



Legal aspects of socially significant diseases prevention among children and young people

E. O. Tchinaryan, M. S. Lavrentieva, I. Y. Nikodimov

Russian State Social University (RSSU), Wilhelm Pieck Street, 4/1, Moscow, 129226, Russia

Abstract

The article discusses issues related to the identification and prevention of social diseases from a legal point of view, to the legal framework study. At the same time, we are talking about socially significant diseases among children and young people. The article reveals the problems of implementation of the child's basic rights to a healthy lifestyle, general early warning of diseases, the introduction of health technologies to all spheres of life, and the provision of omnipresent qualified medical care. It provides for the rehabilitation and prevention of diseases, medical diagnosis, treatment of diseases, including follow-up care, medical rehabilitation of children with disabilities and children suffering from chronic diseases, and sanatorium-resort treatment of children. An explanation is given to socially significant diseases, rare diseases, and the problem is raised in the field of rare diseases diagnosing.

Keywords: healthy lifestyle, disease, disease prevention, medical assistance.

INTRODUCTION

One of the key principles of the National Children's Strategy for 2012-2017 approved by a presidential decree is to protect the health of each child. In the Russian Federation, measures were taken to promote the family formation and the children's need for a healthy lifestyle, general early warning of diseases, the introduction of health technologies in all spheres of life and the provision of omnipresent qualified medical care. In this regard Art. 10 of the Law on Basic Guarantees of the Rights of the Child in the Russian Federation should be mentioned, according to which, in order to ensure children's rights to health care, in compliance with the procedure established by the legislation of the Russian Federation, medical organizations of the state health care system and the municipal health care system take steps to provide children with free medical care ensuring rehabilitation and prevention of diseases, medical diagnosis, treatment of diseases, including follow-up, medical rehabilitation for children with disabilities and children suffering from chronic diseases, and sanatorium-resort treatment of children [1, 2].

It should be noted that the development and implementation of measures to prevent the occurrence and spread of diseases, including socially significant diseases, comprises the activities of several federal and municipal bodies (institutions). We should not forget about the importance of institutions of preschool, secondary, vocational and higher education [3]. For example, in accordance with the Moscow City Law "On the Prevention of the Spread of the Disease Caused by the Human Immunodeficiency Virus (HIV) in Moscow", the authorized Moscow executive body in the field of education and Moscow public educational institutions implementing educational programs ensure the implementation of techniques aimed at the formation of a socially safe behavior model among students [4]. The Moscow regional component of the state educational standard contains modules of information blocks of interdisciplinary special lessons on HIV prevention. The rules for conducting interdisciplinary special lessons on HIV prevention are developed by the authorized executive authority of Moscow in the healthcare sector, the authorized executive authority of Moscow in the field of education, and the city's specialized agency for the prevention of HIV infection. Scientific and educational institutions may be involved in creating the methodology. The content of educational programs should be correlated with the students' age and aimed at strengthening the family institution, reviving and preserving the spiritual and moral traditions of family relations, promoting a healthy lifestyle including eliminating risky sexual behavior, and developing tolerance towards HIV-infected [5].

MATERIALS AND METHODS

The principle of preventive health measures priority includes the transition from the health care system, which is primarily aimed at treating various diseases, to a new health care system aimed at setting priorities for a healthy lifestyle, improving the functioning of the body, and preventing diseases. This principle is already part of the existing foundations of the Russian legislation in the field of health care and has long been known in medicine, but it is difficult to overestimate its importance in our country, where the number of smokers and alcoholics per capita is much higher than anywhere else is. This principle is discussed in more detail in Art. 12 of the Law "On Fundamentals of Health Protection in the Russian Federation" dated 21.11.2011 No. 323, which is dedicated to the basics of health protection, in accordance with which the priority of diseases prevention in the health care sector is guaranteed in the following ways:

- 1) the development and implementation of a healthy lifestyle, including a program aimed at reducing the consumption of alcohol and tobacco, the prevention and control of the non-medical use of narcotic drugs and psychotropic substances;
- 2) the implementation of sanitary and preventive measures;
- 3) the implementation of measures for the prevention and early detection of diseases, including the prevention of socially significant diseases and their control;
- 4) preventive and other medical examinations, clinical examination, clinical supervision in accordance with the legislation of the Russian Federation;
- 5) the implementation of measures aimed at preserving the life and health of citizens in the process of research and work in accordance with the legislation of the Russian Federation.

RESULTS

We have revealed that "Socially significant diseases" usually refer to those diseases, the growth and spread of which strongly correlate with social and economic conditions. The danger of such diseases is that they cause significant damage to society and the state.

