MECHANISM OF THE STATE REGISTRATION AND MARKET AUTHORIZATION OF NEW MEDICINES FOR USE IN UKRAINE. INTELLECTUAL PROPERTY RIGHTS IN HEALTH CARE

Theoretical questions

1. Registration of medicines as a mechanism of the pharmaceutical market authorization. The procedure for the expert examination of drugs submitted for the state registration (re-registration).
2. The order of keeping the State Register of Medicinal Products of Ukraine.
3. The concept of intellectual property in healthcare.
4. Objects of the intellectual property law: marks for goods and services, patented inventions, industrial samples, objects of copyright.
5. Legal mechanisms for the protection of intellectual property rights.

List of recommended literature

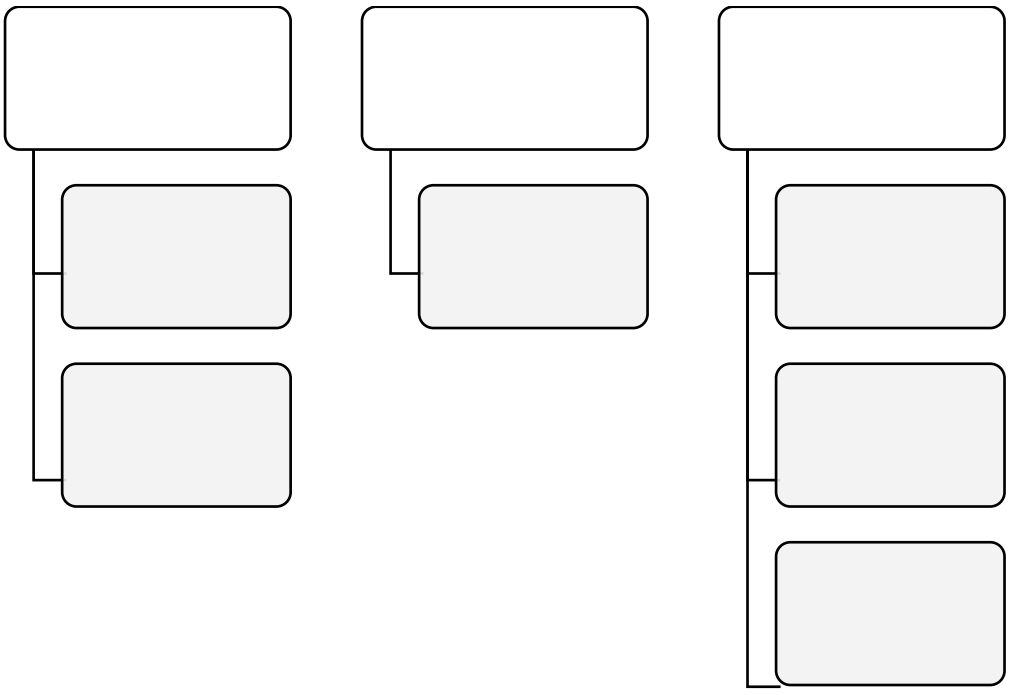
1. Pharmaceutical Law and Legislation : the textbook for applicants for higher education / A.A. Kotvitskaya, I.V. Kubarieva, A.V. Volkova, A.V. Cherkashyna, I.V. Zhirova, A.A. Surikov, I.A. Surikova. – Kharkiv : NUPh : Golden Pages, 2019. – 204 p. http://irbis.nuph.edu.ua/full_text/2019/2019_Farm_law_textbook_angl.pdf

Tasks:

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

1. Describe medications, which are the subject to state registration, complete the scheme.

MEDICATIONS, SUBJECT TO STATE REGISTRATION



2. Describe subjects of interaction in the process of state registration of medicines, complete the scheme.

State Expert Center

Scientific-expert organization of the Ministry of Health of Ukraine, whose activities are concentrated on the solution of scientific and methodological issues of creation, study, examination, registration and post-registration medicines surveillance of their application in medical practice

_____

_____

3. Name the main stages of the procedure for the expert examination of medicines submitted for the state registration, describe them.

the **primary expert evaluation**

- *the possibility of the drug registration (re-registration) in terms of its belonging to the drugs forbidden for use in Ukraine,*
- *as well as the correctness of determining the application type*

