

Item card

Th. 1

General information about the item		
1. Field of study: Pharmacy	2. Level of education: uniform master's studies	
	3. Form of studies: full -time	
4. Year: V	5. Semester: IX	
6. Item name: Pharmaceutical law		
7. Course status: compulsory		
8. The curriculum of the subject and the learning outcomes assigned to them		
Learning and understanding by the student of: legal acts specifying the principles of the functioning of pharmaceutical law in the health care system, legal grounds for pharmaceutical care in the Polish health system; legal and social conditions of performing the profession of pharmacist; procedures regulating the performance of pharmaceutical services and problems related to the supervision and control of the production and sale of medical products, including narcotic drugs and psychotropic drugs; standards in force in the European Union countries in the field of pharmaceutical law.		
Learning outcomes / reference to learning outcomes included in the standards		
in terms of knowledge, the student knows and understands: E.W1, E.W2, E.W3, E.W4, E.W8, E.W18, E.W22, EW26; in terms of skills, the student is able to E.U1, E.U3, E.U4, E.U17, E.U19, E.U21; in terms of social competences, the student is ready to: observe the confidentiality of health, patient's rights and the principles of professional ethics; presenting an ethical and moral attitude, undertaking professional activities based on the code of ethics of the pharmacist profession; accepting responsibility related to decisions made in the course of professional activity, including in terms of one's own safety and that of others.		
9. Number of hours per course		60
10. Number of ECTS points for the subject		4
11. Methods of verification and assessment of learning outcomes		
Learning outcomes	Methods of verification	Assessment methods *
In terms of knowledge	Tests and written test - short, structured questions, questions MRQ, and open-ended questions	*
In terms of skills	Reports, Individual presentations, Assessment of prepared presentations, the level of communication and implementation of procedures	*
In terms of competence	Observation of communication skills and demonstration of the application of regulations in the assigned pharmaceutical law issues	*

* it is assumed that the rating means on the level

- Very good (5.0)** - the assumed learning outcomes have been achieved and significantly exceed the required level;
- More than good (4.5)** - the assumed learning outcomes have been achieved and slightly exceed the required level;
- Good (4.0)** - the assumed learning outcomes have been achieved on the required level;
- Fairly good (3.5)** - the assumed learning outcomes were achieved on the average required level;
- Sufficient (3.0)** - the assumed learning outcomes were achieved at the minimum required level;
- Poor (2.0)** - the assumed learning outcomes have not been achieved.

Item card

Th. 2

Other useful information about the item		
12. Unit carrying out the course, e-mail address: Department of Pharmacy Pharmacy, 41-200 Sosnowiec, ul. Kasztanowa 3; farmacja_apteczna@sum.edu.pl		
13. Name and surname of the person responsible for the implementation of the course: prof. dr hab. n. farm. Pawel Olczyk, prof. SUM polczyk@sum.edu.pl ;		
14. Prerequisites for knowledge, skills and other competences: none		
15. Group size	In line with the resolution of the Senate SUM	
16. Materials for classes	Acts and regulations, published judgments of the Supreme Administrative Court;	
17. Place of the classes	Sosnowiec, ul. Kasztanowa 3	
18. Place and time of consultation	Upon agreement, announced on the website	
19. Learning outcomes		
Learning outcome number	Subject learning outcomes	Reference to learning outcomes included in the standards
P_W01	Knows and understands the legal basis and the rules of organizing the pharmaceutical market in the field of retail trade in the Republic of Poland and the operation of public and hospital pharmacies.	EW1
P_W02	knows and understands the principles of the organization of the pharmaceutical market in the field of wholesale trade in the Republic of Poland and the operation of pharmaceutical wholesalers;	EW2
P_W03	knows the rules for issuing, recording and fulfilling prescriptions as well as the rules for dispensing drugs from a pharmacy;	EW3
P_W04	Knows and understands the legal basis and rules of practicing the profession of pharmacist, regulations regarding obtaining the right to practice the profession of pharmacist and the functioning of the pharmacy self-government;	EW4
P_W05	Knows and understands the rules of marketing medicinal products, medical devices, dietary supplements, foodstuffs for particular nutritional uses and cosmetics ;	EW18
P_W06	Knows and understands the legal basis and principles of conducting and organizing drug research, including experimental research and research involving humans; rules for monitoring the safety of medicinal products after they have been placed on the market;	EW22 EW26
P_W07	He knows and understands the principles of the operation of public and hospital pharmacies, as well as the functioning of wholesalers, supplying pharmacies. Knows and understands the idea of pharmaceutical care and concepts related to pharmaceutical care, in particular relating to problems and needs related to the use of drugs;	EW3 EW8
P_U01	is able to determine the scope of duties, supervise and organize the work of staff in the pharmacy; define the rules of drug management in hospitals and pharmacies	EU1 EU3

