

LEGAL FRAMEWORK AND STANDARDS OF GOOD PHARMACY PRACTICE IN PHARMACEUTICAL WASTE MANAGEMENT

ABSTRACT: Recognizing the importance of proper pharmaceutical waste management is of utmost significance from several different perspectives. Pharmaceutical waste may pose a potential problem for all types of healthcare institutions. It is not limited to expired medicines, but also includes various types of packaging containing traces of toxic substances, protective equipment, instruments used in the administration or preparation of medicines, as well as veterinary medicinal products. Naturally, different types of pharmaceutical waste carry different types of risks. It can be said that many chemical substances primarily used in healthcare may become a risk to human health and may adversely affect the environment if handled improperly. Following the conceptual definition of medical and pharmaceutical waste and an overview of their characteristics, the paper analyzes the legal framework governing the treatment of pharmaceutical waste in Serbia and also provides an overview of the standards of good pharmacy practice in pharmaceutical waste management.

Keywords: *pharmaceutical waste, medical waste, pharmacy practice, legal framework in the Republic of Serbia.*

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1. Introduction

Recognizing the significance of proper pharmaceutical waste management, along with the legal and factual regulation of the methods and procedures of pharmaceutical waste management is extremely important, considering various aspects. As it is increasingly being emphasized in theory, “unsystematic and inadequate waste management represents one of the biggest issues of environmental policy in Serbia”. This condition is principally consequential of a lack of a definite attitude of society towards waste, insufficient understanding as to the relevance of waste management and failure to recognize the positive effects of the process” (Belgrade Open School, 2011, p.2).

For the most part, “there is no process which, in addition to producing the desired product or service, does not also generate certain by-products which, if not properly managed, ultimately become waste” (Đukić, 2018, p.157) having manifold adverse effects on a number of processes in society. With regard to the dynamics of waste generation in a broader sense, authors emphasize that “the situation in Serbia, as in many countries in transition, is extremely difficult to assess due to the lack of data on quantitative and qualitative waste analysis, more precisely on waste categorization” (Šerović, Madžgalj & Jelić, 2019, p. 129). It has been estimated that “2.5 million tons of waste is generated in Serbia, and various types of waste are often disposed of together with municipal solid waste in landfills” (Urošević, Pejčić & Đorđević, 2012, p. 160).

As Young (2012) maintains, a particularly significant challenge, pertaining also to the field of environmental protection in Serbia is “the low level of waste management. High costs, irrational organization, poor quality of service and insufficient concern for the environment, are the result of the dismal state in waste management organization” (p.169). Many authors hold this opinion noting that “waste management definitely reflects significantly on the state of the environment” (Počuča & Matijašević, 2022, p. 416). In this context, Bukumirić, Alivojvodić, Stamenović and Đarmati (2017), state that the “environmental impact of waste is adverse in numerous respects, the underlying causes in the Republica Serbia being: insufficient and unequal municipal coverage by public utility services, the inadequate regulation and overcapacity of landfills, as well as the low level of public awareness regarding proper waste management practices and environmental protection in general” (p. 87; Matijašević Obradović, Kovačević & Gradinac, 2018, p. 936). Given that harmful environmental impact has, from the outset, most often been

associated with the “generation, inadequate direction and final disposal of waste” (Matijašević Obradović & Milojević, 2018, p. 2), over time the waste management process in Serbia has become “reconciled with the principles of environmental protection” (Jovanović, 2016, p. 34), as prescribed by article 9 of the Environmental Protection Act (2004). Analyzing aspects of waste management planning, Josimović, Ilić and Filipović (2009) state that “proper waste management requires professional expertise in the field and a multidisciplinary approach” (p. 1).

