

BOGOMOLETS NATIONAL MEDICAL UNIVERSITY

Department of Forensic Medicine and Medical Law

GUIDELINES to the lecture No. 1 ON TOPIC No. 2:

"Pharmaceutical law and pharmaceutical legislation. Basic concepts and categories"

Study discipline	Pharmaceutical Law and Legislation
Educational qualification	second (master's) level of higher education
Branch of knowledge	22 "Healthcare"
Specialty	226 "Pharmacy, Industrial Pharmacy"
Educational program	educational-professional program "Pharmacy" for second (master's) level of higher education, specialty 226 "Pharmacy, Industrial Pharmacy"

Approved: at the meeting of the department of forensic medicine and medical law on August 27, 2024, protocol No. 1.

Considered and approved: at the meeting of the cyclic methodical commission for natural sciences dated August 28, 2024, protocol No. 1.

The methodical development was made by **A.B. Berzina**, associate professor of the Department of Forensic Medicine and Medical Law of Bogomolets National Medical University, candidate of legal sciences, associate professor.

Type of lecture: traditional.

Competences: ability to use knowledge of regulatory and legislative acts of Ukraine and recommendations of proper pharmaceutical practices in professional activities.

Purpose: within the scope of this topic, special attention is paid to the formation of knowledge and ideas among future employees of the pharmaceutical industry about the theoretical foundations of law and pharmaceutical legislation; acquisition of systemic legal knowledge regarding the regulation of pharmaceutical activity and the circulation of medicinal products, as well as the formation of skills for reasoned decision-making to ensure the effective functioning of pharmaceutical enterprises and pharmaceutical provision of the population.

Lecture equipment: personal computer.

Tasks of the lecture:

1. Get acquainted with the basics of pharmaceutical jurisprudence, the system of pharmaceutical law and pharmaceutical legislation, determine the relationship between pharmaceutical law and pharmaceutical legislation, find out the peculiarities of legal relations arising in the process of pharmaceutical activity.
2. Know and learn: the concept and system of pharmaceutical law and pharmaceutical legislation and their relationship; the relationship of pharmaceutical jurisprudence with medical and legal disciplines; concepts, types and composition of pharmaceutical legal relations.
3. Master the skills: independently read and understand the content of legislative acts that are of general importance, be able to work with legal literature and regulatory acts; know the content and comply with the provisions of those normative legal acts that relate to the future specialty and operate only in the field of public health protection; independently acquire the necessary legal knowledge, organize and quickly find the necessary regulatory documents, understand their requirements and choose a lawful option of behavior.

Lecture plan:

№	The main stages of the lecture and their content	1) Type of lecture. 2) Means of student activation. 3) Methodological support materials.	Time
1	2	3	4

1) Preparatory stage			
	Determination of relevance of the topic, educational goals of the lecture and motivation (I, II, III, IV)	Thematic lecture.	5
2) The main stage			
	Plan 1. What is pharmaceutical law? 2. What are the components of pharmaceutical law? 3. What is the difference between the system of pharmaceutical law and the system of pharmaceutical legislation? 4. What is the subject of regulation of pharmaceutical legislation? 5. What is the system of pharmaceutical legislation? 6. What normative legal acts are constituent elements of the system of pharmaceutical legislation? 7. What is the field of law? 8. How does pharmaceutical law relate to other areas of law? 9. What medical and legal disciplines is pharmaceutical law related to? What is the manifestation of such a relationship? 10. What are legal relations in the field of pharmaceutical activity? 11. What are the elements of legal relations in the field of pharmaceutical activity?	Questions, problematic situations.	70
3) The final stage			
	Summary of the lecture, general conclusions. Answers to possible questions. Tasks for self-training of students.	Educational literature, tasks, questions	15

Recommended literature

International legal standards

1. Dyrektyva 2001/83/YES Yevropeys'koho parlamentu i Rady YES vid 06.11.2001 r. «Pro zvid zakoniv Spivtovarystva shchodo likars'kykh zasobiv dlya lyudyny».
2. Yevropeys'ka sotsial'na khartiya: Rada Yevropy; Khartiya vid 18.10.1961 r. № ETS № 35. – [Elektronnyy resurs]. – Rezhym dostupu: http://zakon1.rada.gov.ua/laws/show/994_062.
3. Konventsiya pro zakhyst prav lyudyny i osnovopolozhnykh svobod: Rada Yevropy; Konventsiya vid 04.11.1950 r. – [Elektronnyy resurs] – Rezhym dostupu: http://zakon4.rada.gov.ua/laws/show/995_004.