P_U02	can define the conditions for the storage of medicinal products, medical devices and dietary supplements, identify products that require special storage conditions and control the storage conditions	E.U4
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P_U03	Is able to monitor and report adverse drug reactions, implement preventive measures, provide information related to complications of pharmacotherapy to health care system employees, patients or their families; identify the role and tasks of individual organs of the pharmacy self-government as well as the rights and obligations of its members;	E.U17 EU19
P_U04	Can indicate the appropriate pharmaceutical organization or authority dealing with the data professional problem	EU21
20. Forms and topics of classes		number of hours
21.1. Lectures		45
Pharmaceutical law as a part of medical law, directive and regulation European Union applicable in the field of pharmaceutical law; Legal acts relating to the pharmaceutical market		4
General concepts and definitions of the Pharmaceutical Law		3
Principles and procedure of admitting medicinal products, medical devices and dietary supplements to the market		3
General principles of good distribution manufacturing practice		3
Issues related to the operation of public pharmacies, hospital pharmacies, pharmacy departments, including the powers of professional personnel		3
Principles of monitoring of adverse effects and principles of reporting quality defects of drugs - suspension and recall of medicinal products		3
Issues related to trade in psychoactive, psychotropic and narcotic substances		3
Issues related to drug counterfeiting, illegal trade, mail order sale of drugs		3
Advertising of medicinal products; Advertising of pharmacies - in the light of applicable regulations		3
Public institutions responsible for controlling and supervising the activities of entities in the field of manufacturing, wholesale and retail trade		3
Forms of practicing the profession of pharmacist and regulations regarding obtaining the right to practice the profession of pharmacist in Polish pharmaceutical law and European Union law		3
Penal provisions in pharmaceutical law		3
Issues related to cooperation between medical professions		3
State drug policy		3
Pharmaceutical law - summary		2
22.2. Seminars		15
Trade in medicinal products and import of medicinal products. Principles of organizing the pharmaceutical market in Poland and the EU		2
Dispensing of medicinal products, advertising of medicinal products		2
The role of a generally accessible pharmacy as a public health facility		2
Issues related to drug counterfeiting, illegal trade, mail order sale of drugs		2
Principles of trade in narcotic drugs and psychotropic drugs in a pharmacy		2
Principles of functioning of the pharmacy self-government		2
Public institutions (state and local government) responsible for supervision and control in the pharmaceutical sector		2
Legal aspects - news summary		1

24. Literature

1. ACT of September 6, 2001 Pharmaceutical Law. Journal of Laws 2019.499;
2. ACT of April 19, 1991 on Pharmaceutical Chambers. Journal of Laws 2019.1419;
3. ACT of July 29, 2005 on Counteracting Drug Addiction. Journal of Laws 2019.852;
4. ACT of April 15, 2011 on medical activities. Journal of Laws 2018.2190;
5. ACT of May 12, 2011 on reimbursement of drugs, foodstuffs for particular nutritional uses and medical devices. Journal of Laws 2019.784;
6. REGULATION OF THE MINISTER OF HEALTH of 11 September 2006 on narcotic drugs, psychotropic substances, category 1 precursors and preparations containing these substances or substances. Journal of Laws 2015.1889;
7. REGULATION OF THE MINISTER OF HEALTH of 18 October 2002 on the basic conditions for running a pharmacy, Journal of Laws 2002.187.1565;
8. REGULATION OF THE MINISTER OF HEALTH of 30 September 2002 on detailed requirements to be met by a pharmacy premises, Journal of Laws 2002.171.1395;
9. Pharmaceutical law. Medical Law System. Volume 4, CH Beck, 2019;
10. Practical Pharmacy edited by Renata Jachowicz. PZWL, 2016;
11. Professional magazines: Pharmacy Polska, Aptekarz Polski, Manager of the Pharmacy.
12. Additional executive acts to the Pharmaceutical Law Act designated by the persons responsible for the implementation of the subject.

25. Assessment criteria - details

As recommended by the controlling authorities.
Completion of the course - the student has achieved the intended learning outcomes.
Detailed criteria for passing and grading the course are set out in the course regulations.