COURSE UNIT (MODULE) DESCRIPTION

Course unit (module) title	Code
HEALTH- AND BIOTECHNOLOGY LAW	

Lecturer(s)	Department(s)
Coordinator: lect. dr. Jevgenija Vienažindytė **Other(s):**	Vilnius University, Faculty of Law, Department of Public Law Sauletekio av. 9, Building 1, LT-10222, Vilnius, 405 room, phone (8 5) 2366175, e-mail: vtkatedra@tf.vu.lt

Study cycle	Type of the course unit (module)
Second	Optional

Mode of delivery	Course unit delivery period	Language(s) of instruction
Face-to-face	1 (autumn) semester	English

Requirements for students	
Pre-requisites: Basic knowledge of EU *acquis*	**Co-requisites (if any):** None

Number of credits allocated	Total student's workload	Contact hours	Self-study hours
5	133	32	101

Purpose of the course unit (module): programme competences to be developed		
The purpose of this course is to develop legal skills in practicing life sciences law: navigating through different personal healthcare systems, thorough understanding of main activities of biotechnology sector and employing foundations and dynamic development of bioethics. Students should obtain profound knowledge about organisation of different healthcare systems, regulation of various medical technologies and biotechnologies at national and EU level, shall be able to apply legal reasoning, interpret and assess framework of human rights and challenges while applying biotechnologies within the EU law and national healthcare systems as well as complex situations where there are no established regulation or existing legal precedents.		
Learning outcomes of the course unit (module)	**Teaching and learning methods**	**Assessment methods**
Students will gain in-depth knowledge on the life sciences legal sector, activities that are covered under practice of this legal area: including regulatory framework of different healthcare systems (healthcare services/patients' rights, etc.), activities of biotechnology companies (bio-technology, medicinal products, medical devices), foundation of Bio-ethics; and will be able to critically analyse and assess legal, economical and ethical consequences of the developments in this sphere.	An interactive method of teaching during lectures and seminars (the analysis of problematic issues, presentations on assigned topics, group discussions), individual studies (analysis of the relevant legal framework, policy and case-law, reading of academic literature)	Participation in discussions; presentation of assigned topics; practical exercises; writing of individual project and presenting it
Students will be able to apply relevant case law and compare relevant regulations, *inter alia*, biomedical research regulation, placing new medical technologies and biotechnologies to the market at national level and EU level, health technology assessment, will be able to interpret regulatory requirements and to apply them to hypothetical practical situations or provide their own assessment on their application.	An interactive method of teaching during lectures and seminars (comparative assessment and systemic analysis of legal norms, the analysis of problematic issues, case studies, group discussions), individual studies (analysis of the relevant legal framework, policy and case-law, reading of academic literature)	Participation in discussions; practical exercises, writing of individual project and presenting it
Students will be able to identify emerging challenges in the healthcare field, arising out of the developments of medical technologies and biotechnologies, to assess upcoming trends and to provide legal insights to	An interactive method of teaching during lectures and seminars (comparative assessment and systemic analysis of legal norms, the analysis of problematic issues, case studies, group	Participation in discussions; practical exercises

developing solutions based on their interests and continuous education.	discussions), individual studies (analysis of the relevant legal framework, policy and case-law, reading of academic literature)	
Students will be able to apply their knowledge to practical situations, analyse hypothetical cases and base their arguments on the relevant ECJ and national case-law and the regulations of respective agencies in medical technology and biotechnology field, *inter alia*, to consult and give recommendations due to problems to concerned clients.	An interactive method of teaching during lectures and seminars (comparative assessment and systemic analysis of legal norms, the analysis of problematic issues, case studies, group discussions, presentations on assigned topics), individual studies (analysis of the relevant legal framework, policy and case-law, reading of academic literature)	Participation in discussions; presentation of assigned topics; practical exercises; writing of individual project and presenting it
Students will be able to actively and productively participate and collaborate in cross-cultural team activities, *inter alia* as leaders, as well as to ensure group members integration by applying ethical values and moral sensibility in respect to cultural and social diversity.	An interactive method of teaching during seminars (the analysis of problematic issues, presentations on assigned topics, group discussions), individual studies (analysis of the relevant legal framework, policy and case-law, reading of academic literature)	Participation in discussions, presentation of assigned topics, practical exercises
Students will professionally communicate orally and in written, unambiguously and reasonably convey owns well-grounded ideas, arguments and conclusions based on theoretical and practical knowledge and will be able to trigger or to contribute to the discussion with specialists and non-specialists providing their own insights in an international context.	An interactive method of teaching during seminars (the analysis of problematic issues, presentations on assigned topics group discussions), individual studies (analysis of the relevant legal framework, policy and case-law, reading of academic literature)	Participation in discussions; presentation of assigned topics; practical exercises; writing of individual project and presenting it

