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The Evolution and Innovation in the Regulation of Priority Areas of a Sustainable Development of Pharmaceutical Sector

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***Abstract*—The priority direction of the domestic economy is the sphere of public security. In a stable economy, the state is able to provide the population with all the necessary means to preserve life and health. Data allow sequence of events of scientific ideas and legal problems to be established as a result of studies of the materials. The implementation of reforms has allowed the country to improve the quality of medicines and access to medicines. The Russian stood at the dawn of a period that has seen the restoration and accomplishment. However, they have been disrupted as a result of political and socio-economic changes. The pharmaceutical sector is a priority industry. The concept of sustainable development has the potential to set the framework for improve the pharmaceutical sector. Societies must change the legal regulation mechanism. Those measures should include the prevalence of the information and telecommunications technologies. Since the Internet opportunities for the exchange of experience and technologies in the world community, including in the pharmaceutical sector, have expanded.**

Keywords—priority areas, priority industry, sustainable economy, legal issues, pharmaceutical sector, medicines

I. INTRODUCTION

The fundamental component of the health care system is medicines. They are necessary to provide the population with high-quality medical care. This guarantees the health and free qualified medical care. Medicines are diagnostic, therapeutic, prophylactic and rehabilitative medicinal drug. The pharmaceutical industry is the basis for their creation. Its construction is based on a system of legal, socio-economic and medical measures. They should contribute to raising the level of protection and preservation of public health.

The study of the evolution of sustainable development of pharmaceutical sector has been the subject of many articles, including by foreign authors. For example, about pharmaceutical medicine and law [1-3], pharmaceuticals [4-10], pharmacy users [11], pharmaceutical formulation science [12-14], pharmaceutical documentation [15], pharmaceutical policy [16-20] and others. However, there is no comprehensive approach to the research not yet.

The importance of the information and telecommunications network "Internet" as a dissemination vehicle is constantly increasing. There are opportunities for sharing experiences and technologies in the world community, including in the pharmaceutical sector. This made it possible not only to improve medicines, but also to create new ones. For sustainable development and effective activity were created: World Health Organization, The Global Health Workforce Alliance, developed the Country Coordination and Facilitation, The International Medical Cluster and etc. With the help of the Internet, all people around the world have

access to qualified health workers and the ability to obtain the medicine they need to treat.

II. Materials and methods

The methodological basis of the study consisted of general scientific and private scientific methods such as abstracting, concretization, content analysis, formal legal, comparative legal. The research materials are presented by regulatory legal acts, law enforcement practice and doctrinal sources. The evaluation of the legal regulation of pharmaceutical sector identified challenge, based on an overall data.

III. Results

In the Russian Socialist Federative Soviet Republic (hereinafter the RSFSR), the legal regulation of the pharmaceutical sector was carried out through legal and professional regulation, such as the control of quality, production, development, storage, transportation, packaging, sales, destruction of medicines, pricing, and professional requirements for specialists.

Pharmaceutical plants in Russia appeared in the second half of the 19th century. They produced galenicals and pharmaceutical goods until 1917 [21]. Synthetic organic medicines and alkaloids were not produced, and the need for them was satisfied by import. Enterprises were created by private individuals and some public organizations, for example, the Red Cross Society. However, with a significant lack of raw materials and qualified personnel, this did not satisfy the country's needs. The production of medicines, both before the formation of the RSFSR and immediately after, was carried out by pharmacies and industrial enterprises.

The enterprises of the pharmaceutical industry were engaged in the production of perfumes, cosmetics and household goods, the bottling of vinegar essence, weighed out pepper, soda and laundry blue. The products were sold through the state system of sales and supply, medical supply systems on transport, etc. Direct dispensing of medicines to consumers was carried out through the pharmacy network. The medicines were both packaged and dosed.

In the first years of Soviet state, the task of free of charge qualified medical care was difficult because of a destroyed healthcare infrastructure and pharmaceutical business. As a result effort was expended in the conduct to create a regulatory framework in order to improve society [13, p. 470]. In 1917 the regulation on workers' control was enacted, introducing working control over the production and distribution of products. The nationalization of individual industrial complexes is ensured by the decree of the Council of People's Commissars of June 28, 1918 "About the Nationalization of the Largest Enterprises ..." In 1919, twenty two of the largest plants and the main chemical industry were nationalized.

