Moreover, we developed practical point of view and knowledge during the visit of R&D and manufacturing department of the main players and distributors on the market.

Comparative analysis of international regulatory practice

The table below compares the current Russian regulations with regulations implemented in Estonia, Netherlands, and Australia. It is based on World Health Organization's information and data, in this case study there is a comparison between Russian's and other countries' regulation functions.

The criteria for choosing the countries was made by type of the authorities, developed country, and existing of medicine regulation bodies.

Functions	**Russia**	**Estonia**	**Netherlands**	**Australia**
Licensing of manufacturing	●	●	●	●
Licensing of importation	●	●	●	□
Licensing of wholesale	●	●	●	□
Licensing of retail	●	●	□	□
Product assessment & registration	●	●	●	●
GMP standarts and control	●	●	●	□
Inspection of distribution channels	●	●	●	□
Import control	●	●	●	●
Quality control of products	●	●	●	●
Control of drug promotion & advertising	● *for prescribed drugs* □ *for non-prescribed drugs*	●	□	●
Price control	●	□		□
Generic substitution	●	□	●	●
Control of prescribing	□	●		●

●=*yes* □=*no*

Table 3.2 Regulatory functions by authorities in Russia, Estonia, Netherlands, Australia

Russia is emerging from a two-year recession, with GDP resuming its growth in 2017 and expected to keep increasing in the coming years. The recovery of the economic activities will support an increase in healthcare spending and drive demand for pharmaceuticals as household incomes will gradually improve. BMI Research forecasts that healthcare expenditure will grow at a CAGR of 5.7% over the 2017-2021 period in nominal local currency terms, reaching RUB 7.3tn in its final year. In US dollar terms, however, the CAGR will be much weaker, at 3%, with spending forecast to stand at USD 112bn in 2021. Analysts of the Economist Intelligence Unit (EIU) are more upbeat, projecting that healthcare expenditure will rise at a CAGR of 6.9% in local currency terms and at a CAGR of 6.0% in US dollar terms in the 2017-2021 period. Per capita spending is expected to reach, by BMI Research, USD 779.3 in 2021, up 36% from its 2016 level of USD 573.8. As a share of GDP, healthcare spending is forecasted to edge up to 6.59% in 2021, compared with 6.43% in 2016.

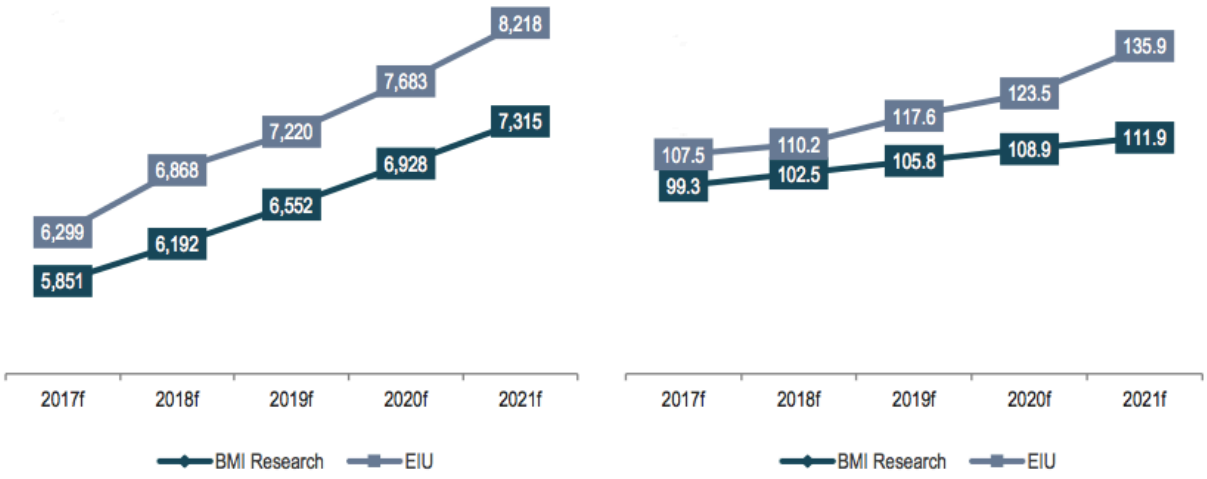


Figure 3.2 Healthcare Spending Forecast, RUB bn and in US dollars
Source: Source: BMI Research, EIU

Cost-benefit analysis

Further research is consisting of policy analysis: with comparing costs and benefits. In provided research paper, the cost and benefit analysis implemented in case of making futher recommendations. Analysis in research paper refers to collection and organization of data relevant to a government regulations, thought public projects, programs. Cost-benefit analysis is a form of evaluation research concerning: program, strategy, technique or an improvement. Steps for achive the current analysis results.

