Sminar № 2.
Structure of the pharmaceutical market. State regulation and social policy in the field of healthcare

Main issues to be discussed at the seminar:

1. Pharmaceutical market. Features and functions of the pharmaceutical market.
2. Main trends in the development of the global pharmaceutical market. Review of the pharmaceutical market in the Russian Federation. The main provisions of the "Strategy for the Development of the Pharmaceutical Industry until 2030" ("Pharma-2030").
3. Structure, subjects and objects of the pharmaceutical market of the Russian Federation. Signs of market classification, elements of the internal and external pharmaceutical market.
4. Features of state regulation in the social sphere. Ways of state regulation in healthcare.
5. Directions and levels of State regulation in the field of circulation of medicines. Elements of state regulation at the federal and regional levels.
6. Basic provisions of the strategy and policy of drug provision for the population of the Russian Federation.
7. State registration of medicinal products.
8. Licensing in the field of circulation of medicines.

The pharmaceutical market is part of the market for consumer goods and services, where the goods are medicines, medical products, and services.

The drug market in the economy of any state has its own socially significant role.

Main functions of the pharmaceutical market:

- ✓ economic provision of material incentives for work in the field of pharmaceutical production;
- ✓ bringing goods to final consumers - patients;
- ✓ achieving structural and assortment correspondence between supply and demand;
- ✓ stimulating the development of scientific and technological progress in the pharmaceutical industry (through competition).

Main trends in the development of the pharmaceutical market

We can identify the main socio-economic reasons that influence the development of the pharmaceutical industry as a whole:

The prevalence of chronic diseases such as diabetes is increasing.

Many governments are raising the retirement age, which means that the onset of chronic diseases occurs during the economically active part of life, further increasing health care cost pressures.

Accordingly, the social and economic value of treating these diseases will increase.

However, pharmaceutical companies will be forced to reduce prices for drugs used to treat chronic diseases, and revenue growth will be achieved through an increase in physical sales volume

From an economic point of view, the drug market is one of the largest consumer markets in the world.

Over the past two decades, the global pharmaceutical market has been characterized by continuous progressive growth dynamics.

Large transnational corporations play a key role in the global pharmaceutical market.

Medicines are one of the world's most important exports, and the pharmaceutical industry is highly export-oriented .

The main exporting countries of these high-tech products are the leading technologically advanced countries .

Noteworthy is the fact that some leading exporting countries can simultaneously be key global importers of pharmaceutical products .

The main conclusion from the presented data is that the modern global pharmaceutical market is one of the largest consumer markets on the planet, with high positive growth dynamics.

It is dominated by powerful transnational giant corporations, multi-billion dollar mega-deals are taking place, and annual sales of even individual blockbuster medicinal products can be comparable to the budgets of even the smallest states.

The pharmaceutical market is largely export-oriented , and current trends indicate not only its large-scale economic, but also its growing political role in the modern world.

The structure of the pharmaceutical market is a system of interconnected and interacting subjects and objects for **the** production, distribution and consumption of medicines, as well as factors influencing them:

Features of the structure of the pharmaceutical market of the Russian Federation:

- ✓ Dynamic growth of market volume
- ✓ Product structure
- ✓ Regional differentiation of the Russian pharmaceutical market
- ✓ Import dependence and import substitution

Signs of market classification:

- ✓ geographical position
- ✓ saturation level
- ✓ nature of sales
- ✓ degree of maturity
- ✓ market objects

Main functions of the pharmaceutical market

- ✓ economic
- ✓ informational
- ✓ mediation
- ✓ pricing
- ✓ stimulating

All market infrastructure elements are classified into groups:

- ✓ elements **of the foreign market** (foreign manufacturers of medicines, foreign trade firms, enterprises with 100% foreign investment, international trade system)
- ✓ elements **of the domestic market** (commodity market, securities market (bills, bonds, shares), foreign exchange market, labor market, credit market, investment market, real estate market and services market in the industrial and social spheres).

The subjects of the pharmaceutical market are divided into:

- ✓ sellers' market
- ✓ buyers' market

Main characteristics of **a "seller's market"**

1. shortage of drugs
2. buyers are the most "active" in the market
3. power belongs to sellers

A sellers' market is the independence of pharmacies in the local market segment

The buyer's market is the sovereignty of consumer behavior when choosing a pharmacy.