4. Konventsia pro pidroblennya medychnoyi produktsiyi ta podibni zlochyntsy, shcho zahrozhuyut' okhoroni zdorov"ya: Rada Yevropy; Konventsia vid 28.10.2011 r. – [Elektronnyy resurs] – Rezhym dostupu: http://zakon2.rada.gov.ua/laws/show/994_a91.

National legislation

1. Hospodars'kyi kodeks Ukrainy: Kodeks Ukrainy vid 16.01.2003 r. № 436-IV (iz zminamy) // Vidomosti Verkhovnoyi Rady Ukrainy. – 2003. – № 18, № 19–20, № 21–22. – St. 144.

2. Etychnyy kodeks likarya Ukrainy. – Pryynyaty ta pidpysany Vseukrayins'kym z"yizdom likars'kykh orhanizatsiy ta X Z"yizdom Vseukrayins'koho likars'koho tovarystva (VULT) vid 27 veresnya 2009 r. – [Elektronnyy resurs]. – Rezhym dostupu: <http://health-ua.com/pics/pdf/19/30-31.pdf>.

3. Kodeks Ukrainy pro administratyvni pravoporushennya: Kodeks Ukrainy vid 07.12.1984 r. № 8073-X (iz zminamy) // Vidomosti Verkhovnoyi Rady Ukrainy RSR. – 1984. – Dodatok do № 51. – St. 1122.

4. Konstytutsiya Ukrainy vid 28.06.1996 r. // Vidomosti Verkhovnoyi Rady Ukrainy – 1996. – № 30. – St. 141.

5. Kryminal'nyy kodeks Ukrainy: Kodeks Ukrainy vid 5 kvitnya 2001 r. (iz zminamy) // Vidomosti Verkhovnoyi Rady Ukrainy. – 2001. – № 25–26. – St. 131.

6. Osnovy zakonodavstva Ukrainy pro okhoronu zdorov"ya: Zakon Ukrainy vid 19.11.1992 r. № 2801-KHII (iz zminamy) // Vidomosti Verkhovnoyi Rady Ukrainy. – 1993. – № 4. – St. 19.

7. Pro dostup do publichnoyi informatsiyi: Zakon Ukrainy vid 13.01.2011 r. № 2939-VI (iz zminamy) // Vidomosti Verkhovnoyi Rady Ukrainy. – 2011. – № 32. – St. 314.

8. Pro zabezpechennya sanitarnoho ta epidemichnoho blahopoluchchya naselennya: Zakon Ukrainy vid 24.02.1994 r. № 4004-XII (iz zminamy) // Vidomosti Verkhovnoyi Rady Ukrainy. – 1994. – № 27. – St. 218.

9. Pro zatverdzhennya Pereliku likars'kykh zasobiv, dozvolenykh do zastosuvannya v Ukraini, yaki vidpuskayut'sya bez retseptiv z aptek ta yikh strukturnykh pidrozdiliv: Nakaz Ministerstva okhorony zdorov"ya Ukrainy vid 06.12.2010 r. № 1081. – [Elektronnyy resurs]. – Rezhym dostupu: <http://zakon4.rada.gov.ua/laws/show/z1316-10>.

10. Pro zatverdzhennya Polozhennya pro Derzhavnu sluzhbu Ukrainy z likars'kykh zasobiv: Ukaz Prezydenta Ukrainy vid 08.04.2011 r. № 440/2011 (iz zminamy). – [Elektronnyy resurs]. – Rezhym dostupu: <http://zakon4.rada.gov.ua/laws/show/440/2011>.

11. Pro zatverdzhennya Poryadku provedennya klinichnykh vyprobuvan' likars'kykh zasobiv ta ekspertyzy materialiv klinichnykh vyprobuvan' i

Typovoho polozhennya pro komisiyi z pytan' etyky: Nakaz Ministerstva okhorony zdorov"ya Ukrainy vid 23.09.2009 r. № 690 (iz zminamy) // Ofitsiyny visnyk Ukrainy. – 2009. – № 87. – St. 2948.