1. List programs and policies

2. Select measurement(s) and measure all cost/benefit elements.
3. Predict outcome of cost and benefits over relevant time period.
4. To adopt the recommendations

The distribution of the existing regulation in the table below is based on Michel Porter's value chain concept principles.

Research	Development	Manufacturing	Market Access	Marketing & Sales
Licensing - the duration of process and price - non-coordination of procedures + quality and trust **IP control** - compulsory licensing + level of quality and safety - expensive and problematic patenting **All types of pre-manufacturing licensing** - the duration of process and price - non-coordination of procedures + quality and trust	**Clinical studies permission** + new investments from government and investors - trust and quality of research - long and formal procedure - costs for process **Licensing** - the duration of process and price - non-coordination of procedures + quality and trust **GMP** - the duration of process and price + quality, international markets entrance	**Licensing** - the duration of process and price - non-coordination of procedures + quality and trust **GMP** - the duration of process and price + quality, international markets entrance	**Marking (Roszdravnadzor)** + analysis of the reliability of traffic and sales data + storage of data arrays + promotion and advertising of medicines is an easier process + ensuring the protection of the population + identification of illegal drugs and disorders + control of commodity flows + tax control - the cost of drugs will increase (1.5 - 2 rubles with a payback period of 2-3 years) - budgetary burden - increase in the cost of medicine - additional equipment costs - possible stoppage of drug movement **Control of falsification** + decrease in counterfeit + security of the population - company costs on documentation	**Price control and VED list** + saving of state budget resources + support of citizens - negative profitability of production and sale of drugs on the list. ultimately, it may lead to a reduction in the production of certain drugs. in particular, up to 50 rubles - work with cheap drugs is not reasonable for the exterminator - cheap drugs can disappear - producer's don’t wish to get on the list - the substance is foreign (the price is rising because of the fluctuation of the exchange rate) - entry criteria is not established **Prohibition of advertising of prescription drugs and possible ban of advertising** - the difficulty of entering new drugs and brands on the market. Especially for small businesses

Pre-clinical studies permission from government and investors - trust and quality of research - long and formal procedure - costs for process **GMP standarts** - the duration of process and price + quality, international markets entrance			-Time testing costs - the costs of organizing monitoring	- advertising can go into poorly controlled Internet + allows domestic producers to enter the market providing import substitution
Supportive regulations				
Procurements regulation + for domestic producers, Russian industry becomes more competitive and export-oriented + for many manufacturers inclusion in the program of state. procurement is an essential aspect of industrial and industrial activities, as well as the				

withdrawal of drugs to the market - fairly stringent measures for foreign products and a mandatory 15% discount with participation in the auction - discrimination of foreign manufacturers of drugs - interchangeability issue - state purchases on obligatory medicinal provision Russian manufacturies **Benefits** Foreign manufactures **Costs**
Registration of manufacturing and implementation GMP standards
+ high level of quality of sites and products + assistance in exporting products - costs of the enterprise for the development and preparation of sites
Strategy 2020 (briefly)
+ increase in the share of sales in value terms + development of the pharmaceutical industry + strengthening the position of Russian companies + stimulation of enterprises to localization + import exceeds export 14 times + innovative developments + establishment of m & a joint ventures as a way to develop business - negative state of affairs in pharmacies (a big competition - pharmacies discounters)

Analysis strategy for the development of the pharmaceutical industry in the Russian Federation for the period to 2020 (Pharma 2020)

Nowadays, the strategy for the development of the pharmaceutical industry in the Russian Federation for the period to 2020 (Pharma 2020), adopted by the Russian government in 2009 has become one of the most successful state development program, it influenced on new pharmaceutical plants and production sites, new high-tech pharmaceutical enterprises equipped with the most modern equipment and corresponding to the international standards of GMP.

