

V E T

XX SIMPOZIJUM ALIMS

16-18.10.2025. | KOPAONIK



Agencija za lekove
i medicinska sredstva Srbije

17.00-18.00 KOKTEL DOBRODOŠLICE / WELCOME COCKTAIL

18.00-20.00 **SVEČANO OTVARANJE**
Svečano otvaranje Simpozijuma,
pozdravni govori zvaničnika
OPENING CEREMONY
Formal opening of the Symposium,
official welcome speech

Konferansije/Master of Ceremonies: Jelena Mitrašinović, ALIMIS

Sanda Savić, Privredna komora Srbije
/ **Serbian Chamber of Commerce**
Bojan Trkulja, direktor INOVIA / **INOVIA director**
Ana Popović,
direktor GENEZIS / **GENEZIS director**
Maja Vučković Krčmar, Delegacija Evropske unije u Srbiji
/ **Delegation of the EU to the Republic of Serbia**
Dorina Pirgari, regionalna kancelarija za Evropski region, SZO
/ **Regional Office for European Region, WHO**

Saša Jačović, direktor ALIMIS / **ALIMIS director**

Predstavnik Ministarstva zdravlja Republike Srbije
**Representative of the Ministry of Health
of the Republic of Serbia**

Panel diskusija:
"Svet zajedno protiv falsifikovanih
i substandardnih medicinskih proizvoda"
Panel discussion:
"The World Together Against Falsified
and Substandard Medical Products"

Moderator: Pavle Zelić, ALIMIS

Učesnici panela / **Panelists:**
Dorina Pirgari, regionalna kancelarija za Evropski region, SZO
/ **Regional Office for European Region, WHO**
Ronny Berkovitz, Univerzitet u Jerusalimu,
Ministarstvo zdravlja Izraela
/ **University of Jerusalem, Ministry of Health of Israel**
Radoslav Ruitchev, Agencija za lekove Bugarske - BDA
/ **Bulgarian Drug Agency - BDA**
David Kočović, Institut za lijekove
i medicinske sredstva Crne Gore - ClnMED
/ **Institute for Medicines
and Medical Devices of Montenegro - ClnMED**

Predavanja / **Lectures:**
Prof. Emil Bienvenu, generalni direktor,
Agencija za lekove i hranu Ruande,
predsednik komiteta za falsifikovane
i substandardne medicinske proizvode SZO
/ **Director General, Rwanda Food and Drugs Authority,
Chair of the WHO Committee on Falsified
and Substandard Medical Products**
Pol Huleat, Administracija za terapijske
proizvode Australije - TGA
/ **Therapeutic Goods Administration - TGA**
Laila Mouawad,
Agencija za regulativu zdravstva Brazila - ANVISA
/ **Brazilian Health Regulatory Agency - ANVISA**
Mark Abdoo, Uprava za hranu i lekove SAD - FDA
/ **US Food and Drug Administration - FDA**

20.00-22.00 VEČERA / DINNER

09.30-11.00

VETERINARSKI LEKOVI: JEDINSTVENO ZDRAVLJE - NEW ERA DIGITALIZACIJE VETERINARY MEDICINES: ONE HEALTH - NEW ERA DIGITALIZATION

Moderator: Gordana Žugić, ALIMIS

Jedinstveno zdravlje: Politike, digitalizacija i vještačka inteligencija
One health: Politics, digitalization and Artificial Intelligence

Prof. Nihad Fejzić, PhD, University of Sarajevo, BiH

Od algoritma do dozvole za stavljanje leka u promet:
AI kao pokretač novih pristupa u regulativi i registraciji lekova
From algorithm to market authorization:
AI as a driver of new approaches in drug regulation and registration

Prof. Svetlana Ibrić, PhD, Faculty of Pharmacy, University of Belgrade

Antimikrobna rezistencija
- Prekomerna, nekontrolisana upotreba antibiotika u stočarskoj proizvodnji
Antimicrobial resistance
- Excessive, uncontrolled use of antibiotics in livestock production