_____

-
-

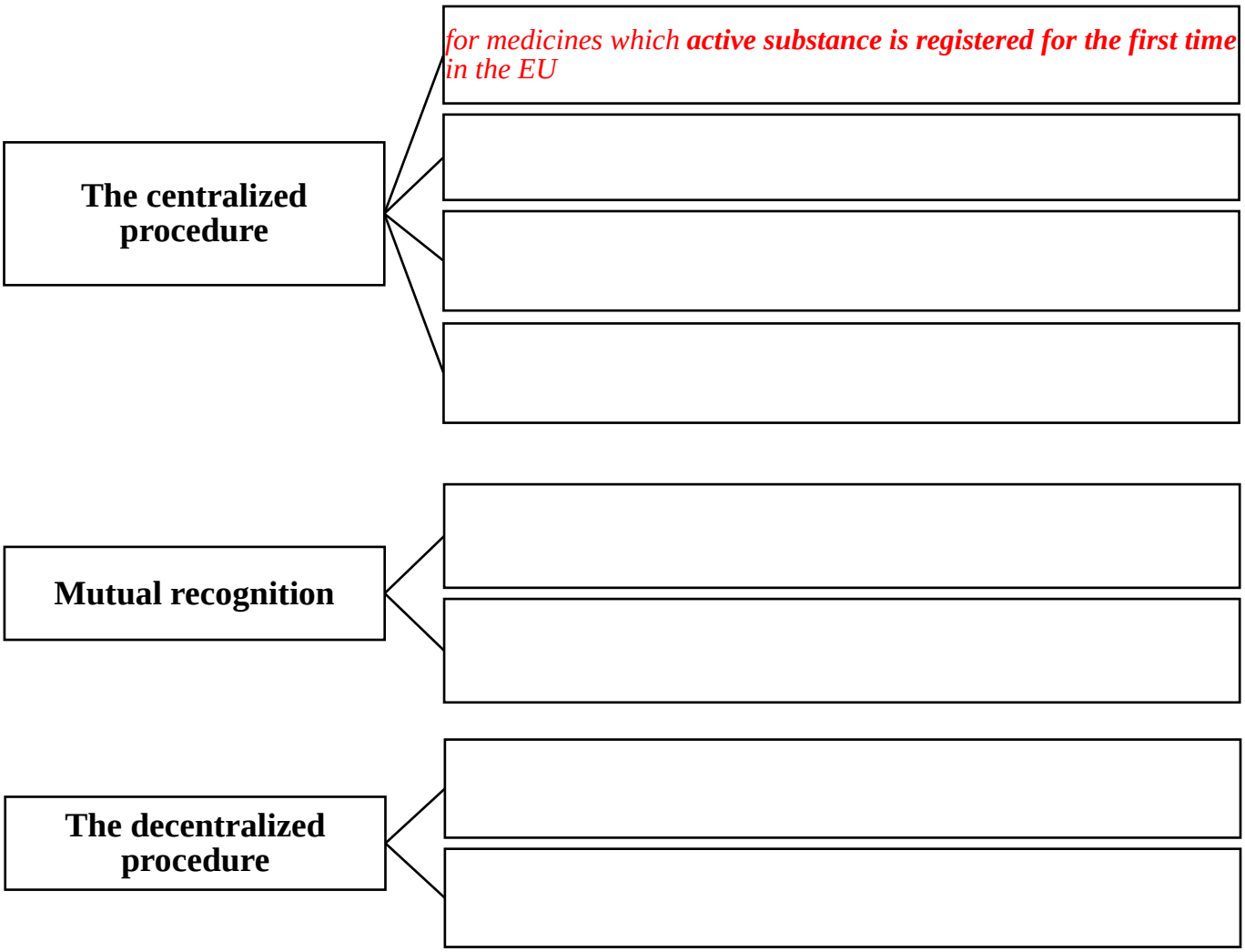
_____

-
-

4. Indicate the name of the organization that carries out the drug registration procedure in USA market

_____

5. Describe procedures by which medicines can receive marketing authorization in the EU countries.



6. From the list of intellectual property objects in the pharmaceutical industry select the right for each classification:

objects of intellectual property law	**Copyrights**	**Inventions**	**Utility models (useful models)**	**Industrial designs**	**Commercial designations**
active pharmaceutical ingredient		+			
company names					
dosage forms (capsule; packaging)					
drug label projects					
finished product manufacturing equipment					
manufacturers logo					
method of producing an active substance					
new medical use of the product					
pharmaceutical composition					
pharmaceutical excipient					
projects of instruction for medical use					
report about development of analytical procedures for quality control of substances and finished pharmaceutical product					
reports on the preclinical and clinical study of drugs					
trade name of medicines					

7. According to the list of characteristics of the patent and utility model, define the main differences:

Distinction criteria	*Patent*	*Utility model*
Types of protection that may be obtained for a product	*The invention which has novel, inventive step and industrial application can be protected*	*The invention which has mainly a novelty, but less or absents in inventive step can be protected*
Statutory benchmarks for patentability		

Distinction criteria	*Patent*	*Utility model*
The term of a patent		
The possibility of extending the patent		
The procedures of examination of a patent		