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**LEGAL REGULATION OF CERTAIN SPECIAL-PURPOSE
WASTE**

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Abstract

The article deals with issues related to the clarification of the relevant special-purpose waste place in legal regulation system, including waste production and consumption, as well as sanitary and epidemiological well-being and public health. The authors examine the status and prospects of medical waste legislative regulation, especially during the coronavirus taking into account legal security and potential risk reduction of such waste at the individual State level and the world community as a whole. The article analyzes the main legal aspects of public health policy in relation to medical waste. In particular, the main criteria for separate legal regulation of special-purpose waste have been established from the standpoint of different health risk levels, sanitary and epidemiological condition. The degree of medical waste legal strategy is determined as not a clear one; focusing simultaneously on numerous waste classifications taken from the activities of medical and healthcare facilities. It should be noted that medical waste legal strategy is characterized by a number of gaps and shortcomings including the preservation of real and potential danger to the health of citizens which are in contact with such waste. The research has formulated practical proposals to improve the Russian Federation current legislation in medical waste legal status regulation.

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1. Introduction

At present, all world community resources are directed to the protection and restoration of public health and saving lives. This problem has become particularly urgent with the spread of coronavirus worldwide (Rahayu et al., 2021). The global community is concerned not only about finding effective measures to combat COVID-19, but also about establishing ways to safely dispose of increasing daily volumes of medical waste at various hazard levels and potential contamination (Suriati et al., 2017)

Most of the waste generated by functioning of medical and healthcare facilities is an ordinary garbage, but approximately 20 % are considered hazardous materials that can be infectious, toxic or radioactive (Marchenko, 2015). There is a problem of improving the legal regulatory strategy, namely, with regard to such by-products as "medical waste" (Ortwin & Vincent, 2011).

2. Problem Statement

The legal classification of medical waste is characterized by a number of theoretical and practical shortcomings, including: the use of different methods in classifications and definitions, the introduction of new classifications, terminological inconsistencies. (National and international waste classifications used in countries of Eastern Europe, Caucasus and Central Asia. United Nations. Economic and Social Council. Geneva. 2012 (ECE/CEP-CES/GE.1/2012/7)

This area uses national and international waste classifications, arrangement by economic activity, category or waste type; and hazardous toxic waste categorization. The multiplicity and heterogeneity of medical waste classification systems significantly reduces the effectiveness of its legal regulation.

3. Research Questions

The following tasks should be solved in the course of research:

1. To analyze the current legislation in the field of medical waste regulation.
2. To identify advantages and disadvantages of medical waste classification, affecting the disparate areas of legal regulation in waste treatment.

4. Purpose of the Study

The aim of the study is to identify the main ways to improve the medical waste legal regulation in mainstreaming environmental, sanitary and civil legislation process.

5. Research Methods

The methodological basis consists of common scientific and special cognitive methods, among which are comparative-legal, environmental-legal; analysis and prediction modus operandi.

6. Findings

Current Russian legislation classifies all waste types that are generated from medical, pharmaceutical activities, in the production of medicines and medical products. In addition, the Federal Law of 2011 «On the fundamentals of public health protection» includes activities in the field of infectious diseases using, genetically engineered organisms, production and storage of cellular products in this concept. Medical and pharmaceutical waste in foreign countries has always been classified to the hazardous waste, disposal, collection and recycling of which is subject to legislative regulation at the state level, in the federations – it is at the federal level. Such close attention to the problem should provide an effective mechanism for their further recycling, decontamination, and safe disposal.

At the national level, the legal regulation of special-purpose wastes, including medical wastes, is carried out by a number of normative acts of different levels of heterogeneous sectoral affiliation.

Firstly, the general provisions and definitions are enshrined in federal laws and normative acts of the international level. These can include: The Constitution of the Russian Federation; the Basel Convention on the Control of Transboundary Transportation of Hazardous Wastes and their Disposal of 1989; the Federal Laws "On the Fundamentals of Public Health Protection," "On Production and Consumption Waste", and "On Radioactive Waste Regulation and Amendments to Certain Legislative Acts of the Russian Federation".