Nenad Budimović, Chamber of Commerce and Industry of Serbia

Klasične farmakološke metode u suzbijanju antimikrobne i antiparazitske rezistencije
i mogućnosti primene veštačke inteligencije
Classical pharmacological methods in combating antimicrobial and antiparasitic resistance
and the possibilities of applying AI

Prof. Saša Trailović, PhD, Faculty of Veterinary Medicine, University of Belgrade

11.00-11.30

KAFE PAUZA / COFFEE BREAK

11.30-13.00

VETERINARSKI LEKOVI: REGULATORNI ZAHTEVI - KVALITET I KONTROLA KAVLITETA LEKA VETERINARY MEDICINES: REGULATORY REQUIREMENTS - PRODUCT QUALITY & QUALITY CONTROL

Moderator: Gordana Žugić, ALIMIS

Antimikrobna rezistencija - Procena rizika po javno zdravlje
Antimicrobial resistance - Assessment of the risk to public health

Jelena Anđelković, ALIMIS

Regulatorni zahtevi za kvalitet leka - tableta
Regulatory requirements for medical product quality - tablet

Aleksandra Labudović, ALIMIS

Regulatorni zahtevi za kvalitet leka - Intramamarna suspenzija
Regulatory requirements for medical product quality - Intramammary suspension

Jelena Stevanović Gročić, ALIMIS

Informacije na neposrednom ili spoljašnjem pakovanju veterinarskog leka
- Obeležavanje (Nacrtno pakovanje)
Information on the immediate or outer packaging of a veterinary medicine
- Labelling (Mock up)

Svjetlana Mihaljica, ALIMIS

13.00-14.30

PAUZA ZA RUČAK / LUNCH BREAK

14.30-16.00 **KLINIČKA ISPITIVANJA LEKOVA - NOVINE I IZAZOVI U ODOBRAVANJU KLINIČKIH ISPITIVANJA**
CLINICAL TRIALS OF MEDICINES - CHANGES & CHALLENGES IN CLINICAL TRIAL AUTHORISATION

Moderator: Biljana Andrić, ALIMIS

Izazovi u radu EOS-a od 2020-2025.
Challenges faced by EOS 2020-2025.

Prof. Darko Antić, PhD, The University Clinical Centre of Serbia and President of EOS

Praćenje bezbednosti lekova u kliničkim ispitivanjima
Drug safety monitoring in clinical trials

Tijana Mičić, ALIMIS

Lekovi za naprednu terapiju (ATMP): Regulatorni okvir
Advanced therapy medicinal products (ATMPs): Regulatory framework

Jelena Mijailović, ALIMIS

Panel diskusija: Vaša pitanja - naši odgovori
Panel discussion: Your questions - ours answered

Panelists: Ana Lakobrija, ALIMIS | Aleksandra Bjelovuk, ALIMIS

16.00-16.30 **KAFE PAUZA / COFFEE BREAK**

16.30-18.00 **ICH GCP (R3) KONAČNO OTKROVENJE, IMPLEMENTACIJA I IZAZOVI 2025**
ICH GCP (R3) FINAL REVELATION IMPLEMENTATION VS CHALLENGES 2025

Moderator: Violeta Ristić, ALIMIS

Panel diskusija
Panel discussion

Panelists: Prof. Vladimir Janjić, PhD, Dean of the Faculty of Medical Sciences at the University of Kragujevac
Nikola Bošković, Abbvie | Aleksandar Đurić, Parexel

18.00-21.00 **VEČERA / DINNER**

21.00 **KOKTEL / COCKTAIL**

*Napominjemo da je ograničen broj mesta na sesijama za klinička ispitivanja i veterinarske lekove i da zbog ograničenog kapaciteta sale, prednost na ovim sesijama imaju učesnici sa plaćenim kotizacijama za ovu kategoriju.

Sve sesije će biti snimljene i postoji mogućnost odloženog gledanja 3 meseca nakon simpozijuma.

*Please note that there are a limited number of places in the sessions for clinical trials and veterinary drugs and that due to the limited capacity of the hall, priority is given to participants with paid registration fees for this category.

All sessions will be recorded and there is a possibility of delayed viewing 3 months after the symposium.