Authors highlight that “many chemical substances and medicines used in healthcare facilities constitute hazardous waste” (Motiekaityte & Venckus, 2016, p. 26). Article 5, paragraph 1, point 10 of the Waste Management Act (2025), stipulates that “pharmaceutical waste includes all medicines, medicinal products and raw materials including their primary packaging as well as all the equipment used for their preparation and application. In this respect, pharmaceutical waste may be classified as: non-hazardous pharmaceutical waste – which does not pose a risk to human health or the environment and is treated in accordance with the procedure prescribed for hazardous pharmaceutical waste, and hazardous pharmaceutical waste – which includes waste generated from medicinal products containing heavy metals and disinfectants, medicines of known and unknown composition and medicines of indeterminate composition, and cytotoxic and cytostatic waste”. Pharmaceutical waste also encompasses “instruments used in the preparation or administration of medicines” (Ministry of Health, 2013, p. 6). Pharmaceutical waste is a category of medical waste which is in principle defined as “heterogeneous mixture of waste, 10–25% of which constitutes hazardous waste posing risks to human health and the environment” (Ministry of Health, 2008, p. 10).

The issue of the legislative treatment of medical and pharmaceutical waste management has, in recent years, become a highly relevant topic in both legal theory and practice. Accordingly, following a conceptual determination of medical and pharmaceutical waste, in addition to an overview of their characteristics, this paper analyses the legal framework governing this matter under the positive law of Serbia, with a view to offering *de lege ferenda* considerations. Furthermore, to that end, the author of the paper, deems it important to review the standards of good pharmacy practice in pharmaceutical waste management as established by the Pharmaceutical Chamber of Serbia.

2. Conceptual definitions and characteristics of medical and pharmaceutical waste

There are various definitions of medical waste, “however, each definition is essentially characterized by the fact that the waste is generated within healthcare facilities, and it is associated with the performance of medical procedures: diagnosis, treatment or research activities. Within healthcare facilities, all medical waste generated is heterogenous in nature: hazardous medical waste and inert municipal waste” (Simeunović, 2021, p. 825). Živković, Milošević, Vranjanac, Vasović and Stević (2018) cite the definition of the World Health Organization according to which medical waste is defined as waste “generated in the course of the diagnosis, treatment, or immunization of humans or animals” (p. 103). According to article 5, paragraph 1, point 18 of the Waste Management Act (2025), “medical waste is defined as waste generated from facilities providing healthcare to humans or animals and/or from other sites providing healthcare or other services (including diagnostic activities, experimental work, laboratories, cleaning, maintenance and disinfection of premises and equipment), encompassing both hazardous and non-hazardous medical waste, namely: non-hazardous medical waste which is not contaminated with hazardous or other substances, and which, by its composition, is similar to municipal waste (biodegradable, etc), hazardous medical waste which requires special handling, that is, which has one or more hazardous characteristics rendering it hazardous waste, including: pathological waste, sharps, waste contaminated by blood and bodily fluids, infectious and potentially infectious waste, and other hazardous medical waste (chemical waste, waste with a high content of heavy metals)”. Article 2 of the Rulebook of the Medical Waste Management (2010) classifies pharmaceutical waste as hazardous medical waste requiring special handling, and consisting of “all medicines, including primary packaging (primary packaging being defined under Article 5 of the Packaging and Packaging Waste Act (2009) as the smallest packaging unit in which a product is sold to the end consumer) as well as all equipment used for the administration of such products, held by a legal or natural person engaged in healthcare activities”, which have become unusable due to expiration date, non-compliance with prescribed quality standards, contaminated packaging, spillage, scattering, preparation without subsequent use, return by end users or other reasons preventing their use. Such waste may be classified as: potentially hazardous pharmaceutical waste (waste posing a risk if improperly managed and requiring procedures for hazardous waste management) and hazardous pharmaceutical waste (waste

originating from medicines and disinfectants containing heavy metals, as well as medicines of indeterminate composition, which due to their composition require special treatment procedures)". The Medicines and Medical Devices Agency of Serbia, in the Guidelines on the Recall of Medicines (2021), states that quality defects rendering a medicine pharmaceutical waste "may be divided into three classes: Class 1: Quality defect posing a life-threatening or serious health risk to the patient (e.g. wrong medication strength, etc.); Class 2: Quality defect that may compromise patient's health or result in treatment interruption, but does not fall within Class 1 (incorrect labeling or instruction, etc.); Class 3: Quality defect that is unlikely to seriously compromise patient's health. Class 1 recall is performed immediately, without delay, within 24 hours, class 2 recall within 48 hours, and class 3 recall within 5 days". Article 25 of the Medicines and Medical Devices Act (2010) prescribes that, in order to obtain market authorization, a medicine "must undergo pharmaceutical (pharmaceutical, chemical, biological), pharmaceutical and toxicological, and clinical testing".