Secondly, separate directions of activity in this sphere are regulated by the Government of the Russian Federation in the Resolutions: "On Licensing Activities for Collection, Transportation, Processing, Utilization, Decontamination, and Disposal of Waste of Hazard Classes I– IV", "On Approval of Criteria for Division of Medical Waste into Classes according to the Degree of their Epidemiological, Toxicological, Radiation Hazard, as well as negative impact on the environment", "On the approval of the Regulation on the alienation of radioactive waste disposal sites owned by legal entities to the property of the public administration in the field of radioactive waste regulation".

Thirdly, the specifics of special waste circulation at various stages of its management are established at the departmental level by federal specialized services and agencies: the Letters from Russian Federal State Agency for Health and Consumer rights "On the system of collection and disposal of medical waste during immunization in medical institutions of the Russian Federation", The Letter from Russian Federal Service for Surveillance on Consumer rights Protection and Human wellbeing "On rationing, certification and licensing the waste of health-care preventive facilities and biological waste", the Letter from the Ministry of Natural Resources and Environment of Russia "On regulation of environmental protection activities with medical waste".

This disparity suggests the need to codify special purpose waste legislation, for example, in a special chapter of the Medical Code, the need for which is due to the global spread of coronavirus infection.

Institutionalizing such a provision in practice raises many difficulties and issues, in particular, the waste class definition, the need for its passport, obtaining a license. In this regard, it is necessary to apply the criteria of separating medical waste into classes. The Russian government has approved five classes of waste: "A" – safe from the sanitary and epidemiological condition point of view ("domestic" waste);

"B" – hazardous from the point of view of sanitary and epidemiological condition waste contaminated with patient secretions; "V" – extremely dangerous from the sanitary and epidemiological condition waste point of view, which came into contact with infectious patients; "G" – dangerous toxic waste, close to industrial; "D" – radioactive waste.

Radioactive medical waste is a particular danger. Federal government bodies, medical institutions and personnel deserve special attention on the issues of competent treatment of them. These include wastes in any aggregate state containing radionuclides in an amount exceeding the established standards (used fluorographic, X-ray diagnostics examinations, etc.).

In order to avoid serious negative consequences for the environment and human health, it is necessary to take a responsible approach to the collection, accounting, transportation and disposal of such wastes. One should take into account the fact that medical and preventive institutions for the improper implementation of all the rules established by the legislation in matters of radioactive waste management are legally liable.

The Federal Waste Classification Catalogue does not establish the standards for the disposal of radioactive waste. This catalogue includes only a list of waste types in circulation in the Russian Federation and systematized classification characteristics. Such rules are determined by special organizations that have passed accreditation.

The Federal Service for Supervision of Consumer Rights Protection and Human Welfare (Rosпотребнадзор) draws attention to the fact that obsolete methods of collection and disposal are still used for medical waste, which causes significant harm to the environment, especially the quality of atmospheric air, water, and soil, and increases the risk of infectious diseases. In many regions, medical waste is still simply dumped in landfills or merged into sewers, depending on its aggregate state.

Also, depending on the aggregate state of waste, on its physical and chemical properties, as well as on the quantitative ratio of components and the degree of danger to the environment and human health, each type of waste is handled in a different way. Agencies and organizations that have appropriate permits for handling special-purpose wastes, in accordance with the current legislation, shall carry out the following measures as part of production control:

- 1) at least once a month, conduct visual and documentary check of consumable quantity (stock of packages, containers), small tools, disinfectants; providing staff with personal protective equipment, organizing centralized washing of protective clothing and replacing them regularly; sanitary condition and disinfection regime of temporary storage and special waste management areas, garbage chutes, container sites; compliance with regimes of medical waste decontamination, means of its accumulation, transposition, special clothing; regularity of such waste removal;

- 2) at least once a calendar year provides laboratory and instrumental checks: microbiological monitoring the effectiveness of decontamination, disposal of waste decontamination facilities, disposal according to approved methods.