The All-Russian Congress of Pharmaceutical Subdivisions in 1919 was decided to make medical assistance quick, affordable and rational. Over the past years, nine new large plants have been established to the forty seven liquidated pharmaceutical enterprises base. The increasing concentration of the pharmaceutical industry was produced at the beginning by the New Economic Policy in the creation of trusts.

With the formation of the USSR, new pharmaceutical enterprises and plants were opened, research institutions were organized, control and analytical laboratories were operating, and a pharmacopoeia commission was being created. The volume of production was able to expand in 1924 through profiling of products by a related technological process and the exclusion of non-medical products from their range.

The Supreme Council of the National Economy of the USSR developed a plan for the development of the pharmaceutical industry for 1925/26 - 1929/30. They took into account the needs of the health authorities and the population in medicines. The five-year plans of binding on business entities made it possible to build management on the basis of state plans for economic and social development.

A policy was pursued to bring production, methods of control and price unification into uniformity. In the two five-year plans, especially in the second, the medical industry showed exceptional growth. About 400 items of new products were mastered and produced. The production of over 150 drugs was delivered. A number of substitutes for imported medicines were released, for example, acrychin, novocaine, anestezin and others. The development of pharmaceutical science and industry, the achievements of medical practice allowed the production and use of complex synthetic drugs for the treatment and prevention of diseases in both humans and animals. Each new pharmaceutical product authorized for production and release was entered into a special register of new pharmaceutical products authorized for production and release in the USSR, according to the Decree of the Council of People's Commissars of the USSR of 16.11.1937 N 2038 “About the Production and Output of New Pharmaceutical Products”. The system of the production of medicines from medicinal plants was expanded.

The creation of a solid research base became an important factor in the organization of production, in particular in the introduction of new medicines and the development of new technologies. To strengthen the connection between science and practice, the All-Union Scientific and Pharmaceutical Society was created in 1949, and in 1958 the All-Russian Scientific Society of Pharmacists. The structure of industry and construction management is based on the territorial principle [14].

The pharmaceutical industry was part of the material base on which health authorities relied to maintain public health and increase the average life expectancy of citizens. All actions were aimed at implementing the Decree of the Central Committee of the CPSU and the Council of Ministers of the USSR dated 01/14/1960 No. 58 "About Measures of Further Improvement of Medical Services and Health Protect of the Population of the USSR" [22]. The restoration and growth of pharmaceutical sector in the country was due to the creation of research and production complexes and research and production associations of the pharmaceutical industry.

The control procedure for production was established by the order of the USSR Ministry of Health of 10/15/1976 No.

987. In accordance with which the high quality of medicines was ensured by: strict compliance with the requirements of regulatory and technical documentation; production control; compliance with a number of preventive measures.

The requirements for the storage and transportation of medicines and packaging materials were enacted at enterprises and organizations of the pharmaceutical industry. Premises intended for storage should have been equipped with everything necessary in order to ensure the preservation of the initial medicines and packaging materials. Regulatory and technical documentation established the requirements for containers and packaging for various medicines. The instruction of incoming quality control in production was approved in 1986. They established a uniform procedure for monitoring production, as well as the quality of raw materials. The intention was to prevent the production of products that do not meet the requirements of the current regulatory and technical documentation, and prevent the use of low-quality raw materials in the production. Factories and enterprises were supposed to use raw materials in production, which passed quality control. They were established by scientific and technical documentation, the State Pharmacopoeia of the USSR, State All-Union standard and pharmacopoeia items.

The beginning of economic reforms in Russia was accompanied by the emergence of private property, a change in the system of procurement of medicines. Decree of the Council of Ministers of the USSR of February 18, 1988 No. 236 "About Measures to Increase the Medicines, their Full Provision for the Population, Medical Institutions and the National Economy in 1988-1995" became impossible to implement.

The legal framework allowed the development and improvement of the pharmaceutical sector in the RSFSR and the USSR. The level of production increased due to the intensification and reconstruction of existing enterprises, the mechanization of labor-intensive processes and the improvement of production technologies. Over the years of nine five-year plans, the growth of pharmaceutical sector in the country was due to the creation of a powerful constitutional-legal and material-technical base, the organization of research and production complexes and research and production associations of the pharmaceutical industry. The development of Soviet medical science improved the quality and timeliness of the provision of medical care to citizens and the effectiveness of sanitary and preventive measures.

