Legal Framework Governing the Types and Handling of Medicinal Products with an Overview of Principles of Good Pharmacy Practice in the Provision of Pharmaceutical Services in Serbia

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Abstract

The healthcare system represents one of the most complex systems in any state. Article 65 of the Law on Health Care stipulates that pharmaceutical healthcare is included among the activities constituting healthcare provision at the primary level. At the national level, each country establishes a positive legal framework governing the field related to the types and handling of medicinal products, as well as other key issues, primarily through the adoption of relevant laws and bylaws. It is generally considered that any pharmacotherapy necessarily implies a coherent approach among all participants in the process — patients, physicians, pharmacists, and other professionals whose medical services may be required. Following a brief overview of the concept and significance of pharmaceutical activity, medicinal products, and medical devices, this paper analyzes the legal framework regulating the types and handling of medicinal products. In addition to examining the applicable laws, relevant bylaws are also presented. Finally, the paper provides an overview of the principles of Good Pharmacy Practice in the provision of pharmaceutical services in Serbia.

Keywords: medicinal product, medical device, pharmaceutical activity, Good Pharmacy Practice, healthcare

Introduction

The current Law on Health Care entered into force in 2019. Article 65 of this law stipulates that pharmaceutical healthcare is included among the activities constituting healthcare provision at the primary level of healthcare. Furthermore, Article 79, paragraph 1 of the Law on Health Care (National Assembly, 2019) prescribes that pharmacy activity is performed by a pharmacy institution at the primary level of healthcare. The right to healthcare is a universal human right and is considered a hallmark of modern society. Article 68 of the Constitution of the Republic of Serbia (National Assembly, 2006) contains provisions that generally regulate healthcare in the Republic of Serbia. According to these provisions, “everyone has the right to the protection of their physical and mental health. Children, pregnant women, mothers during maternity leave, single parents with children up to seven years of age, and the elderly are entitled to healthcare funded from public revenues if they do not obtain it in another manner, in accordance with the law. Health insurance, healthcare, and the establishment of health funds shall be regulated by law. The Republic of Serbia shall support the development of healthcare and physical culture.”

At the outset, it should be noted that the healthcare system represents one of the most complex systems in any state. A system implies “a set of interrelated elements that collectively lead to the realization of goals within the environment in which the system exists. A system encompasses the totality or complexity of elements or individual components” (Cucić et al., 2000, p. 20). Healthcare systems are “strongly influenced by the prevailing norms and values within a society; they often reflect the social and cultural expectations of citizens and are shaped by a country’s unique national history, traditions, and

political system" (Jovanović et al., 2015, p. 76). The social security system in Serbia consists of "the system of social insurance, the system of social care for children and families, the system of social protection for veterans, military disabled persons and civilian war invalids, and the system of social welfare" (Kosanović & Anđelski, 2015, p. 49), while the system of social insurance includes "pension and disability insurance, health insurance, and unemployment insurance" (Kosanović, 2011, p. 26). In addition to the importance of health and healthcare itself, particular emphasis is placed on "health insurance as one of the most significant social, economic, and consequently political issues" (Janković, 2011, p. 70). According to Article 4 of the Law on Health Insurance (National Assembly, 2019), "compulsory health insurance includes insurance in the case of illness and injury outside work, as well as insurance in the case of occupational injury and occupational disease." Furthermore, pursuant to Article 5 of the same law, "compulsory health insurance is organized on the principles of obligatoriness, solidarity and mutuality, transparency, protection of the rights of insured persons and protection of the public interest, continuous improvement of the quality of compulsory health insurance, as well as economy and efficiency of compulsory health insurance." However, "in conditions of increased demand for healthcare services, insufficient accumulation of contribution funds within the compulsory health insurance system, organizational challenges within the system, and similar circumstances, the need arises for a stronger presence of voluntary forms of health insurance" (Kočović, Rakonjac Antić & Rajić, 2013, p. 541).