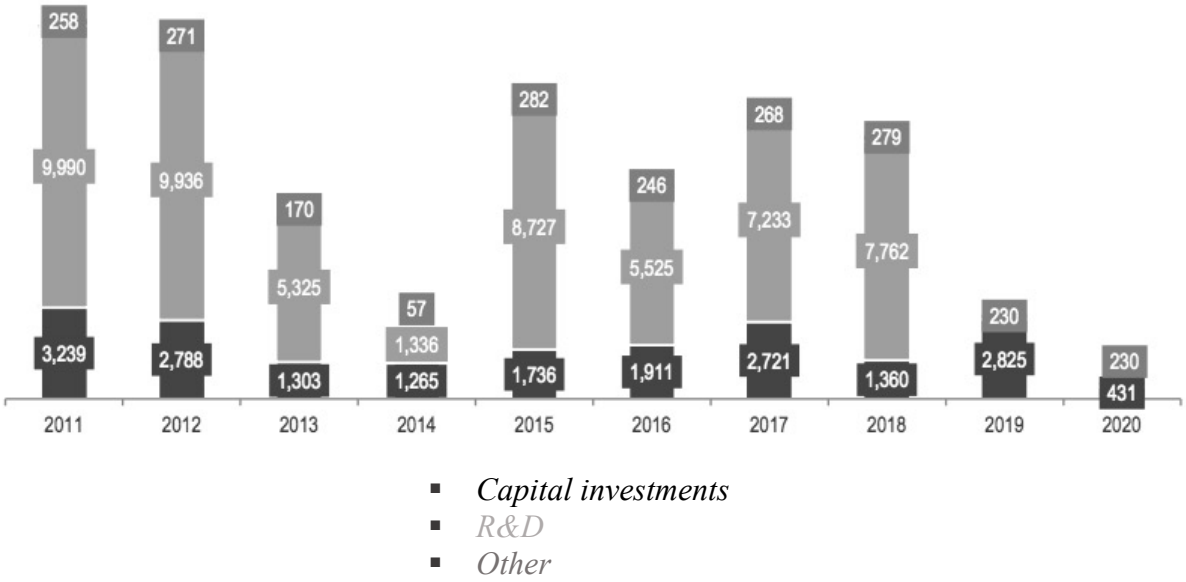


Figure 3.1 Public funding under the Pharma 2020

The government allocated RUB 54.4bn in funding under the Pharma 2020 during the years 2011-2016. In 2016 alone, it spent RUB 7.7bn, down by 28% y/y. Investments in research and development (R&D) had the lion's share of this total in 2016 – with 71% or RUB 5.5bn – though this sum represented a y/y drop of 37% in absolute terms.

After the decline in funding in 2016, allocations were planned to increase by 32.5% y/y to RUB 10.2bn in 2017, on the back of a 31% rise in R&D investments. Capital investments were also slated to be higher than in 2016, registering a 42.4% y/y growth to RUB 2.7bn.

Overall, the Pharma 2020 envisages total funding of RUB 77.7bn in the 2011-2020 period.

The program's main goals include: technological upgrading of the pharmaceutical industry; import substitution for drugs on the VED list; the launch of innovative domestic products; and enhancement of the export potential of local pharmaceutical producers. [Source: Economy Ministry].

In order to conduct an independent evaluation of the effectiveness of this program, interviews with respondents were conducted.

Within the import substitution plans, one more direction is currently developing, which is connected with the localization of foreign productions in the territory of Russia and the transfer of technology. Over the past five years, foreign companies have invested in various forms of localization in excess of $ 2 billion, including not only the construction of enterprises, but also the modernization of production facilities.

Practical realization of this direction is carried out in various forms: construction of own production, contract production of own medicinal forms at Russian production sites, acquisition of industrial Russian assets, organization of joint ventures.

Localization of foreign pharmaceutical manufacturers is promoted by active Russian regional policy.

The most attention in Russia is attracted by transactions involving or with the dominance of Western companies and companies of developed countries. However, in the information on the actions of companies in the Russian market, it is necessary to take into account that the English-language company name with placing information about itself on the Internet in English only can refer to a purely Russian company or a company with Russian registration.