It should be noted, that the environmental legislation, in particular, the departmental normative legal acts of the Ministry of Natural Resources and Ecology of the Russian Federation, is not applied to medical waste. However, it is necessary to distinguish «B» and «V» class from the list, as they are

considered to be production wastes and are not governed by the provisions of Federal Law, 1998 "On Production and Consumption Waste".

This situation is due to the inability to decontaminate medical wastes of «B» and «V» classes other than by physical methods, with the subsequent modification of its vendibility. In addition, the law treats COVID – 19 wastes, as class «V». With regard to class «A», «G» and «D», in the first case, these wastes are placed at solid waste landfills; in the second one the most high-tech thermal disposal methods are used; and in the third case conditioning and utilization at the relevant radioactive waste sites are carried out.

It is necessary to pay attention once again to the fact that medical wastes cannot be equated to production wastes, because their handling is carried out on a different practical, theoretical and, as a consequence, legislative basis. Besides, uncertainty of legal regulation of this sphere entails contradictions in interpretation and application of legal norms regulating all stages of medical waste handling (collection inside organizations, movement, disinfection, transportation, burial or destruction). The Ministry of Natural Resources and Environment of the Russian Federation (Minprirody of Russia) and the Federal Service for Supervision of Natural Resources (Rosprirodnadzor) take explanations in order to clarify the norms in the field of waste management, but their conclusions are not always unambiguous and comparable. For example, the Ministry of Natural Resources of Russia clearly distinguishes the scope and application of norms aimed at regulating relations in the sphere of production and consumption waste from the norms regulating the sphere of medical waste handling. In its turn, the position of Rosprirodnadzor is not so categorical and unambiguous. Thus, the conclusions made in a number of explanations of this executive body, completely coincide with the position of the Ministry of Natural Resources of Russia, but such approach does not prevent from holding a cardinally opposite point of view, explaining it as an exception to the general rule. For comparison, it is necessary to pay attention to the explanations given by Rosprirodnadzor, according to which it is allowed to place certain classes of medical waste after they have undergone appropriate procedures for decontamination and (or) decontamination in landfills (burial sites), in this connection, they fall under the norms in the sphere of production and consumption waste regulation.

Nowadays, the legal situation is as follows: all classes of medical waste, except radioactive ones, appropriately detoxified for the possible disposal and landfill site deposit, belong to the common legislation waste sphere. The global error is this: the strategy of medical waste legal regulation, despite its real and potential danger to the health of citizens and the environment, is not clearly enshrined in the current legislation. The study of foreign experience provides three ways to improve legislation on medical waste. The first approach involves the publication of a special (self-sufficient) act aimed at regulating medical waste. Under the second outlook, all types of waste are regulated by a single act, each section of which is devoted to a separate kind of waste, including medical one. According to the third view point, medical waste is legally regulated by the provisions in public health protection and sanitary epidemiological well-being of the population.

Unfortunately, Russian national legislation, which should be the basis for improving medical waste regulation practices, is far from perfect. Some issues in this area are not addressed at all at the state level. These include: legal and technical conditions for monitoring, accounting and reporting in the sphere

of supervision of medical waste management; lack of distribution of responsibility of public authorities exercising supervision (control) in the sphere of special waste management; legal grounds for effective application of legislative and subordinate normative acts, including for the correct qualification of offenses in the sphere of special waste regulation; implementation of international law norms and legislation of foreign countries regulating special purpose wastes into the Russian legal system.

7. Conclusion

The study of existing legislation in the sphere of medical waste regulation suggests that the Russian Federation is currently following the third way, but the implementation of this approach in our country, as in many other countries, is far from being perfect. It is characterized by numerous gaps in differentiation and regulation, and needs to be seriously refined in the legislative framework proceeding from international experience and modern national standards.

Therefore, in the foreseeable future, the maximum attention should be paid to determining the legal regulation strategy on medical waste by collaborative efforts of state authorities and academics in order to systematize this area of activity and achieve the greatest legal effect in its regulation.

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