The *World Health Report 2000* defined "three intrinsic goals of health systems: improving health, enhancing responsiveness to the legitimate expectations of the population, and ensuring that financial contributions to healthcare are distributed fairly" (Evans et al., 2001, p. 307). In general terms, "there is no single best or universally recommended way of organizing healthcare and health services. For this reason, significant differences exist among countries with regard to the objectives, structure, organization, financing, and other characteristics of healthcare systems. These differences result from historical, economic, geopolitical, sociocultural, and other factors" (Mitrović & Galović, 2013, p. 145). As has already been emphasized, the primary objective of a healthcare system is "the promotion and preservation of people's health. In addition to this primary objective, the healthcare system has two further goals: responsiveness, in terms of meeting the expectations placed upon it, and fairness, in terms of ensuring equal treatment of all individuals within a country" (Radivojević & Vesić, 2020, p. 154). For a healthcare system to function successfully, it must be "adequately organized, properly guided, sufficiently financed, and well structured" (Jovanović et al., 2015, p. 76).

Until the beginning of the twentieth century, as many as 80% of medicines were prepared in pharmacies (Remington, 2012). The rapid development of the pharmaceutical industry in the mid-twentieth century "enabled the large-scale production of high-quality and safe medicinal products, in accordance with the needs of the growing market and the stringent requirements of regulatory authorities" (Đekić, Čalija & Vuleta, 2013, p. 444). Contemporary approaches to therapy increasingly emphasize individualization, that is, a patient-oriented approach in which the patient is viewed as an individual with specific needs (Allen et al., 2011, p. 710).

Following a brief overview of the concept and significance of pharmaceutical activity, medicinal products, and medical devices, this paper analyzes the legal framework governing the types and handling of medicinal products. In addition to examining the applicable laws, relevant bylaws are also presented, bearing in mind that bylaws "define specific areas of pharmaceutical healthcare more precisely and in

greater detail" (Jović & Tasić, 2009, p. 2). Subsequently, the paper provides an overview of the principles of Good Pharmacy Practice in the provision of pharmaceutical services in Serbia, taking into account the growing tendency that "within pharmaceutical management, in both business and healthcare environments, the philosophy of Good Practice is strongly present" (Tasić & Hadži-Arsić Novaković, 2005, p. 225).

Concept and Significance of Pharmaceutical Activity, Medicinal Products and Medical Devices

The beginnings of legal regulation of pharmaceutical activity in Serbia "are linked to the early nineteenth century, specifically the period following the attainment of independence. The first pharmacy in Serbia was opened in 1830 in Belgrade. Six years later, the Court and Military Pharmacy was established in Kragujevac, which subsequently stimulated the opening of other pharmacies throughout Serbia. During this period, pharmacies in Serbia based their operations on the Austrian pharmacy system" (Jovanović, 2016, p. 122). Healthcare systems have undergone numerous processes of change over time, involving varying degrees of reform. The main drivers of these reforms have included "economic changes – acceleration of the global economy, globalization, and the global economic crisis; political changes – transformation of socio-economic systems in former socialist countries and liberalization; demographic changes – shifts in population size, age structure, educational structure, etc.; epidemiological changes – decreases in mortality and morbidity; sociocultural changes – changes in lifestyles, traditional family structures, values, and general expectations" (Simić, 2012). Developments in pharmaceutical activity within healthcare systems abroad have also been shaped by reforms and developmental initiatives. For example, in Sweden, "several initiatives have been implemented to improve pharmaceutical activity. On the one hand, annual thematic campaigns targeting specific patient groups have been introduced, while on the other hand, in recent years, greater emphasis has been placed on the prevention of drug dependence" (Westerlund & Bjork, 2006). After the introduction of pharmacist-led medication counseling, "which has been legally mandated in Finland since 2000, improvements in medication counseling rates have been observed" (Bell et al., 2007). Pharmaceutical practice – including patient care and research – "is well developed in Denmark. In addition to medication counseling and services such as cholesterol, blood glucose, and blood pressure measurements, models of best practice in pharmaceutical care have been established" (Herborg, Sorensen & Frokjaer, 2007). However, "despite positive developments in pharmaceutical activity, top-down approaches to implementing such initiatives have been criticized" (Rossing et al., 2005). In 2005, the National Health Service in England "introduced pharmacy contracts aimed at ensuring that all pharmacies provide seven essential services related to pharmaceutical activity and meet quality standards. Services offered in pharmacies include supervised methadone administration and smoking cessation programs" (Noyce, 2007). In Saudi Arabia, "community pharmacy practice typically focuses on traditional roles, including dispensing prescription and over-the-counter medications and providing brief standard counseling with limited patient care services" (Alrasheedy, 2024; Alanazi, Alfadl & Hussain, 2016; Mohammed et al., 2021).