The International Committee of the Red Cross in its Guidelines on medical waste management (International Committee of the Red Cross, 2011) states that as much as "75% to 90% of hospital waste is comparable to household or municipal waste and does not pose any particular hazard" (p. 12). Nevertheless, a decade later, the Organization for Economic Cooperation and Development (OECD) in its 2022 report notes that pollution from pharmaceutical products may occur when residues are excreted following consumption (as also noted by Straub (2016), or when unused or expired medicines are improperly disposed of. Household medicines may become waste for a number of reasons. Non-compliance with the regulations, early recovery, or prescription and purchasing errors may result in medicines remaining unused or expiring in households (see also Nikolić, Nikolić, Milošević & Milošević Georgiev, 2024, pp. 835–836). Estimates of the proportion of household medicines that become waste, range from 3% to as high as 50%" (p. 8). It is also important to consider veterinary medicines, which enter the environment through various, largely uncontrolled pathways (Shukla, et. al., 2017). Given that pharmaceutical waste can be solid, semi-solid or liquid, "solid (e.g. tablets, capsules, powders) and semi-solid (e.g. ointments, creams) pharmaceutical products can generally be treated by incineration, encapsulation and engineered landfilling, while wastewater treatment plants are recommended for liquid pharmaceutical waste" (Sapkota & Periathamby, 2023, p. 86).

The World Health Organization, in its 2004 report, indicated that “nearly five million people lose their lives each year due to exposure to certain environmental chemicals and that the actual figures are even higher in practice given the cumulative effects of chemical substances on human body” (Ristić, et. al., p. 188), while Živković et al. (2018) emphasize that the risk of “health and environmental hazards posed by hazardous agents originating from medical waste in the environment should by no means be underestimated considering that approximately 15% of medical waste is hazardous while the remaining 85 % of waste is non-hazardous” (p. 106). Jovanović and Živković (2010) report that nearly two decades ago, the population of Serbia was annually exposed to “the generation of between 4,500 and 5,000 tons of infectious healthcare waste, of which one-fifth originated from outpatient healthcare services, two-thirds from hospital care, and approximately 5% from microbiological medical laboratories” (p. 44).

3. Analysis of the legal framework governing the management of pharmaceutical waste in Serbia

As previously noted in the paper, under the Rulebook of Medical Waste Management (2010), pharmaceutical waste classified as hazardous medical waste is hazardous medical waste requiring special handling. The basic principles of medical waste management include: “establishing a waste segregation process, whereby waste is separated according to different methods of processing and disposal and directed into distinct “streams”; reducing the generation and overall quantity of medical waste; managing waste in a manner that does not compromise human health or the environment; organizing treatment and disposal of waste in the most appropriate way within these waste streams; preparing or remediating unregulated temporary or permanent storage facilities; maintaining records and documentation of medical waste management activities; monitoring key indicators related to segregation, disposal, and treatment; planning activities related to medical waste management; implementing corrective measures in annual planning; training personnel in the procedures of segregation, labeling, packaging, disposal, and treatment of medical waste; motivating staff to manage medical waste effectively; raising awareness regarding medical waste management; and fostering multidisciplinary cooperation to establish a regulated medical waste management system both at the healthcare facility level and within the administrative district” (Ministry of Health, 2008, p. 11).

