

# State Legal Regulation of Production and Use of Immunobiological Drugs in Russia

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**Abstract**— The article analyzes legal aspects of regulation of vaccination, production and circulation of medical immunobiological drugs. The state provision of vaccination is necessary for preserving the life and health of the nation in every country. The politics of general vaccination was formed in the Soviet state on the basis of the analysis of spread of epidemics. There has been a change in the socio-economic situation and epidemiological conditions in the country. It resulted in the introduction the principle of voluntary vaccination. A comprehensive study of strategies and policies of vaccination in Russia has shown the need to change the existing mechanisms of the state legal regulation. The introduction of changes is complicated because of the right of citizens for voluntary vaccination. It is necessary to create a reliable system for the eradication of infectious diseases among the population. For this purpose we should develop the harm reduction plan to minimize the damage caused by vaccination to the individual.

**Keywords**— *Legal Regulation, Circulation of Pharmaceutical Products, Biological Drugs, Medical Immunobiological Preparations, Vaccination, Immunization, Production.*

## 1. INTRODUCTION

There are three general strategies [1] for fighting against epidemics: general preventive treatment, local treatment and palliative treatment with no prevention. The choice of the strategy depends on the cost of palliative treatment, prophylaxis, and epidemiological factors.

The social, ecological and economic conditions influence on the development of infectious diseases in humans, on the geographical limits of diffusion of infections, on the adaptation of microbes, and on the development of their steadiness to antimicrobial agents.

These conditions are influenced by the system of arrangements which is available in the state. They are currently undertaken for the prevention, control and reduction of infectious diseases through the implementation of preventive vaccinations. For that we use such immunobiological medicinal preparations as vaccines, anatoxins, serums and other medicines. These medicines are intended for the creation of specific immunity to infectious diseases. Smallpox has completely disappeared from the world

after the global use of the smallpox vaccine, and malaria endemic in many industrialized countries is disappearing because of the use of insecticides and antimalarial drugs [2].

Infectious diseases which can be prevented with the help of immunoprophylaxis are called vaccine preventable diseases. Immunoprophylaxis is an antiepidemic measure taken in order to prevent the spreading of infectious diseases via immunization of the susceptible groups of population.

## 2. THE PRODUCTION OF VACCINES AND LEGAL REGULATION OF VACCINATION IN RUSSIA

Specific recommendations regarding the use of available cost-effective vaccines and the introduction of new vaccines are crucial for maintaining good health, well-being and long life span of Russian peoples. The vaccination of certain groups of population leads to a continuous threat of outbreaks of infectious diseases and death [3].

A vaccine is a biological drug received from bacteria, viruses and other microorganisms or products of their vital activity. It is used for active immunization of people and animals with the purpose of specific prophylaxis and treatment of infectious diseases [4]. For the first time vaccination for the immunization was developed by British physician Edward Jenner at the end of the 18th century.

In the USSR in 1936 there were allocated the following types of vaccines [5]: vaccines containing live quite virulent pathogen; containing live viruses that have been attenuated; sensibilized vaccines; and others.

During the first years of the Soviet Russian State there had been numerous epidemics of infectious diseases, for example, smallpox, plague, cholera, and others. The Soviet Republic took all possible measures to combat them, including the measures for improving the sanitary-epidemiological conditions of the population.

Despite the economic and political difficulties, the manufacture of bacterial preparations was the first step towards better health protection of people. They're now called medical immunobiological preparations. In 1917 in Russia sanitary and bacteriological institutes and specialized laboratories were engaged in their manufacture [6].

The policy of the Soviet state was directed at general prophylaxis. However the limited resources didn't allow the state to embody it in full. Preventive vaccinations in open vaccinating centers for the population were carried out. These centers prioritized assistance to patients, military and the staff who carried out anti-epidemic measures [7].

General preventive treatment became possible with the increase of institutions that produce medical immunobiological preparations. The exception was made for some diseases the treatment and prevention of which required expensive imported drugs. In this case doctors carried out local treatment and palliative treatment with no prevention.

The supply of medical and sanitary institutions by health departments with immunobiological preparations was not properly regulated, except for smallpox detritus [8].

Mainly there was the lack of the most necessary drugs, such as antidiphtheritic, antimeningococcal, antistreptococcal and antiscarlatinal serums. In particular, the biggest deficit was recorded in countryside. Country doctors were forced to reduce the dose or not to help the patient at all.

It was an extremely paradoxical situation. In the institutes the preparations were in abundance, and the health authorities were short of them. Also, many well-known drugs were simply not used. This can be attributed to the limited amount of loans allocated by the National commissariat of health to the medical institutes for the production of vaccines. Therefore, medical institutions had limited opportunities to supply health departments. For this reason, the National commissariat of health established the limits on free provision of medicines for smallpox detritus, cholera-typhoid divalent vaccine and monovalent vaccine at the rate of full demand, and antidiphtheritic serum at a rate of 50% of the need. The rest of the vaccines were given only in emergency situations, for example, large epidemic outbreaks.

A constant stock of widely used serums and vaccines was created in order to provide promptly medical assistance and prevent epidemics. The replenishment of the stock was carried out by individual bacteriological institutes producing sera and vaccines.

By 1937, some of the medicines were available in sufficient quantities, and they were distributed without a prescription [9], for example, serum diphtheria, tetanus, staphylococcal, meningococcal, equine normal, dysentery, streptococcal, scarlet and tuberculin Koch.

