

BOGOMOLETS NATIONAL MEDICAL UNIVERSITY

Department of Forensic Medicine and Medical Law

GUIDELINES to the lecture No. 6 ON TOPIC No. 8:

«Legislative foundations of state supervision (control) in the field of pharmaceutical activity»

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: professional activity by a pharmacist must be carried out under conditions of transparency and openness, because the life and health of a person may depend on it. Therefore, it is relevant to determine at the state level measures of state supervision (control) in the sphere of circulation of medicines and medical devices. In case of non-compliance with the legislation, such persons may be subject to administrative, criminal or civil liability.

Lecture equipment: personal computer.

Tasks of the lecture:

1. Get acquainted with the main grounds of legal responsibility, the concept of legal responsibility and its types; general issues of legal responsibility of pharmaceutical workers; measures of state supervision (control) in the sphere of circulation of medicines and medical devices.
2. Know and learn: the grounds for conducting inspections of business entities to ensure the quality of medicinal products; the concept of legal responsibility of pharmaceutical workers, types and grounds of legal responsibility; the basics of state policy to combat the circulation of unregistered, falsified, substandard medicinal products.
3. Master the skills: use of the rights and fulfillment of the obligations of economic entities during the implementation of state supervision in the sphere of circulation of medicines and medical devices; differentiation of illegal actions of pharmaceutical workers by degree of severity and establishing the type of responsibility.

Lecture plan:

№	The main stages of the lecture and their content	1) Type of lecture. 2) Means of student activation.	Time
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		3) Methodological support materials.	
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			
	<p>Plan</p> <ol style="list-style-type: none"> 1. Legislative principles of state supervision (control) in the field of economic activity. State policy on combating the circulation of unregistered, falsified, substandard medicinal products. 2. Measures of state supervision (control) in the sphere of circulation of medicines and medical devices. 3. Grounds for conducting inspections of business entities regarding the quality assurance of medicinal products. Administrative documents based on the results of inspections: prescriptions and orders. 4. Rights and obligations of a business entity during state supervision. 5. Regulation of the procedure for the selection of samples of medicinal products for state control and quality. Terms of laboratory analysis and drawing up a conclusion on quality. 6. Requirements for the procedure for monitoring compliance with licensing conditions for conducting activities and wholesale trade in medicinal products. 7. Administrative responsibility for violations of legislation in the sphere of circulation of medicines and medical products. 8. Criminal liability for violation of legislation in the field of circulation of medicinal products. <p>International cooperation in the field of combating the distribution of falsified medicinal products.</p> <ol style="list-style-type: none"> 9. The mechanism of interaction of territorial divisions of the State Service of Medicinal Products with law enforcement bodies and other bodies of the executive power. 	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
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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. Konventsiya pro pidroblennya medychnoyi produktsiyi ta podibni zlochyny, shcho zahrozhuyut' okhoroni zdorov'ya: Rada Yevropy; Konventsiya vid 28.10.2011 r. – [Elektronnyy resurs] – Rezhym dostupu: http://zakon2.rada.gov.ua/laws/show/994_a91.

National legislation

1. Hospodars'ky kodeks Ukrayiny: Kodeks Ukrayiny vid 16.01.2003 r. № 436-IV (iz zminamy) // Vidomosti Verkhovnoyi Rady Ukrayiny. – 2003. – № 18, № 19–20, № 21–22. – St. 144.
2. Etychnyy kodeks likarya Ukrayiny. – Pryynyatyy 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 Ukrayiny pro administratyvni pravoporushennya: Kodeks Ukrayiny vid 07.12.1984 r. № 8073–X (iz zminamy) // Vidomosti Verkhovnoyi Rady Ukrayins'koyi RSR. – 1984. – Dodatok do № 51. – St. 1122.
4. Konstytutsiya Ukrayiny vid 28.06.1996 r. // Vidomosti Verkhovnoyi Rady Ukrayiny – 1996. – № 30. – St. 141.
5. Kryminal'nyy kodeks Ukrayiny: Kodeks Ukrayiny vid 5 kvitnya 2001 r. (iz zminamy) // Vidomosti Verkhovnoyi Rady Ukrayiny. – 2001. – № 25–26. – St. 131.
6. Osnovy zakonodavstva Ukrayiny pro okhoronu zdorov'ya: Zakon Ukrayiny vid 19.11.1992 r. № 2801–KHII (iz zminamy) // Vidomosti Verkhovnoyi Rady Ukrayiny. – 1993. – № 4. – St. 19.