The Rulebook on the Method and Procedure for Pharmaceutical Waste Management (2019) establishes the procedures and responsibilities for the handling of pharmaceutical waste. Article 3 defines “pharmaceutical waste management as a set of measures encompassing collection, segregation, packaging, labeling, storage, transport, and treatment of waste with the aim of its final safe disposal in a manner that protects human and animal health as well as the environment. Pharmaceutical waste management must be conducted in accordance with the general principles of waste management prescribed by law. Pharmacies operating as healthcare institutions, veterinary organizations, and privately-owned pharmacies are required to conclude a contract with an entity responsible for collection, transport, treatment, storage, reuse, disposal, or export of pharmaceutical waste in compliance with applicable legislation governing waste management. Article 4 further stipulates that “pharmaceutical waste shall be collected at the point of generation and segregated into hazardous and non-hazardous pharmaceutical waste, or into different categories of hazardous pharmaceutical waste, and shall be temporarily stored in appropriate packaging adapted to its properties, quantity, and method of temporary storage, transport, and treatment. At the point of generation of pharmaceutical waste, uncontaminated secondary packaging shall be separated from the primary packaging of the medicinal product in order to reduce waste quantities and enable more efficient packaging and transport for further treatment. Hazardous pharmaceutical waste shall be classified according to its origin, characteristics, and composition rendering it hazardous. Cytotoxic and cytostatic waste shall be collected separately from other categories of pharmaceutical waste at the point of generation, in a manner preventing direct contact with personnel handling the waste; repackaging thereof in temporary storage facilities or during delivery shall not be permitted”. Pharmacies established as healthcare institutions, pharmacies operating as private practices, as well as veterinary organizations, shall take over pharmaceutical waste generated by citizens (Article 5). Article 6 prescribes that “pharmaceutical waste shall be packaged at the point of generation in special packaging provided and installed by the operator with whom the waste producer has concluded a contract, except for pharmaceutical waste generated by citizens. Segregated pharmaceutical waste at the point of generation shall be packaged in the following manner: 1) pharmaceutical waste – in red bags and containers; 2) cytotoxic and cytostatic waste – in purple bags and containers. Liquid waste shall be packaged in leak-proof containers preventing spillage and securely sealed. Spilled and contaminated medicinal products, as well as packaging containing residues of medicinal products from facilities where pharmaceutical waste is generated, shall, prior to storage, be

packaged in appropriate containers at the point of generation. The packaging of pharmaceutical waste generated by medicinal product manufacturers and wholesale distributors is regulated by Article 7. Namely, “pharmaceutical waste generated at the premises of medicinal product manufacturers and entities engaged in the wholesale distribution of medicinal products and medical devices shall, at the point of generation, be segregated as follows: 1) non-hazardous pharmaceutical waste; 2) hazardous pharmaceutical waste; 3) hazardous pharmaceutical waste – cytostatics; 4) hazardous pharmaceutical waste – medicinal products for which the Medicines and Medical Devices Agency of Serbia has granted a marketing authorization and which contain psychoactive controlled substances; 5) hazardous pharmaceutical waste – medicinal products for which the Medicines and Medical Devices Agency of Serbia has granted a marketing authorization and which contain Category I precursors.

In addition to the aforementioned provisions, the Rulebook on the Method and Procedure for Pharmaceutical Waste Management (2019) also regulates issues relating to the labeling, storage, and transport of pharmaceutical waste, while Article 12 stipulates that “the treatment of pharmaceutical waste shall be carried out by the producer of pharmaceutical waste independently or through an operator with whom a contract has been concluded, in accordance with the conditions set out in the permit issued by the competent authority, and in compliance with the law governing waste management and other specific regulations. Pharmaceutical waste containing live microorganisms shall be treated by sterilization using pressurized steam in an autoclave to achieve a safe level of sterility, in accordance with specific regulations and professional standards. Hazardous pharmaceutical waste shall be treated by incineration or co-incineration, as well as by appropriate physico-chemical processes (neutralization, solidification, adsorption, distillation, etc.) aimed at reducing the hazardous characteristics of the waste, in accordance with best available technologies. Non-hazardous pharmaceutical waste shall be treated by composting, anaerobic digestion, fermentation, or other approved methods in accordance with best available technologies. Cytostatic and cytotoxic waste shall be treated by incineration in facilities holding a permit for the treatment of hazardous waste in accordance with the law governing waste management. Waste originating from medicinal products containing psychoactive controlled substances and precursors shall be treated by incineration, in compliance with the regulations governing psychoactive controlled substances and precursors, the regulations governing medicinal products, as well as the regulations governing waste management. The treatment of pharmaceutical waste by incineration and co-incineration shall be carried out in facilities designated for

that purpose, provided that emissions of pollutants into air, water, and soil do not exceed the prescribed limit values, in accordance with special legislation.

