

**PHARMACEUTICAL LAW AND PHARMACEUTICAL LEGISLATION.  
NORMATIVE AND LEGAL REGULATION OF PHARMACEUTICAL  
ACTIVITY**

**Theoretical questions**

1. The law system and the legislation system. National legal systems and the international law.
2. Regulatory legal acts as the sources of the law. Classification of the normative legal acts.
3. The structure of the legislation system in pharmacy. The hierarchy of normative legal acts in the pharmaceutical branch by legal force.
4. Features of the pharmaceutical legislation in the European Union: the main types of legal acts in the EU legal framework.
5. The concept of an offense and its structure. Types of offenses.
6. The concept, features and bases of legal responsibility. Types of legal responsibility.

**List of recommended literature**

1. Pharmaceutical Law and Legislation : the textbook for applicants for higher education / A.A. Kotvitskaya, I.V. Kubarieva, A.V. Volkova, A.V. Cherkashyna, I.V. Zhirova, A.A. Surikov, I.A. Surikova. – Kharkiv : NUPh : Golden Pages, 2019. – 204 p.  
[http://irbis.nuph.edu.ua/full\\_text/2019/2019\\_Farm\\_law\\_textbook\\_angl.pdf](http://irbis.nuph.edu.ua/full_text/2019/2019_Farm_law_textbook_angl.pdf)
2. Council of Europe Convention on Counterfeiting of Medical Products and Similar Crimes involving Threats to Public Health of 07.06.2012.
3. Directive 2011/83 / EC of the European parliament and of the Council of 6 November 2011 «On the Community codereleting to medicinal products for human use» [Electronic resource]. – Access mode:  
[http://ec.europa.eu/health/files/eudralex/vol-1/dir\\_2001\\_83/2001\\_83\\_ec\\_en.pdf](http://ec.europa.eu/health/files/eudralex/vol-1/dir_2001_83/2001_83_ec_en.pdf)

**Tasks:**

*It's possible to work in your training manual «Pharmaceutical Law and Legislation»*

**1. Give the definition of "law"**

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**2. Define differences between the law system and legislative system according to the following list of characteristics. Place the answer in the table**

<i>Characteristics</i>	<i>Law System</i>	<i>Legislative System</i>
Laws and other normative legal acts (President, Government), that ordered in a certain way		+
Norms, rules of conduct, that established and identified by the State		
The inside of the law – the content		
The outside of the law – the form		
Norms branches of law – the material for a separate branch of law		
The logical distribution of legal norms by industry, institutions of law		
The presence the horizontal structure (on branches)		
The presence horizontal and vertical (hierarchical) structure		
The main element – rules of law		
The main element – an article of the Law		
The presence in the structural elements (NLA) section titles, preambles, common definitions		
The absence the exterior details of structural elements of (names sections, articles, chapters)		
The totality of the NLA		
The totality of legal rules		

**3. Name the main legal systems of the world and fill the table 2 with their characteristics.**

<i>Characteristics</i>	<i>Type of the legal systems</i>	
	<b>Roman-German (Continental; Civil Law)</b>	
The main source of law	<b>legal document (Statutes/legislation)</b>	
The lawmaking bodies	<b>public authorities, except court</b>	
Understanding of the rule of law	<b>mandatory rules of behavior</b>	

System of law	principles are codified into a referable system which serves as the primary source of law – codified laws; hierarchical		
Countries	France, Germany, Spain, Ukraine, Russia, Iraq, Turkey, Egypt, Lebanon, Madagascar...		

**4. Define differences between Community law National law. Give definition of types the law of the European Union and complete the table.**

Comparative characteristic of EU normative documents

<i>legal acts</i>	<i>what is law determine</i>	<i>who is addressed</i>	<i>obligation</i>
Directive	the general principles and bases of regulation	all EU countries	mandatory for implementation in each national legislation
Regulation			
Recommendations			
Decision			

**5. Match normative legal acts with bodies of their formation.**

*Normative legal acts:*

- A. Law
- B. Decree
- C. Resolution
- D. Order
- E. Disposition

*Source:*

- 1. Ministry
- 2. President
- 3. Regional State Administration
- 4. Parliament
- 5. Government

**ANSWERS:**

<b>A.</b>	<b>B.</b>	<b>C.</b>	<b>D.</b>	<b>E.</b>
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**6. Select the correct combination from the list of names and functions of state bodies.**

**Functions:**

- a. Perform operational work on state management of public processes, provide stability, public relations that inviolability enshrined in the state;
- b. Supervises the execution and compliance with laws and other normative acts;
- c. Executive functions represent the state in relations with other countries (receives the credentials of foreign ambassadors, signs laws, issues acts, gives state awards, etc.);
- d. ~~Development and adoption of laws (normative acts having the highest legal force);~~
- e. Performed jurisdictional activity, decide specific legal case: the penalties for violations, legal disputes, conflicts between different subjects (economic, labor, family, administrative, etc.).

**The names of public authorities:**

Court, Monarch, **Parliament**, Office of Public Prosecutor, Government, President, Special Supervisory Authorities (public service).

Types and functions of state bodies of the modern state

<i>Classification of state bodies</i>	<i>Functions</i>	<i>Name the public authority</i>
Legislative authorities	<b>Development and adoption of laws (normative acts having the highest legal force)</b>	<b>Parliament</b>

Executive authorities		
Judicial authorities		
Authorities of control and supervision		
Head of state		