

**PERMISSION SYSTEM IN THE FIELD OF THE ECONOMIC ACTIVITY.
LICENSING OF ACTIVITY IN MANUFACTURING, WHOLESALE AND RETAIL
SALE OF MEDICINES, IMPORT OF MEDICINES.
THE LEGISLATIVE FOUNDATION OF THE STATE SURVEILLANCE (CONTROL)
IN THE SPHERE OF TURNOVER OF MEDICINE AND MEDICAL PRODUCTS.**

Theoretical questions:

1. The permission system of Ukraine in the field of the economic activity sphere: basic concepts, structure, functions and principles.
2. Licensing as a component of the control and permission system in the field of the economic activity. The basic principles of the state policy in licensing.
3. Responsibility for offenses related with turnover of medicines and other medical products.

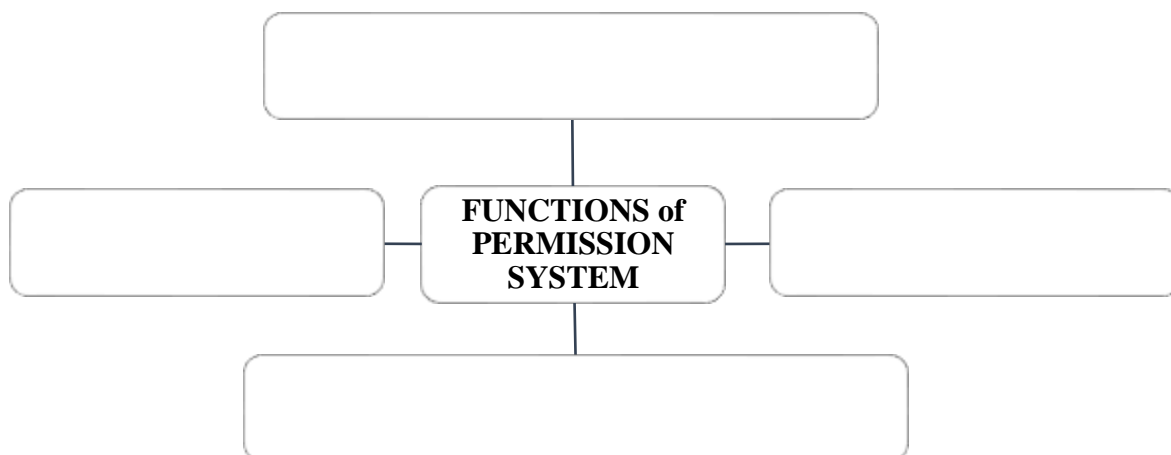
List of recommended literature

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
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

Tasks:

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

1. Describe functions of permission system:



2. Match the terms with their definitions:

<i>terms</i>	<i>definitions</i>
1. AN AUTHORIZATION DOCUMENT	a) a business entity with the license for a definite type of the economic activity
2. A LICENSE	b) a permission, conclusion, decision, approval, certificate, other document, including in the electronic form, that must be issued by a regulatory authority to the business entity in the case of granting the rights in course of certain types of the economic activity
3. A LICENSEE	c) the basic mechanisms of the government control for the activity of the legal and natural persons directed to the concordance of interests of business entities and society as a whole
4. LICENSING CONDITIONS (provisions)	d) a document issued by licensing authority for the right to implement a definite type of the economic activity by an economic entity
5. LICENSING	e) legal acts of Government, provisions which establish an exhaustive list of requirements are mandatory for the licensee and an exhaustive list of documents attached to the application for a license

ANSWERS

1.	2.	3.	4.	5.
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3. Indicate the types of the pharmaceutical activity subjected to licensing *in your country*

4. Describe requirements according to the licensing conditions and documents for obtaining a license for different type of pharmaceutical activity in Ukraine and complete table.

	<i>Production of medicines</i>	<i>Compounding of medicines</i>	<i>Import of medicines</i>	<i>Wholesale</i>	<i>Retail sale</i>
Requirements for business entity					<ol style="list-style-type: none"> 1. Having all the necessary facilities, equipment and facilities for proper storage and trafficking of medicines. 2. The presence of the required number of employees who meet eligibility requirements. 3. 4. 5. 6.
Required documents					<ol style="list-style-type: none"> 1. Application for obtaining of license for activity. 2. Information on the availability of the necessary material and technical base and the qualification level of employees. 3. 4.

5. What are the offenses related with turnover of medicines and medical products? What kind of responsibility is provided for these violations?