Pharmaceutical activity is defined as "a healthcare activity that ensures the pharmaceutical healthcare of the population, carried out within the healthcare system at the primary, secondary, and tertiary levels, as well as in private practice, and encompassing: the supply of medicinal products and medical devices to the public, healthcare institutions, private practices, and other legal entities; implementation of preventive measures to maintain, protect, and promote public health, including health

promotion, disease prevention, and health education; dispensing of medicines and medical devices, together with guidance on storage, shelf life, proper use, adverse reactions and interactions, correct administration, and disposal; optimization of pharmacotherapeutic interventions and procedures for the rational use of medicinal products and medical devices, and provision of information to the general public and healthcare professionals in accordance with the law; participation in the development and implementation of pharmacotherapeutic protocols; reporting of adverse events, adverse reactions to medicines and medical devices, or falsified medicinal products; monitoring therapeutic outcomes to optimize treatment and improve patient outcomes by tracking specific parameters; identification of potential drug interactions with other medicines, food, etc., and prevention of unnecessary therapeutic duplication; preparation and dispensing of magistral or galenic medicines; withdrawal or recall of medicines and medical devices from retail; management of pharmaceutical waste; collaboration with other healthcare professionals regarding the use of medicines and medical devices; and other pharmaceutical services and pharmacy activities in accordance with the law" (Guide to Good Pharmacy Practice, 2021, p. 3). According to Article 2, item 1 of the Law on Medical Devices (National Assembly, 2017), a medical device (general) is "any instrument, apparatus, appliance, software, implant, reagent, material, or other product intended to be used alone or in combination, including software intended by the manufacturer for diagnostic or therapeutic purposes and necessary for its proper application in humans, which is intended by the manufacturer for: diagnosis, prevention, monitoring, prediction, prognosis, treatment, or alleviation of disease; diagnosis, monitoring, treatment, alleviation, or compensation for injury or disability; examination, replacement, or modification of anatomical, physiological, or pathological functions or states; provision of information via in vitro examination of human samples, including donated organs, blood, and tissues; control or support of conception; cleaning, disinfection, or sterilization of medical devices." In addition to the general definition of a medical device, the same legal text recognizes the following categories of medical devices: in vitro diagnostic medical device, active medical device, implantable medical device, active implantable medical device, custom-made medical device for a specific patient, medical device intended for clinical investigation, and single-use medical device.

According to the provisions of Article 14 of the Law on Medicines and Medical Devices (National Assembly, 2010), "a medicinal product is any product placed on the market in a specific strength, pharmaceutical form, and packaging that contains a substance or combination of substances that has been shown to have properties to treat or prevent disease in humans or animals, or a substance or combination of substances that may be used or administered to humans or animals with the intention of restoring, correcting, or modifying physiological functions through pharmacological, immunological, or metabolic action, or for establishing a medical diagnosis. A substance may be of any origin and can include: human origin (blood and blood products); animal origin (microorganisms, whole animals, organ parts, animal secretions, toxins, extracts, blood products); plant origin (microorganisms, whole plants, plant parts, plant secretions, extracts); chemical origin (chemical elements, naturally occurring chemical substances, and chemically synthesized products)." The provisions of Article 4 of the Rulebook on the Manner of Advertising Medicines and Medical Devices (Ministry of Health, 2010) regulate that advertising of medicinal products or medical devices includes: promotion through mass media, including the Internet; advertising in public spaces; and other forms of promotion such as mailings or in-person visits; promotion directed at healthcare and veterinary professionals authorized to prescribe medicines or medical devices,