The Great Patriotic War caused significant damage to the health of children. Health authorities did everything at the national level to deal with the problems caused by the poor children's health and dangerous epidemiological situation. In particular, they paid attention to the organization and improvement of the quality of medical care for children. On the territory of Russia there was introduced obligatory vaccination. In 1940, the vaccination of children against diphtheria was carried out in all cities with the population of more than 50 thousand people; in all nurseries, kindergartens, and in the first form of primary schools. Parents and their substitutes who evaded vaccinations could be prosecuted. On

October 3, 1962, this sanction was abolished by the resolution of the Council of ministers of the RSFSR.

Since the 60s, health authorities and institutions have carried out the number of activities to strengthen and improve the infectious disease service in the country. Since 1960, the mortality from typhus has not been registered, since 1966 it has not been registered the mortality from typhoid fever and scarlet fever. However, the rate of some infectious diseases remained relatively high: infectious hepatitis, scarlet fever, dysentery and others. In the years 1969-1970, there was a rise in meningococcal infection. In 1965 and in the 1970s there were some outbreaks of cholera in a number of cities.

By 1980, the decree on the timing of preventive vaccinations for children and adolescents was replaced by the calendar of preventive vaccinations and basic provisions of their organization and conduct. This happened because some new preparations against infectious diseases were introduced into practice and doctors obtained some new data on the duration of post-vaccination immunity. The calendar was created on the basis of the socio-economic significance of infections, domestic and international experience in the prevention of infectious diseases, the availability of effective, safe, affordable vaccines in the country.

Currently, the legal regulation of vaccination is provided by federal laws on September 17, 1998 "On immunization of people against infectious diseases," on April 12, 2010 "On the circulation of drugs" and on November 21, 2011 "On the Bases for the Protection of the Health of Citizens of the Russian Federation."

Vaccination in the national calendar is made with domestic and foreign vaccines. These medicinal preparations must be registered and approved for use on the territory of the Russian Federation in accordance with the established procedure. In Russia, they are produced by the NGO "Microgen", JSC "Biomed", JSC "Vector-BiAlgam", NGO "Virion", etc. Foreign production is represented by Serum Institute of India Pvt. Ltd., GlaxoSmithKline Biologicals S.A., Chiron Behring GmbH & Co. KG and others.

### 3. RESULTS

Immunization is one of the most effective ways to prevent negative consequences caused by serious diseases. A lot of standard decrees adopted in the 70's - 80's of the last century, were applied in the Russian Federation. Epidemics left their mark in the history and, thanks to the experience of fighting against them; we now successfully identify them and find ways to prevent infectious diseases.

In Russia, a unique preventive system has been established. It includes the state records and reporting of vaccinations and cases of post-vaccination complications, the functioning of specialized vaccination rooms, and the monitoring of collective immunity [10].

The system is based on the existed in the USSR concept of immunization. Plans and the system of obligatory vaccination are the legacy of the Russian Federation. However, there are some differences from the previous system.

One of them is Article 5 of the federal law of 17.09.1998 No. 157 "On the immunization of infectious diseases". It legitimizes the voluntary vaccination. The refusal of vaccination may lead to the following consequences for citizens: the ban on going to countries where specific preventive vaccinations are required; a temporarily refusal to work in health and educational organizations in case of massive infectious diseases or risk of epidemics; refusal of employment or suspension from work which is associated with a high risk of infectious diseases.

The agitation measures held in Soviet Russia were no longer relevant. We can see now the unfolding of the "anti-vaccination" campaign. Public confidence in vaccination is decreasing [11]. We have the opposition to vaccination from the number of parents whose children had health problems after immunization. This mostly reflects parental choice and fears about vaccine safety and efficiency [12]. Refusal from vaccination is associated with the lack of a preliminary study of the immune status of a child and without such study it is impossible to determine in detail the possibility of complications and the level of individual specific immunity. In addition, the components of vaccines may raise questions, including the degree of virulence of vaccine strains. Thus, the population has the right to interfere into the political decisions of the state. But there exists a social dilemma between individual benefits and public health [13], which includes collective interests and social responsibility [14]. So, public participation is a strategic health policy leading to the decentralization of health system management [15].

There is a tendency to minimize the cost of developing new immunobiological preparations with regular epidemic control of infectious diseases. The current national calendar in Russia includes vaccinations against 12 infectious diseases. While in developed countries immunization programs include protection against 11–16 types of infections [16]. If the stock of preparation is not sufficient for general vaccination, then the welfare of the population will decrease [17].

Some countries have established national technical advisory bodies for the legal regulation of preventive vaccination of the population [18].

#### 4. CONCLUSIONS

Vaccination is one of the measures undertaken to improve the health of the nation. There are several concepts in vaccination: from the obligatory general vaccination to a complete refusal of it. The value of obligatory vaccination and the purpose of organizing this system were in reducing the incidence and mortality among the population in the period of epidemics.

However, carrying out only artificial immunization is not enough for complete protection against any infectious disease. Vaccination does not give a hundred percent guarantee of the body's biological resistance to certain infectious diseases. The effectiveness of some medical immunobiological preparations may decrease due to genetic variability of the pathogen, individual characteristics and the state of the human immune

system, age, nutrition, and lifestyle. The mood of a person can also act as "immune modulator" [19].

Social-environmental factors including cultural traditions and beliefs as well as the norms of social groups may also play a role when choosing the concept of vaccination [20].

A compromise between the benefits of obligatory immunization and violations of individual rights and freedoms should be sought in the field of vaccine quality, and attention to people's individual peculiarities. In order to improve immunization, the introduction of an obligatory certificate of vaccination and an immunological passport of the child would seem a good idea. This will help strengthen the registration and control, avoid complications after vaccination, and also show the child's susceptibility to vaccine.

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