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U pripremi Novi Zakon o apotekarskoj delatnosti koji će regulisati celokupnu oblast apotekarske delatnosti

Dana 02. februara 2017. godine završena je javna rasprava koju je sproveo Ministarstvo zdravlja Republike Srbije povodom nacra Zakona o apotekarskoj delatnosti (u daljem tekstu: „Zakon“).

Zakon (i podzakonski akti koji bi trebalo da budu doneti na osnovu ovog Zakona) bi trebalo da reformiše apotekarsku delatnost uvođenjem brojnih novina poput uvođenja pojačanog inspeksijskog nadzora, formiranja jedinstvenog registra apoteka za teritoriju Republike Srbije, kao i uvođenja novih demografskih i geografskih kriterijuma za otvaranje apoteka (poput odredbe čl. 10. nacra Zakona kojom je propisano da najmanja udaljenost između apoteka, merena po osnovu rastojanja na mapi postojeće putne mreže, iznosi 300 metara). Dodatno, jedan od glavnih predloga Farmaceutске komore Srbije u vezi sa nacrtom Zakona jeste da bi Zakon trebalo da obezbedi uslove za uvođenje jedinstvene maloprodajne cene lekova, a sve u cilju obezbeđivanja dostupnosti lekova pod jednakim uslovima svim pacijentima u Republici Srbiji.

Međutim, posebnu pažnju privukla je i odredba čl. 13. nacra Zakona kojom je onemogućeno osnivanje apotekarske ustanove fizičkim i pravnim licima koja obavljaju poslove iz oblasti proizvodnje lekova, odnosno medicinskih sredstava, poslove prometa lekova i medicinskih sredstava na veliko, kao i nosiocima dozvole za stavljanje leka u promet, direktorima, članovima nadzornog, odnosno upravnog odbora, zaposlenima u tom pravnom licu, kao i drugim licima sa posebnim ovlašćenjima u tom pravnom licu, neposredno ili posredno preko povezanih lica, a sve u cilju izbegavanja sukoba interesa.

Dodatno, jednu od značajnih novina uvedenih novim nacrtom Zakona predstavlja i odredba čl. 23. nacra Zakona kojom je zabranjen prenos osnivačkih prava nad apotekama čiji je osnivač Republika Srbija, odnosno autonomna pokrajina na druga pravna ili fizička lica. Međutim, određena organizaciona jedinica apotekarske ustanove može se dati u zakup fizičkom ili pravnom licu na način i pod uslovima propisanim novim

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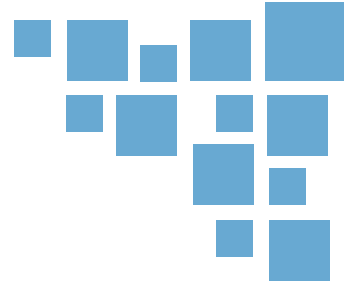
The new Law on Activities of Pharmacies which will regulate entire field of the pharmaceutical activity is in preparation

On 2th February 2017 the public hearing related to the draft of the Law on Activities of Pharmacies (hereinafter: the “Law”) held by the Ministry of Health of the Republic of Serbia has been finished.

The Law (and bylaws which should be enacted on the basis of the Law) should reform activities of pharmacies (both state owned and private practices) by introduction of a number of novelties such as providing an intensified inspection, forming unique registry of pharmacies for the territory of Republic of Serbia, as well as introduction of new demographic and geographic criteria for opening of the pharmacies (such as the provision of Article 10 of the draft of the Law which prescribes that the minimum distance between pharmacies, measured on the basis of the distance on the map of the existing road network, is 300 meters). In addition, one of the main suggestions of the Pharmaceutical Chamber of Serbia with respect to the draft of the Law is that it should provide conditions for introduction of single retail medicines price, all in order to ensure availability of medicines under equal conditions to all patients in the Republic of Serbia.