including direct communication at professional meetings, in professional journals, and through other forms of professional promotion; provision of free samples to the professional community; and sponsorship of scientific and promotional events involving professional participants. The Rulebook on the List of Medicines Prescribed and Dispensed at the Expense of Compulsory Health Insurance (Republic Fund for Health Insurance, 2025) establishes the list of medicines that are prescribed and dispensed at the expense of compulsory health insurance. According to Article 3 of the Rulebook on the Method of Quality Control of Medicines and Medical Devices (Ministry of Health, 2011), "quality control of a medicinal product, regardless of the type of marketing authorization, is performed in accordance with its registration by: laboratory quality control and documentation quality control." Article 2, item 1 of the same Rulebook stipulates that "pharmaceutical testing of a medicinal product or medical device is a physico-chemical, biological, or microbiological examination aimed at determining the quality of the product." Medicinal products may also undergo clinical testing in accordance with the standards of Good Clinical Practice, as established by the Guidelines for Good Clinical Practice (Ministry of Health, 2025). Pursuant to Article 2 of the Rulebook on Clinical Trials of Medicinal Products in Human Medicine (Ministry of Health, 2022), "a clinical trial of a medicinal product is an investigation conducted in humans to determine or confirm the clinical, pharmacological, and pharmacodynamic effects of the medicinal product, to identify any adverse reactions to the investigational product, to examine its absorption, distribution, metabolism, and excretion, and to establish its safety and efficacy." Pharmacovigilance, defined as "a set of activities relating to the collection, detection, assessment, understanding, and prevention of adverse reactions to medicines, as well as other drug-related problems," is regulated by the Rulebook on the Method of Reporting, Collecting, and Monitoring Adverse Reactions to Medicines (Ministry of Health, 2011).

Legal Framework Governing the Types and Handling of Medicinal Products in Serbia

The legal framework regulating the types and handling of medicinal products represents a critical component in safeguarding patients' rights and, more broadly, the protection of human rights in relation to health. The medico-legal perspective "does not yet provide answers to all open questions regarding the use of medicines. It concerns an approach from the perspective of patient rights, which requires consideration of medicinal products as a source of health, and, to a lesser extent, as pharmaceutical goods on the market. Patient treatment and the professional aspects of medical and pharmaceutical practice are understood in a therapeutic sense and are appropriately balanced in the interest of each patient" (Mujović Zornić, 2008, p. 12).

Article 2 of the Law on Medicines and Medical Devices (National Assembly, 2010) recognizes specific categories of medicinal products. A reference medicinal product is "a medicine for which a marketing authorization has been issued in the Republic of Serbia or in the European Union based on complete documentation demonstrating quality, safety, and efficacy in accordance with applicable requirements." A well-established use (WEU) medicinal product is defined as a medicine "whose active substance is well-known, whose efficacy is established, and whose safety is at an acceptable level, which has been in use for at least ten years as a medicine in the European Union, and for which the marketing authorization is based on bibliographic data." A fixed-combination medicinal product is a medicine "whose fixed combination of active substances has not been used as a medicinal product for therapeutic purposes prior to marketing authorization, while each individual active substance is part of a medicine authorized

