

BOGOMOLETS NATIONAL MEDICAL UNIVERSITY

Department of Forensic Medicine and Medical Law

GUIDELINES to practical classes of students

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.

Topic 3. Harmonization of pharmaceutical legislation with European norms

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.

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

Purpose: understanding the mechanisms of harmonization of pharmaceutical legislation with European norms is relevant given the presence of international standards in ensuring the quality of medicinal products. Clarifying the features of such mechanisms is one of the basic elements in the pharmaceutical education system. In order to gain knowledge on this issue, it is necessary to find out the peculiarities of the legislation of the European Union in the pharmaceutical field, as well as to understand and distinguish the main types of regulatory documents in the legal field of the EU (directives, regulations, decisions, recommendations).

Equipment: personal computer

Lesson plan and organizational structure

Organizational structure of the lesson				
№	The main stages of the lesson, their content	Control and training methods	Methodological support materials	Time
1	Determination of the basic level of students	Teacher control	Test tasks	30
2	Individual student's work of students when solving situational problems	Oral survey	Teacher's question	30
4	Correction of knowledge, skills and abilities by the teacher	Discussion	Teacher's question. Situational tasks.	20
6	Summary of the lesson		Teacher's conclusions	10
Total 90 minutes (2 academic hours)				

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'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. – Pryynyaty 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 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) // Ofitsiyny 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 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 produktsiyi 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 naselelnya 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. Spasokukotskiy. – K.: Moryon LTD, 1998. – 384 s.
3. Pravovi osnovy diyal'nosti medychnykh i farmatsevychnykh pratsivnykiv: navchal'nyy posibnyk / Babanin A.A., Yasins'kyi 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'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. Farmatsevychne i medychne pravo: pro neobkhdnist' reformuvannya okhorony zdorov'ya Ukrayiny dlya pokrashchennya narkolohichnoyi ta kryminohennoyi sytuatsiyi sered naselelnya / 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. Farmatsevtycheskoe 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 / Farmatsevtycheskoe 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. Farmatsevtychne 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) 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 farmatsevtychnoho 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 farmatsevtychnoho 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 Ukraini: 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 practical training:

1. International organizations that define requirements for pharmaceutical activity in global practice.
2. Peculiarities of the legislation of the European Union in the pharmaceutical field.
3. The main types of regulatory documents in the legal field of the EU: directives, regulations, decisions, recommendations.
4. Normative acts of a recommendatory nature.
5. Legislative bases for harmonization of the domestic regulatory framework of the pharmaceutical sector of health care with directives and norms of the EU and WHO.