

# BOGOMOLETS NATIONAL MEDICAL UNIVERSITY

Department of Forensic Medicine and Medical Law

## GUIDELINES to the lecture No. 8 ON TOPIC No. 11:

**«Legal aspects of foreign economic activity and customs regulation. State quality control of medicinal products and medical devices imported into the customs territory of Ukraine»**

<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:** relevance is also due to the need for future specialists in the field of pharmaceutical activity to possess material devoted to the issue of importing unregistered medicinal products into the territory of Ukraine and exporting controlled groups of medicinal products, combined medicinal products containing a small amount of narcotic drugs or psychotropic substances and precursors.

**Lecture equipment:** personal computer.

**Tasks of the lecture:**

1. Familiarize yourself with the essence of measures regarding the implementation of state control of substances and unpackaged products ("inbulk" products) imported for the production of finished medicinal products, the importation of unregistered medicinal products into the territory of Ukraine and the export of controlled groups of drugs, combined medicinal products containing a small amount of narcotics or psychotropic substances and precursors.
2. Know and learn: legal aspects of foreign economic activity and customs regulation of import/export of medicines and medical products.
3. Master the skills: differentiating the features of import/export of medicines and medical products; to be able to apply theoretical knowledge in practice in the implementation of state quality control of medicinal products.

**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			

	<p>Plan</p> <ol style="list-style-type: none"> <li>1. Licensing and quota system. The mechanism for the implementation of quotas and licenses for the export and import of medicinal products.</li> <li>2. Import of pharmaceutical products into the territory of Ukraine: conditions of import of medicinal products; entities, documents that are the basis for the circulation of imported medicinal products.</li> <li>3. Measures regarding state control of medicinal products imported into the customs territory of Ukraine. Grounds for conducting laboratory analysis of series of imported medicinal products.</li> <li>4. Peculiarities of state control of substances and unpackaged products ("inbulk" products) imported for the production of finished medicinal products.</li> <li>5. Importation of unregistered medicinal products into the territory of Ukraine: grounds for importation determined by law, procedure for importation and issuance of a one-time permit.</li> </ol> <p>Regulatory regulation of importation into the customs territory of Ukraine and exportation beyond its borders of controlled groups of drugs, combined medicinal products containing a small amount of narcotic drugs or psychotropic substances and precursors.</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 zlochynty, 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 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 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 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 naseleण्या 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 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) 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 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. Licensing and quota system. The mechanism for the implementation of quotas and licenses for the export and import of medicinal products.
2. Import of pharmaceutical products into the territory of Ukraine: conditions of import of medicinal products; entities, documents that are the basis for the circulation of imported medicinal products.
3. Measures regarding state control of medicinal products imported into the customs territory of Ukraine. Grounds for conducting laboratory analysis of series of imported medicinal products.
4. Peculiarities of state control of substances and unpackaged products ("inbulk" products) imported for the production of finished medicinal products.
5. Importation of unregistered medicinal products into the territory of Ukraine: grounds for importation determined by law, procedure for importation and issuance of a one-time permit.

Regulatory regulation of importation into the customs territory of Ukraine and exportation beyond its borders of controlled groups of drugs, combined medicinal products containing a small amount of narcotic drugs or psychotropic substances and precursors.

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

1. How is foreign economic activity defined in the legislation of Ukraine?
2. Describe the mechanism of implementation of quotas and licenses when exporting and importing medicinal products.
3. What are the legal principles for the organization and implementation of customs affairs in Ukraine?
4. What is the procedure for customs clearance of goods? What is customs value?
5. What are the conditions and procedure for importing pharmaceutical products into the territory of Ukraine?
6. What can be attributed to the measures regarding the implementation of state control of medicinal products imported into the customs territory of Ukraine?
7. Name the features of state control of substances and unpackaged products ("in bulk" products) imported for the production of finished medicinal products.
8. What are the features of importing unregistered medicinal products into the territory of Ukraine?
9. Are there any peculiarities of importing into the customs territory of Ukraine and exporting controlled groups of drugs, combined drugs containing a small amount of narcotic drugs or psychotropic substances and precursors?