in Serbia or in the European Union." A consent-based medicinal product is a medicine "with the same qualitative and quantitative composition in terms of active substances and of the same pharmaceutical form, for which, in the marketing authorization procedure, documentation on the quality, safety, and efficacy of a medicine already authorized in the Republic of Serbia is used, provided that written consent is obtained from the marketing authorization holder." A generic medicinal product is defined as a medicine "containing the same qualitative and quantitative composition of active substances and the same pharmaceutical form as the reference medicinal product, with demonstrated bioequivalence through appropriate bioavailability studies. Different salts, esters, ethers, isomers, mixtures of isomers, complexes, or derivatives of the active substances of a generic medicine are considered the same active substance unless there are significant differences in safety or efficacy. Different oral forms with immediate release are considered the same pharmaceutical form." A generic medicinal product with mixed safety and efficacy data is a medicine "that does not fully meet the definition of a generic medicinal product, i.e., for which bioequivalence cannot be fully demonstrated through bioavailability studies, or in cases where one or more active substances, therapeutic indications, strength, pharmaceutical form, or route of administration differ from the reference product." A similar biologic medicinal product is "a biologic medicine similar to a reference biologic product that does not meet the criteria for a generic product due to differences in raw materials and manufacturing processes between the similar biologic product and the reference biologic product." A hybrid generic medicinal product is "a medicine that does not fully meet the definition of a generic medicinal product, i.e., for which bioequivalence cannot be fully demonstrated through bioavailability studies, or in cases of changes in one or more active substances, therapeutic indications, strength, pharmaceutical form, or route of administration compared to the reference product. A hybrid generic product is similar to the reference medicinal product because it contains the same active substance, but certain differences exist, such as strength, indication, or pharmaceutical form. The requirements for obtaining marketing authorization for a hybrid medicinal product are partially based on studies conducted with the reference product and partially on new data" (Vrcelj Jovanović, Vukajlović & Stajković, 2022, p. 15).

The Law on Medicines and Medical Devices (National Assembly, 2010), in Article 2, further recognizes the term "pharmaceutical equivalents," which refers to medicines "containing the same quantity of the same active substance(s) in the same pharmaceutical form, administered in the same way, and meeting the requirements of the same or comparable standards." A pharmaceutical form is defined as "the form in which a medicinal product is suitable for administration (e.g., tablet, capsule, ointment, injection solution, premix, etc.)." The same law, in paragraph 36, addresses the category of falsified medicinal products. A falsified medicinal product or medical device is defined as a medicine or device "that is manufactured, prepared, marketed, or distributed with the intention to deceive those who use or handle it, containing false information regarding identification (manufacturer, place of production, marketing authorization holder, registration holder as maintained by the Agency, analysis certificate, and other product-related documentation), or that may contain correct or incorrect ingredients relative to the declared composition, may lack active substances, may contain insufficient quantities of active substances, may have false packaging, or any other medicinal product or medical device considered falsified according to European Union or World Health Organization standards."

Interchangeability of medicines is defined by the Rulebook on the Form and Content of Medical Prescriptions, Method of Dispensing and Prescribing Medicines (Ministry of Health, 2018). According to Article 2, item 8 of this Rulebook, "interchangeable medicines are those containing the same active substance (identical INN), the same quantitative composition of the active substance, and the same pharmaceutical form, differing only in excipients and brand name, which, based on product documentation, demonstrate a degree of similarity such that their effects in terms of efficacy and safety are essentially equivalent." In certain circumstances, medicines "may not be considered interchangeable even if they meet the above criteria. For example, this applies when there are clinically significant differences between products, or if substitution cannot be safely performed (e.g., specific pharmaceutical forms, medicines administered via a medical device, or medicines with a narrow therapeutic index). In such cases, interchangeability is determined on a case-by-case basis. The concept of interchangeability does not apply to biological or similar biologic medicines" (Vrcelj Jovanović, Vukajlović & Stajković, 2022, p. 15).

The following table presents the types of medicinal products and their key characteristics as stipulated by the Law on Medicines and Medical Devices (National Assembly, 2010).

