

# BOGOMOLETS NATIONAL MEDICAL UNIVERSITY

Department of Forensic Medicine and Medical Law

## GUIDELINES to the lecture No. 10 ON TOPIC No. 14 :

**«State control over compliance with legislation on sanitary-epidemic well-being, environmental safety, protection of consumer rights and fire prevention supervision Fire prevention supervision. Liability for violation of current legislation»**

<b>Study discipline</b>	Pharmaceutical Law and Legislation
<b>Educational qualification</b>	second (master's) level of higher education
<b>Branch of knowledge</b>	22 "Healthcare"
<b>Specialty</b>	226 "Pharmacy, Industrial Pharmacy"
<b>Educational program</b>	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:** understanding the specifics of state control over compliance with legislation on sanitary-epidemiological well-being, consumer rights protection is relevant given the presence of state standards and prescriptions. Clarifying the features of such mechanisms is one of the elements in the pharmaceutical education system. In order to gain knowledge on the mentioned issue, it is also necessary to find out the specifics of fire prevention supervision and to determine the specifics of responsibility for violating the current legislation.

**Lecture equipment:** personal computer.

**Tasks of the lecture:**

1. Familiarize yourself with the main features of state control over compliance with legislation on sanitary and epidemiological well-being, consumer rights protection.
2. Know and learn: what are the types of liability for violations of current legislation in the field of control and supervision in pharmacy; how can you protect your rights as a consumer.
3. Master the skills: use of regulatory legal acts in the field of pharmaceuticals; international legal standards, international legal norms of pharmaceutical direction.

**Lecture plan:**

No	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			

	<p>Plan</p> <ol style="list-style-type: none"> <li>1. Sanitary and epidemiological surveillance in Ukraine.</li> <li>2. Normative and legal regulation of sanitary and epidemiological well-being.</li> <li>3. Inspections by SES bodies, registration of inspection results. Measures to eliminate violations of sanitary legislation.</li> <li>4. Liability of legal entities and individuals for violation of the requirements of the legislation on sanitary and epidemiological well-being of the population.</li> <li>5. Legislation of Ukraine on environmental safety. Demarcation of powers of SES bodies, fire supervision and protection of consumer rights.</li> <li>6. Implementation of state policy in the spheres of state control over compliance with legislation on the protection of consumer rights and legislation on advertising.</li> <li>7. Powers, tasks and functions of the State Service of Ukraine for the Protection of Consumer Rights. State supervision of compliance with technical regulations, standards, norms and rules. Issuance of inspection results. Liability for violation of consumer protection legislation and advertising legislation.</li> </ol> <p>State fire supervision in Ukraine. Rights and responsibilities of citizens and officials to ensure fire safety. The procedure for issuing a permit for the start of work of pharmaceutical organizations by the fire control authorities. Inspections of state fire supervision bodies. Liability for offenses in the field of fire prevention.</p>	<p>Questions, problematic situations.</p>	<p>70</p>
<p>3) The final stage</p>			
	<p>Summary of the lecture, general conclusions.  Answers to possible questions.  Tasks for self-training of students.</p>	<p>Educational literature, tasks, questions</p>	<p>15</p>

**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](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](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](http://zakon2.rada.gov.ua/laws/show/994_a91).

### **National legislation**

1. Hospodars'kyy 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 pidpysanyy 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 naseleння: 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) // Ofitsiynyy visnyk Ukrayiny. – 2009. – № 87. – St. 2948.

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

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

22. Pro ratyfikatsiyu Konventsiyyi Rady Yevropy pro pidroblennya medychnoyi produktsiyyi ta podibni zlochyny, shcho zahrozhuyut' okhoroni zdorov"ya: Zakon

Ukrayiny 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 Ukrayiny»: Postanova Verkhovnoyi Rady Ukrayiny vid 06.10.2011 r. № 3901–VI // Vidomosti Verkhovnoyi Rady Ukrayiny. – 2012. – № 21. – St. 205.

24. Pro rishennya Rady natsional'noyi bezpeky i oborony Ukrayiny vid 25 travnya 2012 roku «Pro zabezpechennya naseleNNya yakisnymy ta dostupnymy likars'kymy zasobamy»: Ukaz Prezydenta Ukrayiny 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 farmatsevycheskom 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: 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 Ukrayiny: 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'nistyuu «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. Farmatsevytchne 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. Farmatsevytcheskoe 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 / Farmatsevytcheskoe 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. Farmatsevytchne 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 posobyе / 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 farmatsevytchnoho 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 derzhavnoho 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 farmatsevytchnoho 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. Sanitary and epidemiological surveillance in Ukraine.
2. Normative and legal regulation of sanitary and epidemiological well-being.
3. Inspections by SES bodies, registration of inspection results. Measures to eliminate violations of sanitary legislation.
4. Liability of legal entities and individuals for violation of the requirements of the legislation on sanitary and epidemiological well-being of the population.
5. Legislation of Ukraine on environmental safety. Demarcation of powers of SES bodies, fire supervision and protection of consumer rights.
6. Implementation of state policy in the spheres of state control over compliance with legislation on the protection of consumer rights and legislation on advertising.
7. Powers, tasks and functions of the State Service of Ukraine for the Protection of Consumer Rights. State supervision of compliance with technical regulations, standards, norms and rules. Issuance of inspection results. Liability for violation of consumer protection legislation and advertising legislation.
8. State fire supervision in Ukraine. Rights and responsibilities of citizens and officials to ensure fire safety. The procedure for issuing a permit for the start of work of pharmaceutical organizations by the fire control authorities. Inspections of state fire supervision bodies. Liability for offenses in the field of fire prevention.

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

1. What is the essence of sanitary and epidemiological surveillance in Ukraine?
2. What normative legal acts regulate sanitary and epidemiological well-being in Ukraine?
3. What is the procedure for inspection by SES bodies?
4. How are the results of inspections of SES bodies processed?
5. Peculiarities of the responsibility of legal entities and individuals for violation of the requirements of the legislation on the sanitary and epidemiological well-being of the population.
6. Describe the legal framework of Ukraine in the field of environmental safety.



7. How are the powers of SES bodies, fire supervision and protection of consumer rights delineated?
8. How is state policy implemented in the spheres of state control over compliance with legislation on the protection of consumer rights and legislation on advertising?
9. Describe the powers, tasks and functions of the State Service of Ukraine for the protection of consumer rights?
10. What liability is established for violation of consumer protection legislation and advertising legislation?
11. What are the features of state fire supervision in Ukraine?
12. What are the rights and obligations of citizens and officials to ensure fire safety?
13. What is the responsibility for offenses in the field of fire prevention.