However, the special attention has attracted the provision of the draft of the Law by which is forbidden to natural persons and legal entities who perform activities of the production of the medicines or medical devices, wholesale of the medicines and medical devices, as well as the holders of the marketing authorizations, directors, members of supervisory or management board, employees of that legal entity, as well as other persons with special authorization in that legal entity, directly or indirectly through their affiliated persons to establish pharmacies, all in order to avoid conflict of interests.

Additionally, one of the most important novelties introduced by the new draft of the Law represents the provision of Article 23 of the draft of the Law which prohibits transfer of founder's rights over the pharmacies established by the Republic of Serbia or autonomous province to other legal entities or natural persons. However, certain organizational unit of the pharmaceutical facility may be leased to natural person or legal



novim nacrtom Zakona.

Nacrt Zakona propisuje i nove uslove u pogledu opremljenosti, kvadrature i broja zaposlenih farmaceuta u apotekama. Tako, minimalna kvadratura apotekarske ustanove iznosi 60 m², naspram nekadašnjih 45 m². Sa druge strane, kada su u pitanju apoteke privatne prakse, novi Zakon propisuje istu kvadraturu kao i prethodni (30 m²), međutim ukoliko radno vreme apoteke privatne prakse zahteva prisustvo dva zaposlena farmaceuta, ista mora imati najmanje 40 m² korisnog prostora.

U pravnom sistemu Republike Srbije, oblast apotekarske delatnosti do sada je bila uređena većim brojem zakona i podzakonskih akata (Zakonom o zdravstvenoj zaštiti, Pravilnikom o bližim uslovima za obavljanje zdravstvene delatnosti u zdravstvenim ustanovama i drugim oblicima zdravstvene službe, itd.). Stoga donošenje jednog unifikovanog pravnog akta ima za cilj da u velikoj meri olakša uređenje celokupne oblasti apotekarske delatnosti, kao i drugih pitanja od značaja za istu.

Odredbama nacrta Zakona, predviđen je rok od 12 meseci od njegovog stupanja na snagu za usklađivanje poslovanja svih oblika apotekarske delatnosti, te stoga apotekarske ustanove i privatne prakse koje u navedenom roku ne usklade svoje poslovanje sa odredbama ovog Zakona prestaće da postoje po sili zakona.

Imajući u vidu da je u okviru održane rasprave pristigao veliki broj predloga za izmene i dopune Zakona, te da se pristupilo analizi i implementiranju navedenih predloga u Zakon, očekuje se da će u skorije vreme biti objavljen konačan tekst Zakona na internet portalu Ministarstva zdravlja.

Za više informacija o ovome kontaktirati



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entity in the manner and under the conditions prescribed by the new draft of the Law.

The draft of the Law also prescribes new requirements related to equipment, size and number of employed pharmacists in pharmacies. Thus, the minimum size of state owned pharmacies is 60 m² instead of the former 45 m². On the other hand, when it comes to pharmacies private practices, the new Law prescribes the same size as the previous one (30 m²). However, if working hour of pharmacy private practice requires the presence of two employed pharmacists, then it must have at least 40 m² of usable space.

In the legal system of the Republic of Serbia, activities of pharmacies have been so far regulated by many laws and by-laws (Law on Health Care, Rulebook on Detailed Conditions for Performing Health Activity in Health Facilities and Other Forms of Health Services etc.). Therefore, enactment of one unified legal act has the aim to significantly simplify legal framework of the whole activity of pharmacies, as well as other important questions related to it.

The provisions of the draft of the Law stipulate a period of 12 months from its coming into effect for harmonization of the activities of all forms of pharmacies (state owned and private practices). Therefore, state owned pharmacies and pharmacies private practises which fail to harmonize their activities with provisions of this Law within provided period shall cease to exist by force of the law.

Considering that the huge number of suggestions for amendments and modification of Law have been submitted and that analysis and implementation of stated suggestions in Law is in process, it is expected that the final text of the Law will be published soon on the website of the Ministry of Health of the Republic of Serbia.

For more information about this please contact:



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