It should also be noted that, pursuant to the provisions of Annex 11 to the Rulebook on Waste Categories, Testing and Classification (2010), pharmaceutical waste generated in the provision of healthcare to humans and animals “is designated by the following index numbers: 18 01 08* for waste medicinal products intended for human use, and 18 02 07* for waste medicinal products arising from the treatment of animals, where such products belong to the groups of cytotoxic and cytostatic medicines; and 18 01 09 and 18 02 08 for other categories of medicinal products originating from human and veterinary healthcare respectively”.

4. Standards of good pharmacy practice for pharmaceutical waste management

Good pharmacy practice is defined as “a system of standards and guidelines enabling the provision of pharmaceutical services of appropriate quality to each user, with the aim of ensuring optimal, evidence-based pharmaceutical healthcare” (Pharmaceutical Chamber of Serbia, 2021, p. 2). Good pharmacy practice is founded upon four fundamental principles: patient welfare, the optimal use of medicines through the promotion of rational and cost-effective prescribing and dispensing, effective communication, and multidisciplinary cooperation in the provision of pharmaceutical services.

Pharmaceutical waste management within a pharmacy is defined as “a set of measures encompassing the collection, segregation, packaging, labeling, and transport of pharmaceutical waste between organizational units of the same healthcare institution, as well as the temporary storage of pharmaceutical waste generated within the pharmacy and waste taken over from citizens, and its handover to an authorized operator” (Standards and Guidelines of Good Pharmacy Practice for Pharmaceutical Waste Management, 2021). The Standards of Good Pharmacy Practice for Pharmaceutical Waste Management, together with their accompanying guidelines, which provide further elaboration of the requirements set out in the standards and offer examples of good practice in meeting those requirements, are fully aligned with the Rulebook on the Method and Procedure for Pharmaceutical Waste Management (2019) and the Waste Management Act (2025).

The said Standards and Guidelines of Good Pharmacy Practice for Pharmaceutical Waste Management (2021) “require that pharmacies or healthcare institutions with integrated pharmacies adopt a Waste Management

Plan in accordance with waste management legislation, establish written procedures for handling pharmaceutical waste, and designate a responsible officer”. It further stipulates that “during waste segregation, special attention is given to medicines containing psychoactive controlled substances, cytostatics, and other hazardous chemicals which contain hazardous substances in accordance with the law.” Containers and bags used for the disposal and packaging of pharmaceutical waste must be suitable for their specific purpose (shape, volume, color, material, safety), in compliance with the law. Pharmaceutical waste must be stored temporarily in a designated, separate area in a manner that ensures safety and prevents harm to human health and the environment in compliance with the regulations. Labeling and documentation of pharmaceutical waste must comply with relevant legislation. Transport of pharmaceutical waste between organizational units of the same healthcare facility may be conducted using the facility’s vehicle; a transport permit is not required if the quantity of waste transported is less than ten kilograms. Pharmaceutical waste must be transferred to an authorized operator under a contract ensuring regular collection. Authorized operators must hold the appropriate permits for waste management activities, issued by the ministry responsible for environmental protection. Proper records must be maintained regarding the amounts of generated pharmaceutical waste (daily waste record) and its transfer to the authorized operator (waste movement document, including hazardous waste documentation). Based on these records, an annual waste report is prepared and submitted to the Environmental Protection Agency in accordance with relevant legislation”.

The Standards and Guidelines of Good Pharmacy Practice for Pharmaceutical Waste Management (2021) also stipulate that “both public and privately-operated pharmacies are required to accept pharmaceutical waste from citizens and ensure its transfer to an authorized operator. Management of pharmaceutical waste collected from the public must be conducted in full compliance with applicable waste management regulations”.