Content: breakdown of the topics	**Contact hours**							**Self-study: hours and assignments**	
	Lectures	Consultations	Seminars	Practical sessions	Laboratory activities	Internship/work	**Contact hours**	**Self-study hours**	**Assignments**
1. Life Sciences Law as a legal practice field. "Red" and "white" biotechnologies (related to health field): health apps, virtual consultations, bioinformatics, gene editing, precision medicine.	2						**2**	**6**	Analysis of the relevant academic and other literature
2. Healthcare systems and social security policies. General rights of patients' or research participants' (right to make decisions regarding medical care, the right to accept or refuse treatment, right to be involved in biomedical research).	2		2				**4**	**12**	Overview of the relevant legal framework and literature. Preparation for presentation on assigned topics
3. EU jurisprudence on cross-border healthcare	1		1				**2**	**6**	Analysis of relevant case law, academic literature
4. Licencing of pharmaceutical activities: manufacturing, distribution and retail. Code of medicinal products. Legal issues of authorisation process for medicinal products (centralised, de-centralised, mutual recognition, national procedures). Regulatory data protection. Market exclusivity.	2		2				**4**	**10**	Analysis of the relevant academic literature and regulatory cases, preparation for discussion and practical exercise

5. Pricing and reimbursement (market access) of medicinal products and medical devices, Code of Conduct (ethics and transparency requirements in the relationship between biotechnological companies and healthcare organizations, specialists and patient organizations)	2		2				**4**	**18**	Analysis of the relevant academic literature and regulatory cases, preparation for discussion and practical exercise. Preparation for individual project (moot case)
6. Biomedical researches (epidemiological, Clinical trials (pre-clinical, stage 1 – 4, post-authorisation monitoring) and borderline products (pharmaceuticals vs medical devices)	2		2				**4**	**8**	Reading of scientific literature; case study on related court judgements or academic view, preparation for discussion and practical exercise
7. GDPR application in health field. Big data in the industry of biotechnology: application, legal risks, protection scope.	2		2				**4**	**8**	Analysis of relevant study materials, preparation of presentations on assigned topics / discussion
8. Upcoming biotechnologies and novel therapies. Human modifications and precision medicine (medicinal innovations and legal/ethical obstacles, advances in cell and gene therapies). Narcotics and psychedelics for medicinal use.	2		2				**4**	**13**	Analysis of relevant study materials, preparation of presentations on assigned topics / discussion
9. Bioethics (Oviedo convention, organizational structure) and law principles of human rights protection in the context of biotechnologies (priority of human rights vs public interest, honour and dignity, autonomy, voluntarism, justice and equity, public benefit, protection of vulnerable persons, right to know about health, etc.).	2		2				**4**	**20**	Analysis of relevant study materials, preparation of presentations on assigned topics / discussion. Preparation for individual project (moot case)
Total	**17**		**15**				**32**	**101**	

Assessment strategy	Weight, percentage	Assessment period	Assessment criteria
Participation in class activities	40	During semester	Students will be expected to demonstrate both the knowledge gained during the course as well as their abilities to apply it in a given situation. Assessment of participation in class activities consists of: - individual or group presentation of assigned topics (capability to critically assess the issues, to identify the most significant features, tendencies and developments related to the particular topic, to provide orally clear arguments in support of their points made in a logical, coherent and structured manner); - practical exercises (comprehensive analysis of practical situations while reviewing regulatory cases, relevant case-law and preparing for moot-exercises); - participation in discussions (capability to provide correct answers to questions, formulate problems and suggest (search for) solutions, offer thoughtful critical remarks, contribute to other participants' ideas). During the class activities knowledge will be assessed based on student's ability to interpret most recent case law and case-studies from health technology and biotechnology fields in the EU, to identify legal challenges and suggest viable solutions to the regulatory environment.
Individual project	60	At the end of course	Students ought to prepare and present arguments for moot court cases on application of principles of bioethics, data protection and activities of pharma companies in relation with governmental authorities. Assessment of the project consists of:

			- content (comprehensive problem analysis, creativity, proper source application, critical analytical thinking, conclusion/recommendation formulation); - structure and style (clear structural parts, proper language style, exact wording, source references, appropriate and ethical citation use); - presentation (concentrated, efficient and convincing work presentation, adhesive language, the use of informative visual aids); - efficient and active participation in discussion (providing correct answers to questions, formulating problems and suggesting (searching for) solutions, offering thoughtful critical remarks). After individual project students are expected to command necessary legal competencies to advise clients in real life setting on application of different regulatory framework, principles of bioethics, better market access of new products and to represent clients' interest in regulatory matters in front of regulatory bodies.

