



## COURSE DESCRIPTION CARD - SYLLABUS

Course name

Legal and ethical aspects of pharmaceutical engineering [S1IFar2>PiEAIF]

### Course

Field of study Pharmaceutical Engineering	Year/Semester 4/7
Area of study (specialization) –	Profile of study general academic
Level of study first-cycle	Course offered in Polish
Form of study full-time	Requirements compulsory

### Number of hours

Lecture 15	Laboratory classes 0	Other 0
Tutorials 0	Projects/seminars 0	

### Number of credit points

1,00

### Coordinators

dr hab. Tomasz Zaprutko  
dr hab. Krzysztof Kus  
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### Lecturers

### Prerequisites

The student starting the class should have a basic knowledge of pharmacology, drug technology, intellectual property protection. The student should also be able to obtain and verify information from different sources.

### Course objective

The course aims to provide students with basic knowledge of law and ethics in pharmaceutical engineering. Information acquired during course will be necessary for a proper understanding of the job market. It will also allow to conduct a multilevel analysis of legal and ethical problems in pharmaceutical engineering.

### Course-related learning outcomes

Knowledge:

1. The student has general knowledge in the field of pharmacy, cosmetology, technology, and chemical engineering as fields directly related to pharmaceutical engineering. [K\_W1]
2. The student has the general knowledge to understand the social, economic, legal and other non-

technical conditions of engineering activities and understands the relationship between the achievements of engineering and natural and medical sciences, and the possibilities of their use in socio-economic life, including the sustainable use of biological diversity. [K\_W22]

3. The student knows the basics of pharmaceutical law, has a basic knowledge concerning pharmacy management. It includes e.g., the drug distribution system and the principles of ethics and protection of industrial property and copyright as well as the transfer of technology. The student can use patent information resources and knows the rules of Good Manufacturing Practice. [K\_W23]

Skills:

1. The student takes into account and applies regulations in both industrial and research environments. [K\_U21]

Social competences:

1. The student critically assesses their knowledge, understands the need for further education, and raising their professional, personal, and social competences. The student understands the importance of expertise in solving problems and is ready to seek expert opinions. [K\_K1]

2. The student is aware of the importance of understanding non-technical facets and effects of engineering activities, including its impact on the environment and the associated responsibility for decisions. The student correctly recognizes problems and makes the right choices related to the exercise of the profession, following the principles of professional ethics, care for achievements and traditions of the profession. [K\_K3]

### Methods for verifying learning outcomes and assessment criteria

Learning outcomes presented above are verified as follows:

The acquired knowledge will be verified by the final test. The final test is carried out online using the examination platform or in the form of a stationary test - closed test questions The credit threshold is 60% of the points.

### Programme content

The program covers the following topics:

1. Principles of drug ordinance in relation to currently applicable law.
2. Drug distribution models (medical benefit baskets) and drug programs.
3. Parallel trade and reverse traffic of medicines. Drug policy
4. GDPR and medical and pharmaceutical law.
5. The concept of morality in the pharmaceutical industry.
6. HTA in the realities of the country and the European Union.
7. Ethics in everyday practice.

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### Teaching methods

Lecture, presentation, case studies.

### Bibliography

Basic:

1. Prawo farmaceutyczne. Krekora M, Świerczyński M, Traple E. Wolters Kluwer 2020.
2. Dyrektywa fałszywkowa a RODO. Bezpieczeństwo leków. Obowiązki wytwórców, hurtowników i aptek. Wzory umów i procedur. Sieradzka A. C. H. Beck 2019.
3. Etyka medyczna z elementami filozofii. Łuków P, Pasierski T. PZWL 2019

Additional:

1. Fałszowanie produktów leczniczych. Zagadnienia prawne i kryminologiczne. Kalinowska-Maksim I. Wolters Kluwer 2020.

2. Biznes, etyka, odpowiedzialność. Gasparski W. Wydawnictwo Naukowe PWN 2020.

### Breakdown of average student's workload

	Hours	ECTS
Total workload	30	1,00
Classes requiring direct contact with the teacher	15	0,50
Student's own work (literature studies, preparation for laboratory classes/ tutorials, preparation for tests/exam, project preparation)	15	0,50