We have determined that a significant part of the medical equipment currently used is outdated and cannot be used for high-quality diagnostics and treatment of patients. The frequency of life-threatening complications from diabetes, including vascular complications such as diabetic retinopathy, diabetic nephropathy and other cardiovascular complications, is high. The number of registered HIV-positive people continues to grow. The rates of disability and mortality from undetected malignant tumors are still high. The incidence of sexually transmitted diseases among adolescents also continues to grow.

The number of neurosyphilis cases is increasing. The number of chronic forms of viral hepatitis B and C, as well as acute forms of viral hepatitis C, is increasing annually. New cases of diphtheria, measles, and whooping cough, as well as mumps outbreaks, are constantly recorded. There is a marked increase in the number of mental and behavioral disorders among the population. Every year, 60,000 people, including children, commit suicide (Concept of the Federal Targeted Program "Preventing and Combating Social Diseases in 2007 - 2011"). These diseases are specific in the fact that some of them are infectious (for example, hepatitis, HIV), while others pose a serious threat although they are not contagious.

We have established that today the preventive measures are implemented in several stages: development of programs and action plans for the prevention of infectious diseases; financing of approved programs and plans; implementation of measures to prevent the introduction and spreading, and early detection of infectious diseases; analysis of the measures' implementation and evaluation of their effectiveness for consideration in further prevention. At the state level, the focus is on the prevention of infectious diseases.

DISCUSSION

Article 43 of the Federal Law "On Fundamentals of Health Protection in the Russian Federation" provides that citizens suffering from socially significant diseases have the right to medical care and follow-up actions in the corresponding medical institutions. However, the law does not contain a definition of "socially significant diseases". As for the list of socially significant diseases, it is approved by the Government of the Russian Federation based on a high level of primary disability and mortality, as well as the life expectancy of patients. In accordance with the decree of the Government of the Russian Federation "On approving the list of socially significant diseases and the list of diseases that pose a danger to others", socially significant diseases are tuberculosis, venereal diseases, hepatitis B, hepatitis C, HIV, cancer, diabetes, mental and behavioral disorders, and diseases characterized by high blood pressure. For the patients suffering from socially significant diseases, their need for medical care increases in proportion to the deterioration of their condition and the occurrence of complications. Their treatment requires additional resources and the strengthening of the financial and technical base of health facilities.

In accordance with Article 30 of the Federal Law "On Fundamentals of Health Protection in the Russian Federation", the prevention of infectious diseases falls into competence of public authorities (the Ministry of Health of Russia, the Federal Service for Supervision of Consumer Rights Protection and Human Welfare, and other state executive bodies that protect the welfare of the Russian Federation subjects), local governments (represented by regional administrations and city districts administrations), employers, public health organizations (state, municipal and private) and public organizations created specifically to protect the rights of citizens in the health care sector. A draft federal law "On National Youth Policy in the Russian Federation", which provides for the creation of institutions for youth affairs, is currently under discussion. According to the authors, these institutions should take responsibility for prevention of socially negative events and socially significant diseases among the young population [6]. Immunoprophylaxis of infectious diseases is a system of measures aimed at preventing, curbing and eliminating the spread of infectious diseases through preventive vaccination (Article 1 of the Federal Law "On Immunoprophylaxis of Infectious Diseases"). Prophylactic vaccination is aimed at combating infectious diseases and is based on the use of vaccines and toxoids to protect the population susceptible to infections. Vaccinations