Author	Year of publication	Title	Issue of a periodical or volume of a publication	Publishing place and house or web link
Compulsory reading				
Herring, J.	2018	Medical Law and Ethics	7th Edition	Oxford University Press
World Health Organization on behalf of the European Observatory on Health Systems and Policies	2008	Health Technology Assessment and Health Policy-Making in Europe Current status, challenges and potential		http://www.euro.who.int/__data/assets/pdf_file/0003/90426/E91922.pdf
Dute, J.	2019	European Court of Human Rights	Vol 26: issue 1	European Journal of Health Law https://brill.com/view/journals/ejhl/26/1/article-p61_5.xml
Watson, K., Kottenhagen, R.	2017	Patients' Rights, Medical Error and Harmonisation of Compensation Mechanisms in Europe	Vol 25: issue 1	European Journal of Health Law https://brill.com/view/journals/ejhl/25/1/article-p1_1.xml
Mostert M., Annelien L. Bredenoord, A.L., van der Slootb, B. Johannes J.M. van Delden J.J.M.	2017	From Privacy to Data Protection in the eu: Implications for Big Data Health Research	Vol 25: issue 1	European Journal of Health Law https://brill.com/view/journals/ejhl/25/1/article-p43_43.xml
Roscam Abbing, H.D.C.	2018	European Governance of Health Systems. It Takes Two to Tango: The Council of Europe and the European Union	Volume 25: Issue 2	European Journal of Health Law https://brill.com/abstract/journals/ejhl/25/2/article-p121_121.xml
Ploem, C., Colin Mitchell, C. Wim van Harten, W. Gevers, S.	2018	A Duty to Recontact in the Context of Genetics: Futuristic or Realistic?	Volume 25: Issue 5	European Journal of Health Law https://brill.com/view/journals/ejhl/25/5/article-p537_5.xml
Glenn Cohen, I.	2013	The Globalization of Health Care: Legal and Ethical Issues		Oxford University Press
Tamara K. Hervey, T., McHale, J.V.	2015	European Union Health Law: Themes and Implications (Law in Context)		Cambridge University Press
Jackson, E.	2012	Law and the Regulation of Medicines		Hart Publishing
Recommended reading				
Glenn Cohen, I., Fernandez Lynch, H., Effy Vayena, E., Gasser, U.	2018	Big Data, Health Law, and Bioethics		Cambridge University Press

Sorenson, C.	2015	Toward Effective Health Technology Regulation		London School of Economics http://etheses.lse.ac.uk/3066/1/Sorenson_Toward_Effective_Health_Technology_Regulation.pdf
Evers, S.	2002	Cross Border Health Care: An Analysis of Recent ECJ Rulings		European Journal of Law and Economics https://www.academia.edu/22979197/Cross_Border_Health_Care_An_Analysis_of_Recent_ECJ_Rulings
Björkman, B., Hansson, S.O.	2006	Bodily rights and property rights.	32 (4)	Journal of Medicine Ethics, https://www.ncbi.nlm.nih.gov/pmc/articles/PMC2565785/
Dute, J.	2005	The leading principles of the Convention on Human Rights and Biomedicine.	P. 3-12.	Dordrecht: Martinus Nijhoff Publishers.
Rieder, C.M.	2017	Cross-border Movement of Patients in the eu: A Re-Appraisal	Vol. 24: issue 4	European Journal of Health Law https://brill.com/abstract/journals/ejhl/24/4/article-p390_390.xml
Kirchner, S.	2013	Natural law as biolaw	ISSN internet 2029-2058	Juriprudencija https://www3.mruni.eu/ojs/jurisprudence/article/view/428/394?gathStatIcon=true
Hervey, T., Vanhercke, B.	2010	Health care and the EU: law and policy patchwork		Cambridge University Press http://www.euro.who.int/__data/assets/pdf_file/0008/138149/E94886_ch02.pdf
Glenn Cohen, I., Holly Fernandez Lynch, H. Amy L. Davis, A.L., Hurley, E.A.	2014	Human Subjects Research Regulation: Perspectives on the Future (Basic Bioethics)		The MIT Press