

# **REGULATORY AND LEGAL SUPPORT FOR TURNOVER OF VARIOUS NOMENCLATURE AND LEGAL AND CLASSIFICATION-LEGAL MEDICINE GROUPS**

## **Theoretical questions**

1. Nomenclature and legal and classification-legal groups of medicines. Regulatory lists of medicines.
2. The state regulation and control of the turnover of narcotic drugs, psychotropic substances, precursors in healthcare and pharmacy institutions.
3. Responsibility for violation of legislation in the sphere of circulation of nomenclature and legal and classification-legal groups of medicines.

## **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)

## **Tasks:**

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

### **1. Match the concepts with definitions listed below:**

- |                                      |   |
|--------------------------------------|---|
| 1. <i>Narcotic drugs</i>             | a) group, which indicates the safety profile of the effects of drugs on the body of the patient (potent, poisonous, narcotic drugs, psychotropic substances, precursors, etc.).   |
| 2. <i>Precursors</i>                 | b) group that indicates the form of drugs realization (prescription and OTC).   |
| 3. <i>Psychotropic substances</i>    | c) natural or synthetic substances, drugs, plants, psychoactive drugs, which upon administration to a human influence on his psyche and behavior, change the emotional condition, will, mind, and included in the List of narcotic drugs, psychotropic substances and precursors. |
| 4. <i>Classification legal group</i> | d) natural or synthetic substances, drugs, natural materials included in the list of narcotic drugs, psychotropic substances and precursors, and that affects the functioning of the central nervous system, leading to a change in mental status.                                |
| 5. <i>Nomenclature legal group</i>   | e) legislative requirements, regulatory and methodological documents for legal nomenclature and legal classification characterization of drugs.   |

6. Control regime
- f) substances used for the production, manufacture of narcotic drugs, psychotropic substances included in the List of narcotic drugs, psychotropic substances and precursors.

**ANSWERS**

1.	2.	3.	4.	5.	6.
----	----	----	----	----	----

**2. Describe the main provisions of the UN Conventions in the control of turnover controlled drugs and the main results of their implementation at the international level. Results issued in Table.**

Normative and legal regulation of the narcotic drugs, psychotropic substances and precursors turnover at the international level

<i>Year of adoption</i>	<i>Name of the Convention</i>	<i>The main results</i>
<b>1961</b>	<b>UN Single Convention «On Narcotic Drugs»</b> (New York), March 30, 1961	<ul style="list-style-type: none"> <li>• <i>Narcotic drugs are classified and placed under international control by the 1961 UN Single Convention on Narcotic Drugs, as amended in 1972.</i></li> <li>• <i>The Single Convention limits 'exclusively to medical and scientific purposes the production, manufacture, export, import, distribution of, trade in, use and possession of drugs'</i></li> </ul>
<b>1971</b>	<b>Convention on Psychotropic Substances</b>	
<b>1988</b>	<b>United Nations Convention against Illicit Traffic in Narcotic Drugs and Psychotropic Substances</b>	

3. Analyze the provisions of *The Single Convention on Narcotic Drugs (UN, 1961)* [http://www.emcdda.europa.eu/system/files/attachments/10448/convention\\_1961\\_en.pdf](http://www.emcdda.europa.eu/system/files/attachments/10448/convention_1961_en.pdf) and classify narcotic, psychotropic substances and precursors in accordance with the Convention, the results place in Table.

Classification of narcotic drugs, psychotropic substances and precursors

<i>List of drugs</i>	<i>Measures of control and restrictions</i>
<b>Schedule I</b>	
<p><i>Coca leaf, cocaine, ecgonine;</i>  <i>Natural opioids sources:</i>  <i>opium;</i>  <i>Natural opioids: oripavine,</i>  <i>morphine, thebaine;</i>  <i>Semisynthetic opioids: heroin,</i>  <i>fentanyl....</i></p>	<p><i>The substance is liable to similar abuse and productive of similar ill effects as the drugs already in Schedule I or Schedule II, or is convertible into a drug;</i>  <i>is the category of drugs whose control provisions "constitute the standard regime under the Single Convention</i></p>
<b>Schedule II</b>	
<b>Schedule III</b>	
<b>Schedule IV</b>	

**4. Compare criteria for classifying medicines into the category of prescription and non-prescription, using the provisions of Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use (Article 70-72).**

*Results fill in table.*

<i>Criteria</i>	<i>Group of medicines</i>	
	<i><u>a medicine is a subject to medical prescription</u></i>	<i><u>a medicine is not a subject to medical prescription</u></i>
Medicines and its ingredients don't cause direct or indirect damage to health of the consumer		+
Medicines are frequently and to a very wide extent used incorrectly, and as a result are likely to present a direct or indirect danger to human health	+	
Medicines are intended mainly for outpatients (using in ambulatory)		
Medicines are normally prescribed by a doctor to be administered parenterally		
Medicines present a danger either directly or indirectly, even when used correctly, if utilized without medical supervision		
Medicines don't contain substances or preparations thereof, the activity and/or adverse reactions of which require further investigation		
Medicines are likely, if incorrectly used, to present a substantial risk of medicinal abuse, to lead to addiction or be misused for illegal purposes		
Medicines are used in the treatment of conditions which must be diagnosed in a hospital environment or in institutions with adequate diagnostic facilities, although administration and follow-up may be carried out elsewhere		
Medicines, because of its pharmaceutical characteristics or novelty or in the interests of public health, are reserved for treatments which can only be followed in a hospital environment.		
Medicine contains, in a non-exempt quantity, a substance classified as a narcotic or a psychotropic substance within the meaning of the international conventions in force, such as the United Nations Conventions of 1961 and 1971.		

**5. Analyze the list of medicines in Table 5 and determine the form of prescription on the basis of Directive 2001/83 / EC of the European Parliament and of the Council "On the Community code relating to medicinal products for human use":**

<i>Brand Names of the Medicines</i>	<i>Dosage Forms</i>	<i>INN</i>	<i>Prescription / non-prescription</i>
<b>SOMAXON</b> , (Mili Healthcare, United Kingdom)	solution for injection 500 mg 2 ml, 5 amp.	Citicolinum	<i>Prescription</i>
<b>ACC®200</b> , (Sandoz, Germany)	powder 200 mg	Acetylcysteinum	
<b>PEROXYGEL</b> , (GEMI, Poland)	gel 3% 40 G	Hydrogenii peroxidum	
<b>ACIDUM ASCORBINICUM-DARNITSA</b> , (Darnitsa, Ukraine)	solution for injection 100 mg 2 ml, 10 amp.	Acidum ascorbicum	
<b>DEPO-PROVERA</b> , (Pfizer Inc., USA)	injectable susp. 400 mg/ml	Medroxyprogesterone acetate	
<b>OTRIVIN®</b> , (Novartis Consumer Health SA, Switzerland)	0.1% nasal spray 10 ml	Xylometazolinum	
<b>DEPODUR</b> , (Pacira Pharmaceuticals, USA)	oral tablet 5 mg № 50	Morphinum	
<b>RELIUM</b> (Polfa, Poland)	oral tablet 5 mg № 20	Diazepamum	
<b>RETINOLI ACETAS</b> (Vitamin, Ukraine)	oil sol., dermal, 10 ml, № 1	Retinolum	
<b>CONCERTA</b> (Janssen Pharmaceuticals, Belgium)	oral tablet 36mg № 28	Methylphenidate	