Table 1. Types of medicinal products and their characteristics as defined by law

	Type of medicinal product	**Key characteristics**
1	Biological medicinal product	A biological medicinal product is a medicine whose active substance is a biological substance, meaning a substance derived or extracted from a biological source, for which physicochemical and biological testing, as well as a description and control of the manufacturing process, are required for classification and quality assurance.
2	Immunological medicinal product	In human medicine, an immunological medicinal product is any medicine consisting of vaccines, toxins, sera, or allergens. In veterinary medicine, an immunological medicinal product is administered to animals to induce active or passive immunity, or to diagnose their immune status.
3	Advanced therapy medicinal products	Advanced therapy medicinal products include: gene therapy medicinal products; somatic-cell therapy medicinal products; and tissue-engineered products.
4	Medicinal products derived from blood and plasma	Medicinal products obtained from human or animal blood or plasma.
5	Radiopharmaceuticals	Radiopharmaceuticals include radiopharmaceutical medicinal products, radionuclide generators, radiopharmaceutical kits, and radionuclide precursors. A radiopharmaceutical medicinal product contains one or more radionuclides for medical purposes (radioactive isotopes) when prepared for use. A radionuclide generator is any system containing a parent radionuclide from which a derived radionuclide is produced, typically by elution, for use in a radiopharmaceutical product. A radiopharmaceutical kit is a preparation intended to be combined with or dissolved in radionuclides immediately prior to use. A radionuclide precursor is any other radionuclide produced for the purpose of labeling another substance prior to its application.

	Type of medicinal product	Key characteristics
6	Herbal medicinal product	A herbal medicinal product is any medicine whose active ingredients consist exclusively of one or more substances of plant origin, one or more herbal preparations, or a combination of one or more substances of plant origin with one or more herbal preparations.
7	Traditional and traditional herbal medicinal product	A traditional medicinal product is based on scientific principles and the results of tradition or other conventional therapeutic approaches. Marketing authorization is granted for traditional medicines in accordance with the Law.
8	Homeopathic medicinal product	A homeopathic medicinal product is a medicine prepared from substances, products, or compounds constituting homeopathic substances according to the homeopathic manufacturing process, following the methods of the European Pharmacopoeia or pharmacopoeias valid in an EU member state.
9	Veterinary medicinal product	A premix is a pharmaceutical form of a veterinary medicinal product intended for mixing with animal feed. A medicated feed premix is a special pharmaceutical form of a veterinary medicinal product produced exclusively for the preparation of medicated feed.
10	Magistral and galenic medicinal product	A magistral medicinal product is prepared in a pharmacy according to a prescription (formula) for a specific patient or user. A galenic medicinal product is prepared based on valid pharmacopoeias or magistral formulas in a galenic laboratory and is intended for patients of a pharmacy, other healthcare institutions, or other forms of health services when no authorized medicinal product is available under the conditions prescribed by law and subordinate regulations.

Principles of Good Pharmacy Practice in the Provision of Pharmaceutical Services in Serbia

Good Pharmacy Practice is defined as “a system of standards and guidelines that enables the provision of pharmaceutical services of appropriate quality to every patient, with the aim of delivering optimal, evidence-based pharmaceutical healthcare” (Guide to Good Pharmacy Practice, 2021, p. 2). Good Pharmacy Practice (GPP) in Serbia is based on four core principles: patient well-being, optimal use of medicines, promotion of rational and cost-effective prescribing and dispensing, effective communication and multidisciplinary collaboration in the provision of pharmaceutical services.

The role of pharmacy practice is “to supply citizens with medicines, medical devices, and other health-relevant products; to provide services and offer advice and guidance on the correct use of medicines and other products, adverse effects, and potential drug interactions. In recent years, the term ‘pharmaceutical healthcare’ has been adopted as the essence of pharmacy practice, with patients and society as the primary beneficiaries of pharmacists’ activities” (Jović & Tasić, 2009, p. 2). The healthcare system as a whole “is reflected in the delivery of services. Pharmaceutical services provided in pharmacies directly impact people’s health and quality of life. Pharmacists are obliged to ensure that the service provided to each patient meets appropriate quality standards, achieved through compliance with the requirements of GPP” (Jović & Tasić, 2009, p. 3).