An example of projects involving private equity funds may be an ongoing transaction for the acquisition by Gazprombank and UFG Private Equity of an 80.55% stake in OBL Pharm, a pharmaceutical group that develops and manufactures medicines61. Shares of the Russian company OBL Pharm were bought from its founders through Alvansa Limited, the main beneficiaries of which are the customers of Gazprombank and UFG Private.

In the near future, the Russian pharmaceutical industry is expected to increase the number of mergers and acquisitions involving both foreign and domestic pharmaceutical companies. Trends in the growth of M&A transactions in the domestic pharmaceutical industry reflect the globalization processes in the global pharmaceutical industry, they will increase in connection with the tightening of global competition in the global pharmaceutical market. The acquisition by foreign pharmaceutical companies of domestic pharmaceutical production is due to legislative initiatives on import substitution.

However, according to representatives of large foreign pharmaceutical companies, there are very few serious objects on the Russian pharmaceutical market for takeover, taking into account the fact that the value for potential buyers is not represented by factories, but portfolios. In Russia, on the one hand, there is an excess of production capacity, and on the other hand, a shortage of capacities for conducting R&D. A number of domestic manufacturers have mastered the biopharmaceutical production of drugs previously supplied only from abroad.

So, the company "GEROFARM" organized the production of domestic genetically engineered insulin for a full cycle - from the synthesis of the substance to the finished dosage form. The drug is supplied not only in the form of vials and cartridges, but also with pen-syringes. The share in the domestic genetic engineering insulin market approximated to 10% in physical terms. And, taking into account the launch of a new production within the pharmaceutical cluster in St. Petersburg, the company "GEROFARM" will be able to meet 100% of Russia's needs, develop exports. And this will significantly reduce the state budget expenditures on medicines in the segment of diabetes mellitus, the volume of which exceeds 13 billion rubles. Together with the Korean company Dong-A ST, "GEROFARM" is developing an oral hypoglycemic drug for patients with type II diabetes (class of glyptins). The volume of the Russian glyptin market is about 2.5 billion rubles.

The Russian biotechnology company Biocad implements the Program "Organization of experimental production of substances and drugs based on monoclonal antibodies". Biocad is a fairly young biotechnology company that is a full-cycle research and production structure and is implementing a bio-analogue project (BCD-020) designed to replace rituximab purchases abroad. The annual amount of its sales in Russia is more than 4.5 billion rubles. And the purchase is made mainly from the federal budget in the framework of the "7 Nosologies" program. The implementation of this project, according to the company, will allow to stop purchases abroad66, and in connection with the access to the market of public procurement of this drug, the share of domestic medicines in the cost of all public procurement has doubled.

"Generium" works in the field of biotechnological development and production of drugs for the treatment of hemophilia, tuberculosis, multiple sclerosis, oncological and cardiovascular diseases. The main articles of the company's revenues are innovative drugs for the diagnosis of tuberculosis and the treatment of hemophilia. The production of an innovative Diaskintest preparation, which provides accurate diagnosis of tuberculosis, has been mastered. The Ministry of Health included Diaskintest in methodological recommendations and the wide use of the drug for mass screening of tuberculosis in children throughout the country began. Studies show that as a result of the use of the drug, early diagnosis of tuberculosis in children has improved. Diaskintest sales in the CIS countries are growing, export earnings from supplies to countries such as Bangladesh and Mauritius have increased. Another source of revenue growth has been preparations for the treatment of hemophilia - coagulation factors (Coagil-VII, Octofactor, Innonafactor). "Generium" is the only company in the world that can produce all three recombinant coagulation factors for the treatment of hemophilia.

3.7 Recommendations for further regulations

1) Enhancement the procurement regulation rule "Third extra"

The introduction of the rule "Third extra" is clear from the point of view of the state. Nevertheless, after the analysis and interviews, it can be said that incentive measures will affect much more effectively restrictive measures. It is necessary to create favorable conditions that support investments, not only in the construction of production capacities, but in the development of innovations in Russia. At the moment, the state of foreign investors does not stimulate. In this recommendation, it is proposed to expand the "Third Extra" rule, acting on the market of medicinal state order, by creating a new procurement model - three-stage.

First of all, preferences at auctions should be received by domestic full-cycle enterprises. In the second - manufacturers, producing products with the highest degree of localization. And only then all others can be admitted to the auction.

