

**UČNI NAČRT PREDMETA / COURSE SYLLABUS**

<b>Predmet:</b>	<b>Uvod v biološka in biološkim podobna zdravila</b>
<b>Course title:</b>	<b>Introduction to biologics and biosimilars</b>

<b>Študijski program in stopnja</b> Study programme and level	<b>Študijska smer</b> Study field	<b>Letnik</b> Academic year	<b>Semester</b> Semester
Farmacija, 2. stopnja		1.	2.
Pharmacy, 2. level		1.	2.

**Vrsta predmeta / Course type** obvezni/obligatory

**Univerzitetna koda predmeta / University course code:**  

<b>Predavanja</b> Lectures	<b>Seminar</b> Seminar	<b>Vaje</b> Tutorial	<b>Klinične vaje</b> Clinical training	<b>Druge oblike študija</b> Other forms of study	<b>Samost. Delo</b> Individual work	<b>ECTS</b>
30	15				45	3

**Nosilec predmeta / Lecturer:** red. prof. dr. Uroš Maver, mag. farm.

**Jeziki / Predavanja / Lectures:** slovenski/slovene  
**Languages: Vaje / Tutorial:** slovenski/slovene

**Pogoji za vključitev v delo oz. za opravljanje študijskih obveznosti:** **Prerequisites:**  
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**Vsebina:**  
 Razumevanje bioloških in podobnih bioloških zdravil.  
 Postopek regulativne odobritve.  
 Uporaba bioloških in podobnih bioloških zdravil v klinični praksi.  
 Varnost in učinkovitost podobnih bioloških zdravil.  
 Klinična, proizvodna, regulativna in strateška vprašanja, ki izzivajo globalne poti komercializacije bioloških izdelkov.

**Content (Syllabus outline):**  
 Understanding Biologics and Biosimilars.  
 Regulatory Approval Process.  
 Use of biologics and biosimilars in clinical practice.  
 Safety and efficacy of biosimilars.  
 Clinical, manufacturing, regulatory and strategic issues that challenge the global commercialization pathways of biological products.

**Temeljni literatura in viri / Readings:**

**TEMELJNA LITERATURA:**  
 1. Rang HP, Dale M, Ritter JM, Moore PK. Pharmacology. 9th edition (ali novejša). Edinburgh: Churchill Livingstone; 2020, (poglavje o Bioloških zdravilih).

**DODATNA LITERATURA:**  
 1. Xiaodong Feng et al., Biologics and Biosimilars: Drug Discovery and Clinical Applications 1st Edition, CRC Press, 2022.  
 2. Goodman LS, Gilman AG, Limbird LE, Hardman JG, Goodman Gilman A, eds. The pharmacological basis of therapeutics. 13th edition (ali novejša). New York: McGraw-Hill; 2018.

**Cilji in kompetence:**

- Izboljšati znanja o originalnih in podobnih bioloških zdravilih.
- Razumeti znanstvene in klinične dokaze, ki podpirajo ustrezno stroškovno učinkovito uporabo podobnih bioloških zdravil v onkologiji, revmatologiji, gastrointestinalnih boleznih in drugih zdravstvenih stanjih.
- Odpraviti napačne predstave o uporabi podobnih bioloških zdravil.
- Opredeliti koristi in pomen uporabe podobnih bioloških zdravil v klinični praksi in v različnih jurisdikcijah.
- Razprava o posledicah uporabe podobnih bioloških zdravil za klinično prakso in izobraževanje bolnikov za optimalno oskrbo in dobro počutje bolnikov.

**Objectives and competences:**

- Improve knowledge of originator and biosimilar biologic medicines.
- Understand scientific and clinical evidence to support appropriate cost-effective application of biosimilar biologics across oncology, rheumatology, gastrointestinal disease, and other medical conditions.
- Address misconceptions regarding use of biosimilar biologics.
- Identify the benefits and significance of biosimilar biologic use in clinical practice and across jurisdictions.
- Discuss implications of biosimilar biologic use for clinical practice and patient education to optimize patient care and wellness.