To fulfill these principles, the following conditions are necessary: "the pharmacist must conduct pharmacy practice in accordance with the GPP Guide and the established quality system for pharmacy services; assessment and development of competencies should follow the National Framework for the Assessment of Pharmacist Competencies to ensure high-quality pharmaceutical healthcare; educational programs for the pharmacy profession should be competency-based and aligned with current needs and developments in pharmacy practice; the pharmacist must have access to up-to-date, evidence-based, independent, comprehensive, and objective information regarding therapy, medicines, and other health-promoting products; continuous collaboration with other healthcare professionals, particularly physicians, should be established as a partnership related to patient therapy, based on mutual trust regarding all pharmacotherapy matters; the pharmacist must have access to information about the patient's health status and ongoing therapy, which is necessary to provide quality pharmaceutical services; the pharmacist should actively participate in the pharmacovigilance system, including reporting suspected quality defects of medicines and medical devices, as well as suspected falsified medicines, in accordance with relevant laws regulating medicinal products and medical devices, which enables the pharmacist to report and collect feedback on adverse reactions to medicines and medical devices; the pharmacist must identify, document, and report problems related to medicines; the pharmacist must comply with regulations for the management of pharmaceutical waste" (Guide to Good Pharmacy Practice, 2021, p. 11).

Conclusion

The expansive production and use of medicines at the global level has been driven partly by the rapid development of the pharmaceutical industry and partly by the needs of modern medicine, which has evolved toward increasingly combined applications of medicines and medical treatments as an almost universal practice. Modern types of medicines have become not only significantly more effective compared to earlier formulations and effects, but also more specific in their modes of action. It is considered that any drug therapy necessarily implies coherence in the approach of all participants, including the patient, the physician, the pharmacist, and other professionals involved in providing the necessary medical services.

As stated at the outset, the healthcare system represents one of the most complex systems in any country.

At the national level, each state has established a legal framework governing the types and handling of medicines, as well as other key aspects, based on the adoption of relevant laws and subordinate regulations. Rights and obligations are defined, particularly regarding the quality, efficacy, and safety of medicines. It should be noted that the development of legal regulation in this field in most countries has been primarily driven and stimulated by numerous harmful consequences resulting from the consumption of medicines that were not adequately regulated. New laws have been enacted to ensure greater safety of medicines for both humans and animals.

Of particular importance is the upward trend in the adoption of national standards in pharmacy related to healthcare principles, which are included and implemented through the established concept of good pharmacy practice in the majority of countries worldwide.

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Pravna regulativa o vrstama i tretmanu lekova uz osvrt na principe Dobre apotekarske prakse u pružanju farmaceutske usluge u Srbiji

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Sažetak

Zdravstveni sistem predstavlja jedan od najsloženijih sistema u bilo kojoj državi. Članom 65. Zakona o zdravstvenoj zaštiti uređeno je da se u zdravstvenu delatnost na primarnom nivou zdravstvene zaštite ubraja, između ostalog i farmaceutska zdravstvena zaštita. Na nacionalnom nivou svaka država ima uspostavljen pozitivnopravni sistem uređenja oblasti koja se odnosi na vrste i tretman lekova, kao i svih drugih ključnih pitanja, a koji je zasnovan na donošenju odgovarajućih zakona i podzakonskih akata. Smatra se da svaka terapija lekom obavezno imlicira koherentnost u pristupu svih učesnika - i pacijenta, i lekara, i farmaceuta, kao i drugih učesnika u ovom procesu čije su medicinske usluge potrebne. U radu je nakon kraćeg osvrta na pojam i značaj farmaceutske delatnosti, lekova i medicinskih sredstava, analizirana pravna regulativa koja uređuje vrste i tretman lekova, pri čemu su pored analize važećih zakona predstavljeni i relevantni podzakonski akti. Na kraju, učininjen je osvrt na principe Dobre apotekarske prakse u pružanju farmaceutske usluge u Srbiji.

Ključne reči: lek, medicinsko sredstvo, farmaceutska delatnost, Dobra apotekarska praksa, zdravstvena zaštita