12. Pro zakhyst naseleण्या vid infektsiynykh khvorob: Zakon Ukrainy vid 06.04.2000 r. №1645–III (iz zminamy) // Vidomosti Verkhovnoyi Rady Ukrainy. – 2000. – № 29. – St. 228.

13. Pro zakhyst personal'nykh danykh: Zakon Ukrainy vid 01.06.2010 r. № 2297–VI (iz zminamy) // Vidomosti Verkhovnoyi Rady Ukrainy. – 2010. – № 34. – St. 481.

14. Pro zakhyst prav spozhyvachiv: Zakon Ukrainy 12.05.1991 r. № 1023–XII (iz zminamy) // Vidomosti Verkhovnoyi Rady URSR. – 1991. – № 30. – St. 379.

15. Pro Klyatvu likarya: Ukaz Prezydenta Ukrainy vid 15.06.1992 r. № 349. – [Elektronnyy resurs]. – Rezhym dostupu: <http://zakon4.rada.gov.ua/laws/show/349/92>.

16. Pro likars'ki zasoby: Zakon Ukrainy vid 04.04.1996 r. № 123/96-VR (iz zminamy) // Vidomosti Verkhovnoyi Rady Ukrainy. – 1996. – № 22. – St. 86.

17. Pro litsenzuvannya pevnykh vydiv hospodars'koyi diyal'nosti: Zakon Ukrainy vid 01.06.2000 r. № 1775–III // Vidomosti Verkhovnoyi Rady Ukrainy. – 2000. – № 36. – St. 299.

18. Pro narkotychni zasoby, psykhotropni rechovyny i prekursory: Zakon Ukrainy vid 15.02.1995 r. № 60/95–VR (iz zminamy)) // Vidomosti Verkhovnoyi Rady Ukrainy. – 2007. – № 10. – St. 89.

19. Pro polozhennya pro Ministerstvo okhorony zdorov"ya Ukrainy: Ukaz Prezydenta Ukrainy vid 13.04.2011 r. № 467/2011. – [Elektronnyy resurs]. – Rezhym dostupu: <http://zakon2.rada.gov.ua/laws/show/467/2011>.

20. Pro poryadok provedennya reformuvannya systemy okhorony zdorov"ya u Vinnyts'kiy, Dnipropetrovs'kiy, Donets'kiy oblastiakh ta misti Kyievi: Zakon Ukrainy vid 07.07.2011 r. № 3612–VI (iz zminamy) // Vidomosti Verkhovnoyi Rady Ukrainy. – 2012. – № 12–13. – St. 81.

21. Pro ratyfikatsiyu Yevropeys'koyi sotsial'noyi khartiyyi (perehlyanutoyi): Zakon Ukrainy vid 14.09.2006 r. № 137–V // Vidomosti Verkhovnoyi Rady Ukrainy. – 2006. – № 43. – St. 418.

22. Pro ratyfikatsiyu Konventsiyyi Rady Yevropy pro pidroblennya medychnoyi produktsiyyi ta podibni zlochyny, shcho zahrozhuyut' okhoroni zdorov"ya: Zakon Ukrainy vid 07.06.2012 r. № 4908–VI // Vidomosti Verkhovnoyi Rady. – 2013. – № 17. – St. 160.

23. Pro Rekomendatsiyyi parlament's'kykh slukhan' na temu: «Prosuchasnyy stan ta perspektyvy rozvytku farmatsevtichnoyi haluzi Ukrainy»: Postanova Verkhovnoyi Rady Ukrainy vid 06.10.2011 r. № 3901–VI // Vidomosti Verkhovnoyi Rady Ukrainy. – 2012. – № 21. – St. 205.

24. Pro rishennya Rady natsional'noyi bezpeky i oborony Ukrainy vid 25 travnya 2012 roku «Pro zabezpechennya naseleण्या yakisnymi ta dostupnymi likars'kymy zasobamy»: Ukaz Prezydenta Ukrainy vid 30.08.2012 r. №

526/2012. – [Elektronnyy resurs]. – Rezhym dostupu: <http://zakon4.rada.gov.ua/laws/show/n0004525-12>.