5. Conclusion

Pharmaceutical waste may constitute a potential challenge for all types of healthcare institutions, including pharmacies, hospitals, clinics, and others. It is not limited solely to expired medicinal products. Rather, pharmaceutical waste also encompasses various forms of packaging, liquid and solid substances containing traces of toxic compounds, protective equipment, instruments used in the preparation or administration of medicinal products, as well as

veterinary medicines. Certainly, different categories of pharmaceutical waste entail different types and levels of risk. It may therefore be concluded that numerous chemical substances primarily used in healthcare may pose risks to human health and adversely affect the environment if improperly handled, as may substances classified as pharmaceutical waste.

The statutory provisions that directly or indirectly regulate the treatment of medical waste and the method and procedure for pharmaceutical waste management and which are analyzed in this paper, include the Waste Management Act, the Packaging and Packaging Waste Act, the Medicines and Medical Devices Act, and the Environmental Protection Act, while the relevant secondary legislation examined herein comprises the Rulebook on Medical Waste Management, the Rulebook on the Method and Procedure for Pharmaceutical Waste Management, and the Rulebook on Waste Categories, Testing and Classification. The paper also addressed the Standards and Guidelines of Good Pharmacy Practice for Pharmaceutical Waste Management. Some of the conclusions drawn from the doctrinal and normative analysis of the field relating to the elements of the pharmaceutical waste management methods and procedures reflect the viewpoint according to which pharmaceutical waste, at least to a certain extent, is classified as hazardous waste, and must be treated accordingly: also, pharmaceutical waste includes primary packaging, and all instruments and equipment used in the production and/or administration of pharmaceutical products; moreover, pharmacies are obliged to accept unusable medicinal products from citizens free of charge and to maintain records of all quantities of pharmaceutical waste; furthermore, pharmaceutical waste must be stored in premises separate from those used for storing usable pharmaceutical products; finally, pharmacies, or healthcare institutions within which pharmacies operate, are required to adopt a Waste Management Plan and to designate a person responsible for waste management within the pharmacy.

It may ultimately be concluded that, in recent years, the legislative framework governing the treatment and management of medical and pharmaceutical waste has been significantly improved. Certain objectives underlying the amendments to existing statutory and secondary legislation have included the establishment of a safe system for the management of medical and pharmaceutical waste, accompanied by enhanced occupational safety for employees, as well as improved protection of healthcare service users. Additional objectives warranting emphasis include the ongoing effort to reduce the quantities of medical and pharmaceutical waste and the continuous commitment to preserving a healthy environment. Future *de lege*

ferenda developments should continue the process of harmonization with the European Union regulations in the field of waste management, particularly in light of the directives adopted within the framework of the Circular Economy Package, which entered into force in June 2018, replacing several existing instruments in the area of waste management and introducing new recycling targets for municipal and packaging waste.

Conflict of Interest

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PRAVNA REGULATIVA I STANDARDI DOBRE APOTEKARSKE PRAKSE ZA UPRAVLJANJE FARMACEUTSKIM OTPADOM

APSTRAKT: Shvatanje značaja pravilnog upravljanja farmaceutskim otpadom od izuzetnog je značaja, i to sa više različitih aspekata. Farmaceutski otpad može predstavljati potencijalan problem za sve vrste zdravstvenih ustanova. Nije ograničen samo na lekove kojima je istekao rok trajanja,

već obuhvata i različitu ambalažu koja sadrži tragove toksičnih supstanci, zaštitnu opremu, instrumente koji su korišćeni u primeni ili u pripremi lekova, kao i veterinarske lekove. Naravno, različite vrste farmaceutskog otpada nose različite vrste rizika. Može se reći da mnoge hemijske supstance koje se primarno koriste u zdravstvenoj zaštiti mogu postati rizične po zdravlje ljudi i mogu narušiti zdravu životnu sredinu ukoliko se njima neadekvatno rukuje. U radu je nakon pojmovnog određenja medicinskog i farmaceutskog otpada, kao i njihovih karakteristika, analizirana pravna regulativa kojom se uređuje tretman farmaceutskog otpada u Srbiji, a učinjen je i osvrt na standarde dobre apotekarske prakse za upravljanje farmaceutskim otpadom.

Keywords: *farmaceutski otpad, medicinski otpad, apotekarska praksa, pravna regulativa u Republici Srbiji.*

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