The Federal Law "About Medicines" came into force in 1998. It reinforced the provisions on the organization of production and state control of the quality, effectiveness and safety of medicines. The legal term “Production of Medicines” was approved, which was understood as the serial production of medicines in accordance with the rules for the organization of production and quality control of medicines, approved by the federal body for quality control of medicines. For production, enterprises must have a license.

It was forbidden to manufacture medicines that did not pass state registration or in violation of the rules for organizing the production and quality control of medicines. The production of patented medicines and their sale are carried out in accordance with the patent legislation of the Russian Federation.

Now the Federal Law “About Circulation of Medicines” is in force, according to which the production of medicines must comply with the requirements of the rules of good manufacturing practice. This wording appeared in edition No. 17 of 07/13/2015, despite the fact that the Order of “Good Manufacturing Practice” was approved by order of the Ministry of Industry and Trade of Russia dated June 14, 2013 No. 916. Prior to this, the rules for the organization of production and quality control of medicines were in force. The Agreement on common principles and rules for the circulation of medicines within the framework of the Eurasian Economic Union, including decision of the Council of the Eurasian Economic Commission dated 03.11.2016 No. 77 on the rules of good manufacturing practice, was also applied. The policy of import substitution is being re-established. There is an emerging single economic space [18].

Establishing priority areas of a sustainable development of became a new mark in pharmaceutical sector development. The priority areas for the development of the pharmaceutical industry of the Russian Federation were approved in 2020 by the order of the Government of 06.06.2020 N 1512-r. This includes: introduction of scientific and technological competencies; formation of a high-performance export-oriented sector; introduction of digital technologies; production of high-quality, effective and safe pharmaceutical products; prevention of circulation of falsified, counterfeit and non-conforming products; development of the national pharmaceutical industry; provision of the population with vital and essential medicines. The priority product groups for the pharmaceutical industry by 2035 includes vital and essential medicines; immunobiological drugs. The functioning and development of the pharmaceutical sector is influenced by medicines patent laws; test standards; marketing rules for finished products.

The import substitution policy is carried out in relate to vital and essential medicines. Such medicines are included in the list. The list is annually approved by the Government of the Russian Federation for the purpose of state regulation of prices for medicines. Medicines are under international non-proprietary names. They cover most types of health care under the state guarantee. Import substitution rules have deficiency of law and come into conflict with the federal law on the contract system. High-quality foreign medicines began to leave from the Russian market. The medicines procurement system itself requires modernization too.

During a pandemic priorities have shifted. Much attention has been devoted prevention, diagnosis and treatment of new coronavirus infection (COVID-19). A duty-free import regime was introduced on goods to prevent coronavirus infection, for example, personal protective equipment, vaccines, syringes, disinfectants and other goods. The medicines are being patented.

The problems of organizing pharmaceutical sector and providing the population with affordable and high-quality medicines remain unresolved. There was a need not only for

adequate legislative regulation, but also for encourage production [19].

In this regard, it is worth creating an international medical cluster, on the basis of which not only the exchange of experience, but also technologies will take place, looks promising.

IV. DISCUSSIONS

Studying the aspects of the regulation of the pharmaceutical sector allows us to single out several key problems requiring further solutions. The development of the pharmaceutical sector requires not only a stable economic base, but also an exchange system. Firstly, scientific institutes must be explicitly included in the structure of pharmaceutical plants. The creation of research and production complexes for the production of medicines, the so-called "science-production-practice" system will result in the development and introduction of new medicines into circulation. This complex will allow quickly taking out a patent and implementing medicines in practice. Secondly, it is worth considering the foreign experience in the production of medicines, specifically, the establishment of tax benefits for research costs; reimbursement of a portion of the costs of drug development; marketing exclusivity; having priority consideration for authorizing the sale of a number of essential medicines, especially expensive ones. Perhaps a number of such economic incentives, enshrined in law, will improve the pharmaceutical sector. This will lead to an improvement in the life and health of the country's population.

V. CONCLUSION

The mechanism of drug circulation assumed their quality, effectiveness and safety. Pharmaceutical activity is designed to protect the fundamental human values - the life and health of the population. The creation of research and production complexes and the introduction of such changes into legislation, in our opinion, is one of the most effective means of improving the priority development of the pharmaceutical sector.

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