Name of university, Name of faculty: Trnava University
Faculty of Law

INFORMATION SHEET OF THE SUBJECT

Code: YNDVm889	**Name:** Pharmaceutical Law	
Cover: Intellectual Property, Technologies and Product Law Department		
Type of educational activity: Lecture, Practise **Scope of educational activity (in hours):** **Weekly:** 0/1 **For term of study:** LS 30/,12 **Method of educational activity:** Combined	**Number of credits:** 3	**Recommended semester:** ST **Study grade:** Master

Recommended semester	Study programme
1.year ST	Law (YDŠMgr-PR)

Underlie subjects:

Conditions for passing the course:
Method of evaluation: Completion by a continuing assessment

Continuous evaluation: Continuous evaluation: activity at seminars (40 %); preparation of a short test with closed questions (50 %); personal contribution / expressed interest (10 %).
Evaluation: A: 100%-91%, B: 90%-81%, C: 80%-71%, D: 70%-66%, E: 65%-61%, FX: 60%-0%.
Final evaluation: Completion by a continuing assessment
Finished: By continuous evaluation.

Learning outcomes:
After completing the Pharmaceutical Law course, the student will gain a basic orientation in legislation and legal practice related to drugs, state drug policy (pricing and reimbursement of drugs), testing of drugs and medical devices, patent protection of drugs, import and distribution of drugs and medical devices. The student will also get a more accurate idea of specific areas connected to the pharmaceutical industry, such as drug advertising, personal data protection, etc. The student can formulate and support argumentatively, as well as publicly (written and oral) present his/her own professional opinions / interpretations of the subject matter.

Schedule of subject:
1. Sources of legal regulation and definition of basic terms and institutions.
1.1. Who makes the drug policy of the state and how do others intervene in it? The roles of the WHO, the EU and the Slovak Republic.
1.2. What is the difference between ibalgin, vitamin C, plaster, crutches or a heart machine? He is not a flexor like a flexor. Generic, biosimilar or original...are we talking about the same thing?
2. Testing of drugs and medical devices, registration of drugs and medical devices, use of unregistered drugs and off-label use of registered drugs.
2.1. The drug's path to clinical trials is long and winding. Can any drug do it? Clinical trial participants - are they also healthy persons and children? Clinical trial watchdogs.
2.2. The administrative cord of obtaining a "stamp" of the drug's effectiveness and safety? Will you cross the entire EU at once or gradually?
2.3. Can the patient get access to a breakthrough therapy that has not yet arrived in Europe?
3. Patent protection of medicines.
3.1. Who enjoys longer patent protection? Iphone or new medicine?
3.2. Arrival of a generic on the market. Disputes and their settlements (pay for delay).
4. Production, import and distribution of medicines and medical devices.
4.1. Does the manufacturer of the drug also decide on its allocation and at what price will it be sold?
4.2. Distribution models – DHP/DTP - credit risk of pharmacies and hospitals. Emergency system. Home delivery.
5. Current challenges of drug distribution.
5.1. Is this medication out of date? Why? For how long? Can we predict it? Can we prevent it? Is it a problem of Slovakia, Europe or the whole world?
5.2. Who and what does to ensure the availability of medicines? Is that enough? Can we do more?
6. Prescription and dispensing of medicines.
6.1. Prescriptive restrictions. Who can prescribe the medicine? When is a general practitioner sufficient and when is a specialist needed? Can they represent themselves? Mandatory prescription of medication upon discharge from hospital.
6.2. Generic prescription vs. generic substitution. Can the pharmacy dispense a medicine other than the one prescribed by the doctor?
6.3. Dispensing medicine in a pharmacy vs. home delivery (in some countries also by bicycle). Pharmacy vs. pumps, drugstores or Alza boxes. Home delivery, in some countries even by bicycle.
7. Pricing and reimbursement of medicines and medical devices - Part 1.
7.1. Dilemma - price and payment regulation of the state vs. free hand of the market.
7.2. Limited budget. Ethical issues and priorities in the reimbursement of medicines and medical devices. Expensive vs. inexpensive therapies. Orphan drugs vs. drugs intended for a large group of patients.
7.3. Introduction to the regulation of pricing and reimbursement of medicines and medical devices in Slovakia.
8. Pricing and reimbursement of medicines and medical devices - Part 2.
8.1. Drug prices in Slovakia are among the lowest in Europe. Is that a positive? Two worlds of drug price regulation (standard vs. special price regulation).
8.2. The chaos of medical device price regulation – duplicate regulation of one price.
9. Pricing and reimbursement of medicines and medical devices - Part 3.
9.1. The patient does not have the right to request payment of the medicine from the VZP. So who? Exceptional vs. standard mode of payment by health insurance companies.
9.2. How much is the state willing to pay for one year of a patient's life? Categorization and its rules.

9.3. Referencing vs. revision of payments. Why was the Minister of Health sued?
10. Advertising of medicines and medical devices.
10.1. Advertising on stoptusin vs. advertisement for vaccinations vs. advertisement for antidepressants.
10.2. Donation of medicines.
10.3. Tax regime.
11. Human blood and human blood components.
11.1. Donation of blood and human blood components.
11.2. Processing and surplus of human blood or its components (ethical issues).
12. Protection of personal data.

Recommended reading:
Basic recommended literature:
Act No. 362/2011 Coll. on Medicines and Medical Devices and on the Amendment of Certain Laws.
The materials for the course matter will be provided by the teachers in the Moodle system.

Language requirements: Slovak

Notes:
Student‘s workload: 75 hours
Combined study (lectures, seminars, consultations): 12 hours
Study of submitted materials and documents in Moodle (individual study): 63 hours

Course evaluation:
Assessed students in total: 32

A	B	C	D	E	FX
53%	31%	6%	0%	0%	9%

Lecturers:
Mgr. et Mgr. Patrícia Dutková, examiner, instructor
Mgr. Ján Dulovič, examiner, instructor
doc. JUDr. Veronika Zoričáková, PhD., examiner, instructor

Date of last change: 01.09.2026

Approved by: prof. PhDr. JUDr. Tomáš Gábriš, PhD., LLM., MA