Since in Russia 85-90% of imported substances produced in China and India, then there is another idea: if the drug is produced on a full cycle of domestic raw materials, then the price preference for government purchases for it will be 40% if the full cycle, but from the import substance - 20%, if only the packaging - 10% and with the subsequent exclusion of this stage. This approach does not limit competition, stimulates the flow of investment in the industry and the desire of foreign producers to localize in the Russian Federation.

2) The implementation of marking and creation of monitoring system

It is necessary to prevent entry into circulation and the simultaneous withdrawal from circulation in an automated manner throughout the entire territory of the Russian Federation of poor-quality, as well as falsified and fake drugs at any stage of their circulation from the producer to the end user. Also, monitor the targeting of drugs purchased from the budget, the costs of their purchase;

Mandatory labeling of drugs in Russia is a right move in one direction with the EU and the US, where labeling and serialization are already working from 2011 and from 2015 respectively.

The influencing factor for the manufacturer is, of course, large investments in the procedure, additional expenses in the infrastructure of both the producer and the entire commodity distribution chain. In Russia, such expenses can amount to up to 15 billion rubles, according to

various estimates. manufacturers, distributors and pharmacies will be relocated to the end user, according to approximate estimates, the margin will be no more than 1.5 rubles. At the same time, the problem of falsification will be solved, which is due to weak control by the state

Result: Marking will protect the population from poor-quality and counterfeit means.

3) Revise the INN adjustment

Now they called all the names for INN. Therefore, during the competition the cheapest wins. The same situation with consumables. The main criterion is the low price. And the reverse situation, if there are few Russian analogues for imported expensive drugs: imports are being withdrawn from the auction, and the fatherland is on the whole, as an imported original, only the quality is not that.

It is necessary to check the quality and similarity of the substance, action and active substance in the preparations participating in the competition. Often the drug winning the competition by the rules is less effective. However, the difference in price is not significant.

This law, of course, supports domestic production and protects against a substandard drug, but quality imports are being squeezed out and out of the market.

4*) Adjustment of the list of VED*

At the moment, the existing list raises many questions about the establishment of price restrictions, especially on the segment up to 50 rubles. The official marginal margin is low, so cheap goods are washed out of retail because of expensive logistics. The sale of such a segment does not bring benefits, so there are gradually risks that this category of medicines may leave the market. New measures are needed to stimulate the circulation of such a segment in the market. It is necessary to introduce preferences for companies to manufacturers - distributors. The scenario of a situation in which there will be a decrease in the number of manufacturers of medicines of this category is possible, correspondingly a greater benefit from the volume of sales.

5) Revision of the financing of the seven nosologies program

Currently, funding for this state program has decreased, however, statistics show that the number of patients has increased.

It is necessary to review the number of budget subsidies for this program.

6) Prices of government contracts for the supply of most vaccines

The price of contracts has not increased since 2010 and manufacturers constantly point to unprofitable production. In connection with this, the Ministry of Health needs to give maximum attention to supporting domestic vaccine manufacturers with long-term procurement planning, because their production has a special cycle.

7) Continue to improve the regulation of access of new drugs to the market

The procedure for registration of medicinal products based on the separation of the registration procedure and the procedure for obtaining permission to conduct a clinical study of the medicinal product;

the possibility of an expedited registration procedure for individual medicines, including medicines for pediatrics and orphan medicinal products;

Harmonize the standards in accordance with international law on proper practices of preclinical and clinical studies, the formation of a registration dossier, pharmacovigilance, etc .;

Further reforms will help to increase the availability of drugs that meet the established requirements, and will also speed up the withdrawal of new medicines into circulation.

8) Regulation of public procurement

Each year, the cost of procurement of medicines only increases, the list of diseases and categories of citizens is expanded to provide them.

Almost 80% of the Russian pharmaceutical market is occupied by foreign products. It is necessary to adopt a balanced state drug supply program, in which it is necessary to establish clear criteria for selecting categories of citizens to provide them with free medications.

Beneficiary lists should be audited through authorized structures. At the federal level, the government of the Russian Federation must appoint a responsible operator for the procurement of medicines with mandatory public reporting. The same operators should work in the regions of the Russian Federation.