**Predvideni študijski rezultati:**Znanje in razumevanje: Študent

- zna opisati osnovne razlike med različnimi tipi bioloških in podobnih bioloških zdravil,
- našteje in razume posebnosti teh zdravil, tako v smislu lastnosti, kot regulatornih posebnosti,
- razume smiseln njihove uporabe v klinični praksi iz zornega kota izdelovalca, zdravnika, bolnika, zavarovalnice, in drugih deležnikov,
- pridobi pregledno znanje o razpoložljivih bioloških in podobnih bioloških zdravilih,
- zna kritično uporabljati relevantne literaturne vire na področju bioloških zdravil.

Prenesljive/ključne spretnosti in drugi atributi:

- študent zna pojasniti osnove bioloških in podobnih bioloških zdravil.

**Intended learning outcomes:**Knowledge and understanding: The student

- - be able to describe the basic differences between different types of biologics and biosimilars,
- - list and understand the specific features of these medicines, both in terms of properties and regulatory specificities,
- - understands the rationale for their use in clinical practice from the perspective of the manufacturer, the physician, the patient, the insurer, and other stakeholders,
- - acquire an overview knowledge of available biological and biosimilar medicinal products,
- - be able to critically apply relevant literature sources in the field of biologics.

Transferable/Key Skills and other attributes:

- the student can explain the basics of biologics and biosimilars.

**Metode poučevanja in učenja:**

Predavanja  
Seminarji

V okviru seminarjev se bodo obravnavale aktualne teme s področja predmeta

**Learning and teaching methods:**

Lectures  
Seminars

The seminars will cover trending topics in the subject area

**Načini ocenjevanja:**

Način (pisni izpit, ustno izpraševanje, naloge, projekt)

- seminarska naloga

**ŠTUDIJSKE OBVEZNOSTI ŠTUDENTOV**

- 80% prisotnost na seminarjih

POGOJ ZA PRISTOP K IZPITU

**Delež (v %) /****Weight (in %)**

100%

**Assessment:**

Type (examination, oral, coursework, project):

- seminar paper

**STUDENTS' STUDY COMMITMENTS**

- 80% attendance at seminars

ENTRANCE TO THE EXAMINATION

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**Reference nosilca / Lecturer's references:**

1. ELVEREN, Beste, KUREČIČ, Manja, MAVER, Tina, MAVER, Uroš. Cell electrospinning: a mini-review of the critical processing parameters and its use in biomedical applications. *Advanced biology*. March 2023, 10 str.
2. VIHAR, Boštjan, MILOJEVIĆ, Marko, BANOVIĆ, Luka, MAVER, Uroš. Advanced methods for design of scaffolds for 3D cell culturing. V: MOHAN, Tamilselvan (ur.), STANA-KLEINSCHKEK, Karin (ur.). *Functional biomaterials : design and development for biotechnology, pharmacology, and biomedicine*. Weinheim: Wiley-VCH, cop. 2023. Str. 305-334.
3. ARKO, Zoran, TOFANT, Tadej, SIMONČIČ, Boris, MAVER, Uroš, MAVER, Tina, GOLE, Boris, POTOČNIK, Uroš, ZIDARIČ, Tanja. Membrane for separation of stem cells from biological samples, production process of said membrane, and process and device for separation, comprising said membrane = Membran zur Trennung von Stammzellen aus biologischen Proben, Herstellungsverfahren dafür sowie Verfahren und Vorrichtung zur Trennung mit dieser Membran = Membrane pour la séparation de cellules souches d'échantillons biologiques, processus de production de ladite membrane, et processus et dispositif de séparation, comprenant ladite membrane : European patent specification EP 3 687 656 B1, 2022-03-30. München: European Patent Office: = Office européen des brevets: = Europäisches Patentamt, 2022. 9 f.  
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