are delivered by public, municipal and private health organizations or by private medical practices with a license for medical activities (Article 11 of the Federal Law "On Immunoprophylaxis of Infectious Diseases"). Vaccinations delivered in public maternity hospitals and offices, in medical institutions of urban areas, in medical institutions of rural areas of health care, in medical centers, in counseling centers for specific preventive and other organizations regardless of their organizational-legal form, and in exceptional cases, at home, are carried out using registered domestic and foreign medical immunobiological preparations. The annual preventive vaccination plan is compiled in accordance with the national immunization schedule, vaccination schedule for the epidemic indications based on a comprehensive account of children and adults who have previously conducted preventive vaccination, the availability of information on long-term medical release from infectious diseases, and the projected number of births. The national preventive vaccination calendar and the preventive vaccination calendar for the epidemic indications were approved by Order No. 125 of the Ministry of Health of Russia dated March 21, 2014 "On approval of the National Immunization Plan and the vaccination schedule for the epidemic indications". It is very important to remember that, in accordance with the federal law "On the Immunoprophylaxis of Infectious Diseases," citizens have the right to refuse vaccinations. Prevention of noncommunicable diseases is carried out at the level of the population, group and individual levels of state bodies, local governments, employers, health care organizations, educational institutions and sports organizations, public associations by developing and implementing a system of legal, economic and social measures aimed at preventing the occurrence, spread, and early detection of diseases, as well as reducing the risk of developing, preventing or eliminating the negative effects of internal and external environment factors on health, promoting healthy lifestyle [7]. To combat certain types of socially significant diseases, various laws have been adopted in the Russian Federation, both at the federal and regional levels. The following acts may be mentioned as an example: Federal Law No. 77-FZ "On the Prevention of the Spread of Tuberculosis in the Russian Federation" dated June 18, 2001; Federal Law No. 52-FZ "On the Sanitary-Epidemiological Well-Being of the Population" dated March 30, 1999; Federal law No. 38-FZ "On the Prevention of the Spread of the Disease Caused by the Human Immunodeficiency Virus (HIV)" dated March 30, 1995; Law of the Russian Federation No. 3185-1 "On Psychiatric Care and Guarantees of Citizens Rights in its Provision" dated July 02, 1992. The federal law "On the Fundamentals of Health Protection of the Citizens in the Russian Federation", along with common diseases, also covers so-called "orphans" (rare) diseases. Orphan diseases are diseases that affect a small proportion of the population. They occur with some frequency, they are either life-threatening or chronically progressing, and if left untreated, they can lead to death or disability of the patient. In accordance with Article 44 of the aforementioned federal law, rare (orphan) diseases are diseases that have a prevalence of no more than 10 cases per 100,000 people. It should be noted that there is no unified global approach to classifying a disease as rare. For example, in the US Rare Diseases Act (Rare Disease Act) of 2002, a rare disease is defined as "a disease or condition that affects less than 200,000 people in the United States." In Japan, rare diseases are defined as diseases affecting less than 50,000 patients. The European Commission on Public Health defines rare diseases as life-threatening or chronic serious diseases that have low prevalence rates among the population and that require special studying. Low prevalence rates in the population usually correspond to less than 1 case per year. A similar definition has been adopted in the medical literature, with prevalence rates

ranging from 1 to 1000 people. The list of rare (orphan) diseases in Russia is created by an authorized federal executive body based on statistical data and is posted on the official website on the Internet [8]. Today, this list is published on the official website of the Ministry of Health and includes 216 different categories of diseases. However, the Russian Federation Government's Decree No. 403 dated April 26, 2012 sets out the procedure for handling finances from the budget of the constituent entities of the Russian Federation for 24 rare diseases. According to the report of the Ombudsman for 2014, which was published in May 2015, there are about 13,000 patients with orphan diseases in Russia; almost half of them are children. As of March 2015, the Federal Register of persons suffering from life-threatening and chronic progressive rare (orphan) diseases has data on 7038 children [9]. As in many areas of health care, in the case of orphan diseases, in particular, there is a number of difficulties that need to be solved [10]. Among these difficulties, the first diagnosis of these diseases should be noted. This is because there are no special schools in our country for the training of medical specialists in this field. Secondly, there are no educational materials for the study of rare diseases. There are cases when medical institutions in the Russian regions refuse to treat patients with orphan diseases due to the lack of standards in health care, referring to part 1 of Article 37 of the Law on Health Care. In accordance with this article, medical care is organized and carried out in accordance with orders for medical care, mandatory for all medical organizations in the Russian Federation, and based on standards. However, the Ministry of Health of Russia clarified this issue, stating that the lack of standards for caring for certain diseases (conditions) is not grounds for refusing medical care (Letter of the Russian Ministry of Health No. 12-6 / 432 dated February 2, 2014 to Vyksa Town Court of the Nizhny Novgorod Region on civil case No. 2-349.2014). These facts may entail mass appeals of citizens to European courts [11]. Finally, the most important problem in the field of rare diseases diagnosing is the lack of a network of medical and diagnostic centers for orphan children. Unfortunately, today such centers exist only in Moscow. As for serious problems, such as the supply of medicines and funding for the treatment of orphan diseases, the situation is even more aggravating [12]. At the end of July 2015, a new version of the Federal Law "On the Distribution of Medicinal Products" entered into force. This Law introduces for the first time the concept of "orphan drugs", which are defined as medicinal products intended solely for the diagnosis or treatment of rare diseases. Thus, federal executive bodies have the authorities to organize an expert assessment of medicines, perform ethical analysis of the possibility of a clinical trial of a drug for medical use, and examine the submitted documents to determine whether medical use of a drug may be considered after state registration. In June 2015, the Ministry of Health presented a draft departmental order "On approval of the amount of information necessary to form a section of clinical documents for state registration of orphan drugs" for public discussion. During state registration of the orphan drug, in the process of formation of the registration dossier clinical documentation section, reports on the results of clinical studies of the drug efficiency and safety are provided. If it is impossible to submit the reports on the results of orphan drug clinical trials for medical use conducted in the Russian Federation, or the reports on the results of orphan drug international multicenter clinical trials, some of which were conducted in the territory of the Russian Federation, the reports on orphan drug clinical trials made outside the Russian Federation in accordance with the rules of good clinical practice should be submitted, including the reports of bioavailability studies, clinical safety and efficiency [13].