7. Pro dostup do publichnoyi informatsiyi: Zakon Ukrayiny vid 13.01.2011 r. №2939–VI (iz zminamy) // Vidomosti Verkhovnoyi Rady Ukrayiny. – 2011. – № 32. – St. 314.
8. Pro zabezpechennya sanitarnoho ta epidemichnoho blahopoluchchya naselennya: Zakon Ukrayiny vid 24.02.1994 r. № 4004–XII (iz zminamy) // Vidomosti Verkhovnoyi Rady Ukrayiny. – 1994. – № 27. – St. 218.
9. Pro zatverdzhennya Pereliku likars'kykh zasobiv, dozvolenykh do zastosuvannya v Ukrayini, yaki vidpuskayut'sya bez retseptiv z aptek ta yikh strukturnykh pidrozdiliv: Nakaz Ministerstva okhorony zdorov"ya Ukrayiny 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 Ukrayiny z likars'kykh zasobiv: Ukaz Prezydenta Ukrayiny 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 Ukrayiny vid 23.09.2009 r. № 690 (iz zminamy) // Ofitsiyyny visnyk Ukrayiny. – 2009. – № 87. – St. 2948.
12. Pro zakhyst naselennya vid infektsiynykh khvorob: Zakon Ukrayiny vid 06.04.2000 r. №1645–III (iz zminamy) // Vidomosti Verkhovnoyi Rady Ukrayiny. – 2000. – № 29. – St. 228.
13. Pro zakhyst personal'nykh danykh: Zakon Ukrayiny vid 01.06.2010 r. № 2297–VI (iz zminamy) // Vidomosti Verkhovnoyi Rady Ukrayiny. – 2010. – № 34. – St. 481.
14. Pro zakhyst prav spozhyvachiv: Zakon Ukrayiny 12.05.1991 r. № 1023–XII (iz zminamy) // Vidomosti Verkhovnoyi Rady URSR. – 1991. – № 30. – St. 379.
15. Pro Klyatvu likarya: Ukaz Prezydenta Ukrayiny 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 Ukrayiny vid 04.04.1996 r. № 123/96-VR (iz zminamy) // Vidomosti Verkhovnoyi Rady Ukrayiny. – 1996. – № 22. – St. 86.
17. Pro litsenzuvannya pevnykh vydiv hospodars'koyi diyal'nosti: Zakon Ukrayiny vid 01.06.2000 r. № 1775–III // Vidomosti Verkhovnoyi Rady Ukrayiny. – 2000. – № 36. – St. 299.
18. Pro narkotychni zasoby, psykhotropni rehovyny i prekursori: Zakon Ukrayiny vid 15.02.1995 r. № 60/95–VR (iz zminamy) // Vidomosti Verkhovnoyi Rady Ukrayiny. – 2007. – № 10. – St. 89.
19. Pro polozhennya pro Ministerstvo okhorony zdorov"ya Ukrayiny: Ukaz Prezydenta Ukrayiny vid 13.04.2011 r. № 467/2011. – [Elektronnyy resurs]. – Rezhym dostupu: <http://zakon2.rada.gov.ua/laws/show/467/2011>.

20. Pro porjadok provedennya reformuvannya systemy okhorony zdorov"ya u Vinnyts'kiy, Dnipropetrovs'kiy, Donets'kiy oblastiakh ta misti Kyjevi: 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 (perekhlyanutoyi): Zakon Ukrainy vid 14.09.2006 r. № 137-V // Vidomosti Verkhovnoyi Rady Ukrainy. – 2006. – № 43. – St. 418.
22. Pro ratyfikatsiyu Konventsiyi Rady Yevropy pro pidroblennya medychnoyi produktsiyi 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 Rekomendatsiyi parlament's'kykh slukhan' na temu: «Prosuchasnyy stan ta perspektyvy rozvytku farmatsevychnoyi 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 naseleння yakisnymy ta dostupnymy 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 Ukrainy: Kodeks Ukrainy vid 16.01.2003 r. № 435-IV (iz zminamy) // Vidomosti Verkhovnoyi Rady Ukrainy. – 2003. – № № 40–44. – St. 356.