Annually, on the basis of research analysis and statistical reports, the government of the Russian Federation should make the necessary changes.

9) Restrictions on the methods of promotion of medicines

In Russia, there was a practice of using medicines by citizens, when the latter do not trust doctors-specialists, they independently diagnose, including. through the Internet, buy prescription drugs in pharmacy organizations without a prescription and uncontrolled use them.

An important role in this is the recognition of the drug brand. Therefore, it is necessary to teach citizens how to safely use medicines. To do this, it is necessary to conclude a public (possibly ethical) agreement between the producer, the state and the consumer, in which the safety of drug use for the consumer should be in the first place.

10) Regulation of sales of medicines and medical services via the Internet

The Internet market tool, it allows you to see the entire history of the relationship from the producer to the consumer. It is through the Internet that the state needs to enter the maximum possible number of controlling and regulating functions for selling drugs and providing medical services, this will add objectivity, convenience, transparency to the relations between the state and business.

11) State registration of medicines, including GMP certification rules

It is necessary to standardize the activity at each stage of drug circulation from the moment of laboratory practice and preclinical studies to pharmacovigilance.

Also, establish uniform rules for all consumer countries and drug manufacturers when, when implementing and implementing appropriate practices, all parties should not have repeated mandatory registration and other procedures complicating the promotion of medicines from producer to consumer, regardless of the country where the end user is located medicines.

For example, the medicine is produced in Germany, there it is registered and accepted for use. Automatically, the drug should be taken to use in Russia. A periodic verification audit of experts from Russia at the enterprises of the manufacturer of medicines is allowed.

CONCLUSION

The research is devoted to developing the methodology of regulatory impact assessment, based on Michel Porter's value chain, and its application to assess the impact of regulations on pharmaceutical companies in the Russian Federation.

The regulation of the market is necessary for providing the available, safe and effective medicines. First of all, the research results can conclude that nowadays in Russia the politics and measures in the pharmaceutical industry is really strong. The regulatory management in Russia is already completed and functioning productive. The market statistics every year shows better results. The government after crisis situation made all the measures for the domestic production growth. Still, further realistic and effective laws and regulations are needed for the pharmaceutical sector. For providing the national health and develop the pharmaceutical industry inside country and moreover orient the production for export in this research paper provided and made recommendations.

Also, the most effective forms and methods of state regulation of the pharmaceutical industry are determined, the emphasis is on price regulation of medicines included in the VED list, as well as the need to comply with international good practices.

It is noted that legislative and legal regulation continues to be improved, which provides for measures to support the Russian pharmaceutical industry, including the provision of various kinds of subsidies, loans, preferences, conclusion of special contracts and other financial and non-financial measures. At the same time, the mechanisms of state regulation of the industry need to be improved. In particular, there are more than 200 normative documents of the federal level regulating various aspects of activities related to the circulation of pharmaceutical products. The paper reveals the most significant shortcomings of the regulation system of the domestic pharmaceutical industry.

Based on the results of analysis, were offered recommendations to increase the effectiveness of state regulation of the pharmaceutical industry. Priority in terms of importance for its development are improvements in the regulation of drug pricing, including the procedure for updating the list of VED, improving the procedures for public procurement, especially on the practice of applying preferences, restrictions, and on the procedure for the procurement of trade names.

The second most important area for improving the state regulation of the pharmaceutical industry is the improvement of procedures for the state registration of drugs, especially for domestic-produced generics, as well as methods for promoting drugs and the introduction of a unified monitoring system with the further mandatory introduction of marking.

The main results of the implementation of the "Strategy for the development of the pharmaceutical industry of the Russian Federation for the period until 2020" are analyzed, which determines the measures of state support to the industry, getting rid of import dependence and stimulating the export of pharmaceutical products. Thanks to the state policy of import substitution, increasing the effectiveness of scientific research and development on the creation of innovative products of domestic production, new competencies in the production of drugs, claimed by the domestic healthcare system, have been mastered.

The defining vectors of development and competitiveness of the domestic pharmaceutical industry is the growing process of import substitution of drugs, the transition of Russian producers to the international standards of GMP, the localization of production of foreign companies, the formation of clusters that combine to create and market innovative, domestic drugs, generics that reduce the share of foreign products on the Russian pharmaceutical market.

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