25. Tsyvil'nyy kodeks Ukrayiny: Kodeks Ukrayiny vid 16.01.2003 r. № 435–IV (iz zminamy) // Vidomosti Verkhovnoyi Rady Ukrayiny. – 2003. – № № 40–44. – St. 356.

Recommended literature

1. Hrazhdansko-pravovye otnosheniya v farmatsevticheskom sektore Ukrayny: Konspekt lektsyy. / V.A. Shapovalova, A.S. Abrosymov, V.V. Shapovalov, N.M. Khalyn. – KH., 2002. – 17 s.
2. Lytsenzyrovanye v Evropeyskom Soyuze: farmatsevtichesky sektor / Red.-sost. V.A. Usenko, L.A. Spasokukotsky. – K.: Moryon LTD, 1998. – 384 s.
3. Pravovi osnovy diyal'nosti medychnykh i farmatsevtichnykh pratsivnykiv: navchal'nyy posibnyk / Babanin A.A., Yasins'ky V.I. – Simferopol', 2002. – 432 s.
4. Suchasne ukrayins'ke medychne pravo: Monohrafiya / Za zah. red. S.H. Stetsenka. – K.: Atika, 2010. – 496 s.
5. Farmatsevtichne zakonodavstvo Ukrayiny: Zbirnyk normatyvno-pravovykh aktiv stanom na 1 veresnya 2012 r. dlya studentiv farmatsevtichnykh fakul'tetiv / A.A. Kotvits'ka, I.V. Kubaryeva, O.O. Surikov, A.V. Volkova. / Za zah. red. prof. A.A. Kotvits'koyi. – KH.: NfaU, 2012. – 344 s.
6. Farmatsevtichne pravo. Navchal'nyy posibnyk do audytornoyi ta pozaaudytornoyi roboty z farmatsevtichnoho zakonodavstva za spetsial'nisty «Farmatsiya» / V.O. Shapovalova, V.V. Shapovalova, V.V. Shapovalov ta in. – KH., 2008. – 144 s.

Additional literature

1. Bratanyuk L.YE. Osnovy prava i zakonodavstva v okhoroni zdorov'ya: pidruchnyk. – K.: Medytsyna, 2011. – 544 s.
2. Buletsa S.B. Pravo fizychnoyi osoby na zhyttya ta zdorov'ya (porivnyal'no-pravovyy aspekt): monohrafiya / S.B. Buletsa. – Uzhhorod: Lira, 2006. – 172 s.
3. Halatsan O.V. Farmatsevtichne i medychne pravo: pro neobkhidnist' reformuvannya okhorony zdorov'ya Ukrayiny dlya pokrashchennya narkolohichnoyi ta kryminohennoyi sytuatsiyi sered naselennya / O.V. Halatsan., V.O. Shapovalova, V.V. Shapovalov // Problemy bezperervnoyi medychnoyi osvity ta nauky. – 2012. – № 3. – S. 16–18.
4. Hladun Z.S. Derzhavna polityka okhorony zdorov'ya v Ukrayini (administratyvno-pravovi problemy formuvannya i realizatsiyi): Monohrafiya. / Z.S. Hladun – Ternopil': «Ekonomichna dumka», 2005. – 460 s.
5. Hryhoryan S.L. Farmatsevticheskoe zakonodatel'stvo ES: ot pervoyi dyrektyvy po sehodnyashnyy den' // Rossyyskiye apteky. – 2004. – № 11. – S. 4–6.