1. plenty of medicines
2. more power for buyers
3. sellers are the most "active" in the market

Subjects of the pharmaceutical market - market participants, have an active influence on its objects and consist of the following subsystems:

- Management and regulation - represented by pharmaceutical oversight bodies, quality control, effectiveness and safety of medicines at the international, state and regional levels

- Production and distribution - represented by domestic manufacturers of pharmaceutical products, foreign companies, wholesale and retail organizations

-Pharmaceutical information - presented by specialized information and analytical publications, agencies, consulting companies, etc.

- Personnel training - represented by the training of specialists in the field of "Pharmacy" (pharmacists, pharmacists), specialists in the production of medicines, managers and marketers focused on the pharmaceutical industry.

Pharmaceutical market objects :

- pharmaceutical goods and services;

- parapharmaceutical products;
- pharmaceutical information;
- consumer tastes;
- solvent need;
- product quality;
- technologies.

The Russian pharmaceutical market consists of two main segments:
commercial and government.

The commercial segment of the pharmaceutical market includes pharmacy sales of finished dosage forms (FPP) and parapharmaceuticals, excluding sales under the Additional Drug Supply Program (DLO).

The state segment of the pharmaceutical market includes pharmacy sales of FPPs, as well as sales through medical and preventive institutions.

The organizational structure of the pharmaceutical market in Russia has significant differences from other product markets due to the fact that the drug supply system has historically and logically always been organizationally and structurally closely related to a specific healthcare system.

Also a feature of the organizational structure of the pharmaceutical market in Russia is the important role of the state and compulsory health insurance in the provision of medicines to the population.

A specific feature of the domestic pharmaceutical market is government procurement of medicines for preferential provision to certain categories of citizens.

In modern conditions, drug provision for certain categories of citizens is divided into two areas:

1) regional procurement to provide necessary medicines;

2) centralized procurement of medicines for the treatment of high-cost nosologies: hemophilia; cystic fibrosis; pituitary dwarfism; Gaucher disease; myeloid leukemia; multiple sclerosis; after organ and (or) tissue transplantation, etc.

The volume of government procurement is an important factor influencing the dynamics of the Russian pharmaceutical market.

Development strategy for the pharmaceutical industry until 2030

The tasks outlined in this document are more ambitious. Among them:

- ✓ strengthening government policy to support innovation,
- ✓ development of local competencies in the chemical and biological synthesis of active substances and pharmaceutical substances

One of the areas of development should be export. By 2030, the export of Russian medicines should increase 5 times.

The stratagem for the development of the domestic pharmaceutical industry in the horizon of 2030 should be innovative import substitution, based on the

accelerated, effective implementation of promising drug developments, primarily domestic ones.

One of the most knowledge-intensive applied areas in which the most modern technologies are accumulated is pharmaceuticals (chemical and biotechnological).

In terms of innovation, the drug development industry is on par with the aerospace industry.

Therefore, this area is one of the main arenas of technological confrontation between the world's largest players in the 21st century, and only a few of the most technologically advanced regions and countries in the world are capable of creating their own innovative medicines.

Instruments used for government regulation of health care include:

- ✓ legal, economic and administrative regulators;
- ✓ regulatory impact assessments that improve the quality of regulation in health services;
- ✓ administrative regulations for the provision of public services in the field of healthcare;
- ✓ state social standards in the field of healthcare;
- ✓ Program of state guarantees for the provision of free medical care to citizens;
- ✓ federal target and territorial target programs for health protection and promotion;
- ✓ national projects;
- ✓ health standards;
- ✓ licensing of certain types of activities in the field of healthcare;
- ✓ qualifying exams for medical and pharmaceutical workers

The task of regulation is to coordinate the activities of participants to maintain and strengthen the health of the population and increase the expectancy of quality life. Only the state has sufficient information and administrative resources to effectively influence all elements of the market structure:

1. It is possible to predict the dynamics of morbidity, and, consequently, the level of costs associated with the provision of medical care, only at the macroeconomic level. In practice, these forecasts are embodied in a state order for the provision of medical care of a certain type and in a certain quantity. The possibility of forecasting logically implies the possibility of a multiplicative impact on public health through the development of areas of prevention, vaccination, health education, etc.

2. Market imperfections associated with information asymmetry can be leveled out with the help of government licensing and assessment procedures that signal the quality of the product and the integrity of the manufacturer: certification, licensing, accreditation. In this case, the state order is placed exclusively in licensed enterprises and organizations.

3. Artificially inflated prices for certain medicines, medical products and services, due to low price elasticity of demand, can be limited through public procurement based on tenders, quotations, and auctions.

4. The oligopolistic structure of the medical services market can be controlled by applying all known measures of state antimonopoly regulation.