In planning and conducting clinical trials of an orphan drug, in order to implement a clinical research program, a shortened program consisting of one clinical trial of efficacy and

safety after the initial drug safety research should be conducted. Today, the accelerated selection of orphan drugs is already allowed [14]. However, despite all these measures, for the vast majority of patients with orphan diseases, the purchase of medicines is a luxury. Therefore, the only way for them to get these products is through governmental assistance [15]. Article 16 of the Law "On the Fundamentals of Health Protection of the Citizens in the Russian Federation" describes the powers of the state authorities of the Russian Federation constituent entities in the field of health care and defines organizations that provide citizens with drugs and specialized clinical nutrition products for the treatment of diseases included in the list of life-threatening and chronic progressive rare (orphan) diseases that can shorten the life expectancy of a citizen or result in disability. In accordance with the report of the human rights ombudsman in 2014, about 26 billion rubles were needed to finance the treatment of rare diseases. Hence, according to various estimates, the total costs for the Russian Federation amount to 9 billion rubles. This is a huge burden for the budgets of many regions. The cost of drugs for patients with a rare disease exceeds the cost of financing for the entire number of patients with more common diseases, such as cancer. For this reason, many patients with orphan diseases are not treated. The situation is especially difficult in the North-West, Volga, and Far Eastern Federal Districts, in Vladimir, Moscow, Yaroslavl, and Ivanovo Areas. Every year in Russia, hundreds of children with rare diseases die because of the late receipt of medical care.

These data again confirm that urgent reform of the current legislation in the field of orphan diseases is required. This is especially true for the so-called "Seven Nosologies Program." In 2008, the Order No. 2053-P approved "a list of drugs procured centrally for the treatment of patients with malignant neoplasms of lymphoid, hematopoietic and related tissue, hemophilia, cystic fibrosis, pituitary dwarfism, Gaucher disease, multiple sclerosis, and treatment after organ and/or tissues transplantation, which should be covered by the federal budget." For all other diseases, in 2014, the State Duma of the Russian Federation decided that the drug supply function of the "Seven Nosologies Program" would be transferred from the federal level to the regional level only in 2018 (instead of January 1, 2015, as originally envisaged in Article 101 of the Federal Law "On the Fundamentals of Health Protection of the Citizens in the Russian Federation"). This decision was justified by the fact that the decentralization of public procurement would lead to inefficient use of budgetary funds. According to experts, the number of trades would increase at least 83 times. Accordingly, this will significantly increase the amount of overhead expenses in the form of labor and time costs. Experts also believe that the transfer of "Seven Nosologies Program" to regional funding means that pharmaceutical manufacturers could not participate in such a number of transactions. Instead, it will be done by numerous intermediaries, which, in turn, will lead to a significant increase in prices for already expensive medicines. Thus, changing the conditions for the program transferring from federal to regional funding, lawmakers hoped that during this time they would be able to resolve all issues and verify solutions during pilot projects in selected regions of Russia. Today in Russia, both the registered number of diagnosed diseases and the cost of treatment are significantly higher than indicated in the Seven Nosologies Program. That is why in recent years more and more officials are taking the initiative to finance the treatment of patients with rare diseases from the federal budget.

CONCLUSIONS

In 2013, the State Duma of the Russian Federation was invited to consider and amend the law on health care. In particular: 1. Article 14, which lists the powers of the federal

government in the field of health care, was suggested to introduce a new permit for the organization to ensure that citizens have access to medicinal and medical products for the treatment of orphan diseases. 2. Article 16, which lists the powers of the state authorities of the constituent entities of the Russian Federation in the field of health care, was suggested to exclude similar powers. 3. Article 83, which discloses the source of financial support for citizens receiving medical and rehabilitation assistance, was suggested to add an article that instructs the budget of the Russian Federation to finance the needs of citizens in registered medicinal products for the treatment of diseases included in the list of life-threatening and rare chronic progressive (orphan) diseases.

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