6. Kolyada V.V. Stanovlennya ta podal'she reformuvannya normatyvno-pravovoyi bazy, shcho rehulyuye obih narkotychnykh zasobiv, psykhotropnykh rehovyn ta prekursoriv v Ukrayiny // Farmakolohichnyy visnyk. – 2000. – №6. – S. 2–7.
7. Kolyada V.V., Pastalytsa S.V. Normatyvno-pravovaya baza oborota bezretsepturnykh lekarstvennykh sredstv / Farmatsevticheskie pravo v bezopasnom samolechenyy: lekarstvennye sredstva, otpuskaemye bez retsepta vracha. – KH.: Fakt, 2005. – S. 24–29.
8. Kolyada V.V., Shapovalov V.V., Shapovalova V.O. Farmatsevtichne pravo yak osnova udoskonalennya pravyl rehulyuvannya retsepturnoho ta bezretsepturnoho vidpusku likars'kykh zasobiv v Ukrayini // Liky Ukrayiny. – 2004. – №9 (dodatok). – S.82–84.
9. Maleyna M.N. Chelovek y medytsyna v sovremennom prave: uchebnoe y praktycheskoe posobyie / M.N. Maleyna. – M.: BEK, 1995. – 272 s.
10. Medychne pravo Ukrayiny: zakonodavche zabezpechennya tsaryny okhorony zdorov'ya (henezys, mizhnarodni standarty, tendentsiyi rozvytku y udoskonalennya). Materialy V Vseukrayins'koyi (IV Mizhnarodnoyi) naukovo-praktychnoyi konferentsiyi z medychnoho prava (19–21 travnya 2011 roku, m. Odesa) / Upor. I.YA. Senyuta, KH.YA. Tereshko. – L'viv: LOBF «Medytsyna i pravo», 2011. – 416 s.
11. Pashkov V.M. Oznaky hospodars'ko-pravovykh vidnosyn pry zdiysnenni medychnoho ta farmatsevtichnoho obsluhovuvannya / V. M. Pashkov // Pidpryyemnytstvo, hospodarstvo i pravo. – 2008 (149) – № 5. – S. 53–57.
12. Pashkov V. M. Problemy pravovoho rehulyuvannya vidnosyn u sferi okhorony zdorov'ya (hospodars'ko-pravovyy kontekst) / V.M. Pashkov. – K.: MORION, 2009. – 448 s.
13. Pashkov V.M. Problemy derzhavnogo rehulyuvannya pravovidnosyn u haluzi okhorony zdorov'ya / V.M. Pashkov // Ukrayins'kyy medychnyy chasopys. – 2005. – №5 (49). – S. 64–67.
14. Suchasne ukrayins'ke medychne pravo: monohrafiya / za zah. red. S. H. Stetsenka. – K.: Atika, 2010. – 496 s.
15. Tlumachennya norm farmatsevtichnoho prava u vidpovidnosti do yevropeys'kykh standartiv po optymizatsiyi lehal'noho obihu retsepturnykh i bezretsepturnykh likars'kykh zasobiv / V.V. Shapovalov, Z.S. Halavan, V.V. Kolyada, V.O. Shapovalova, V.V. Shapovalov // Visnyk farmakolohiyi ta farmatsiyi. – 2005. – №7. – S.27–30.
16. Shatkovs'kyy YA.M. Obov'yazkove medychne strakhuvannya v Ukrayini: pravovi problemy ta perspektyvy yikh vyrishennya / YA.M. Shatkovs'kyy // Visn. L'viv. un-tu. Ser. yurydychna. – 2008. – № 1. – S. 98–102.

Questions for student self-preparation for the lecture:

1. What is pharmaceutical law?

2. What are the components of pharmaceutical law?
3. What is the difference between the system of pharmaceutical law and the system of pharmaceutical legislation?
4. What is the subject of regulation of pharmaceutical legislation?
5. What is the system of pharmaceutical legislation?
6. What normative legal acts are constituent elements of the system of pharmaceutical legislation?
7. What is the field of law?
8. How does pharmaceutical law relate to other areas of law?
9. What medical and legal disciplines is pharmaceutical law related to? What is the manifestation of such a relationship?
10. What are legal relations in the field of pharmaceutical activity?
11. What are the elements of legal relations in the field of pharmaceutical activity?

Questions for preparation for Final Control, which are revealed by the lecture material

1. What is pharmaceutical law?
2. What is pharmaceutical legislation?
3. What are the components of pharmaceutical law?
4. What is the difference between the system of pharmaceutical law and the system of pharmaceutical legislation?
5. What is the field of law?
6. What is the subject of regulation of pharmaceutical legislation?
7. What is the system of pharmaceutical legislation?
8. What normative legal acts are constituent elements of the system of pharmaceutical legislation?
9. How does pharmaceutical law relate to other areas of law?
10. What medical and legal disciplines is pharmaceutical law related to? What is the manifestation of such a relationship?
11. What are legal relations in the field of pharmaceutical activity?
12. What elements are components of legal relations in the field of pharmaceutical activity?
13. Who is the subject of pharmaceutical legal relations?
14. What is the object of pharmaceutical legal relations?
15. What is the content of pharmaceutical legal relations?