5. The constitutional right to health care should not turn into social dependency; the state must clearly limit its obligations in the field of health care, distinguishing different categories of citizens according to the degree of freedom of access to free medical care. To facilitate understanding of the current approaches to state regulation of industry development, it is necessary to consider the transformation of the mechanisms of state management of healthcare from a historical perspective.

State regulation of the sphere of circulation of medicines in the Russian Federation

State regulation of the circulation of medicines involves:

- ✓ development of public policy
- ✓ legal regulation in this area

State regulation of the sphere of circulation of medicines (directions)

In this regard, the state is called upon to carry out activities in the following areas:

- ✓ development of laws regulating the circulation of drugs;
- ✓ licensing of activities in this area;
- ✓ regulation of export and import of drugs;
- ✓ drug registration;
- ✓ price policy;
- ✓ protection of drug consumers;
- ✓ exercising supervision over the quality of drugs being circulated.

Measures in the field of state regulation of prices for medicines are the establishment of:

- ✓ list of vital and essential drugs
- ✓ maximum selling prices;
- ✓ maximum amounts of wholesale and retail markups to selling prices.

The relevant authorized executive bodies of the constituent entities of the Russian Federation carry out price control for vital and essential medicines by:

- ✓ organizing and conducting inspections of compliance by the object of control with mandatory requirements;
- ✓ systematic monitoring of compliance by the control object with mandatory requirements;
- ✓ taking, in the manner established by the legislation of the Russian Federation, measures to suppress identified violations of mandatory requirements and (or) eliminate the consequences of such violations, issuing

orders to eliminate identified violations of mandatory requirements and taking measures to bring to justice persons who committed such violations.

Procedure for registering a medicinal product in the Russian Federation

The first step in the process of introducing a drug to the market of the Russian Federation is its registration. Registration is a state examination of quality and examination of the ratio of the expected benefit to the possible risk of using a medicinal product with the aim of subsequently authorizing the medical use of the drug in the Russian Federation.

Regulatory legal acts governing the procedure for registration of medicines:

- Federal Law No. 61-FZ "On the Circulation of Medicines" dated April 12, 2010 (came into force on September 1, 2010).

The following categories of medicinal products are subject to state registration:

1. all medicinal products to be put into circulation for the first time in the Russian Federation;
2. medicinal products registered earlier, but produced in other dosage forms in accordance with the list of names of dosage forms, in a new dosage with proof of its clinical significance and effectiveness;
3. new combinations of previously registered drugs.

The following are not subject to state registration:

1. medicines manufactured by pharmacy organizations, veterinary pharmacy organizations, individual entrepreneurs who have a license for pharmaceutical activities, according to prescriptions for medicines and the requirements of medical organizations, veterinary organizations;
2. medicines purchased by individuals outside the Russian Federation and intended for personal use;
3. medicinal products imported into the Russian Federation to provide medical care for the vital indications of a specific patient on the basis of a permit issued by the authorized federal executive body;
4. medicines imported into the Russian Federation on the basis of a permit issued by an authorized federal executive body and intended for conducting clinical trials of medicines and (or) conducting examination of medicines for state registration of medicines;
5. pharmaceutical substances;
6. radiopharmaceutical medicinal products manufactured directly in medical organizations in the manner established by the authorized federal executive body;
7. medicinal products produced for export.

State registration is not allowed:

1. medicinal products that differ from each other in the qualitative composition of active ingredients, under the same trade name;
2. one medicinal product produced by the manufacturer under different trade names and submitted for state registration in the form of two or more medicinal products.

Licensing of pharmaceutical activities is a form of admission of legal entities and individual entrepreneurs to pharmaceutical activities.

The essence of licensing pharmaceutical activities is to comply with a strict procedure for admitting pharmacies and pharmaceutical companies to the production, dispensing and other work with medications.

The government determines the types of work for which a pharmaceutical license is required.

These include:

- ✓ Trade in medicines (retail).
- ✓ Dispensing medications to the population.
- ✓ Storage of medicines.
- ✓ Manufacturing of medicines.
- ✓ Transportation of medicines.

All of the listed activities include work with medicinal products for medical use only.

The essence of licensing pharmaceutical activities is to comply with a strict procedure for admitting pharmacies and pharmaceutical companies to the production, dispensing and other work with medications. To do this, they approve a list of requirements that are checked both at the stage of obtaining a license and throughout the entire period of the pharmacy's activities.

The document for admission to pharmaceutical activities is valid from the date specified in the license. The license for pharmaceutical activities itself is valid indefinitely.