Recommended literature

1. Hrazhdansko-pravovye otnosheniya v farmatsevycheskom sektore Ukrainy: Konspekt lektsyy. / V.A. Shapovalova, A.S. Abrosymov, V.V. Shapovalov, N.M. Khalyn. – KH., 2002. – 17 s.
2. Lytsenzyrovanye v Evropeyskom Soyuze: farmatsevycheskyy sektor / Red.-sost. V.A. Usenko, L.A. Spasokukotskyy. – K.: Moryon LTD, 1998. – 384 s.
3. Pravovi osnovy diyal'nosti medychnykh i farmatsevychnykh pratsivnykiv: navchal'nyy posibnyk / Babanin A.A., Yasins'kyy 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. Farmatsevychne zakonodavstvo Ukrainy: Zbirnyk normatyvno-pravovykh aktiv stanom na 1 veresnya 2012 r. dlya studentiv farmatsevychnykh 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. Farmatsevychne pravo. Navchal'nyy posibnyk do audytornoyi ta pozaaudytornoyi roboty z farmatsevychnoho 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. Farmatsevychnye i medychne pravo: pro neobkhdnist' 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. Farmatsevycheskoe zakonodatel'stvo ES: ot pervoy 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 / Farmatsevycheskoe 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. Farmatsevychnye 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) naukovopraktychnoyi 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 farmatsevychnoho obsluhovuvannya / V. M. Pashkov // Pidpnyemnytstvo, 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 medychno pravo: monohrafiya / za zah. red. S. H. Stetsenka. – K.: Atika, 2010. – 496 s.
15. Tlumachennya norm farmatsevychnoho 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'kyi YA.M. Obov'yazkove medychno strakhuvannya v Ukrayini: pravovi problemy ta perspektyvy yikh vyrishennya / YA.M. Shatkovs'kyi // Visn. L'viv. un-tu. Ser. yurydychna. – 2008. – № 1. – S. 98–102.

Questions for student self-preparation for the lecture:

1. What are the legislative principles of state supervision (control) in the field of economic activity?
2. What is the essence of the state policy aimed at combating the circulation of unregistered, falsified, substandard medicinal products?
3. What measures of state supervision (control) in the field of drug circulation are common in Ukraine?
4. Indicate the grounds for conducting inspections of economic entities regarding the quality assurance of medicinal products.
5. What administrative documents are formed based on the results of inspections in the field of circulation of medicines and medical products?
6. Describe the rights and responsibilities of a business entity during the implementation of state supervision in the sphere of circulation of medicines and medical devices.
7. How is the procedure for selecting samples of medicinal products for state control and quality regulated?
8. Name the requirements for the procedure for monitoring compliance with licensing conditions for conducting activities and wholesale trade in medicinal products.
9. Describe the administrative responsibility for violations of the legislation in the field of circulation of medicinal products.
10. What are the features of criminal liability for crimes in the sphere of circulation of falsified medicinal products?

11. What is the mechanism of interaction between territorial units of the State Service of Medicinal Products with law enforcement agencies and other executive authorities?

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

1. Legislative principles of state supervision (control) in the field of economic activity.
2. What is the essence of the state policy aimed at combating the circulation of unregistered, falsified, substandard medicinal products?
3. What measures of state supervision (control) in the field of drug circulation are common in Ukraine?
4. Indicate the grounds for conducting inspections of economic entities regarding the quality assurance of medicinal products.
5. What administrative documents are formed based on the results of inspections in the field of circulation of medicines and medical products?
6. Describe the rights and responsibilities of a business entity during the implementation of state supervision in the sphere of circulation of medicines and medical devices.
7. How is the procedure for selecting samples of medicinal products for state control and quality regulated?
8. Name the requirements for the procedure for monitoring compliance with the license terms of the wholesale trade of medicinal products.
9. Describe the administrative responsibility for violations of the legislation in the field of circulation of medicinal products.
10. What are the features of criminal liability for crimes in the sphere of circulation of falsified medicinal products?
11. What is the mechanism of interaction between territorial units of the State Service of Medicinal Products with law enforcement agencies and other executive authorities?