

11. tradicionalni godišnji simpozijum ALIMS
“Promene i pravci razvoja aktuelne regulative u oblasti lekova i medicinskih sredstava”, hotel Šumarice, Kragujevac, 6-7.11.2015.

11th traditional annual ALIMS symposium
“Changes and development trends of the current regulations in the field of medicines and medical devices”

Organizatori

Organizers

Agencija za lekove i medicinska sredstva Srbije - ALIMS/Medicines and Medical Devices Agency of Serbia - ALIMS

Grupacija domaćih proizvođača lekova

Association of Local Manufacturers of Medicinal Products

Udruženje inovativnih proizvođača lekova – INOVIA

Association of the Manufacturers of Innovative Drugs - INOVIA

Udruženje inostranih generičkih proizvođača lekova – GENEZIS

Association of Generic Drug Manufacturers and Marketing Authorization Holders - GENEZIS

Pod pokroviteljstvom Ministarstva zdravlja Republike Srbije

Under the auspices of the Ministry of Health of the Republic of Serbia

Simpozijum je prvenstveno namenjen proizvođačima i nosiocima dozvola za lekove, proizvođačima i nosiocima upisa u Registar medicinskih sredstava, kao i zdravstvenim profesionalcima, predstavnicima regulatornih tela i univerziteta

The Symposium is primarily intended for medicines manufacturers and marketing authorization holders, producers of medical devices and holders of registration in the register of medical devices, as well as healthcare professionals, representatives of regulatory bodies and universities.

Sve sesije, pauze, obroci (sem doručka) i svečana večera se odigravaju u hotelu Šumarice.

All the sessions, breaks, meals (apart from breakfast) and official dinner are taking place in hotel Šumarice.

Zahvaljujemo na vašim prijavama i drago nam je što ćete učestvovati na Simpozijumu.

Programski i Organizacioni odbor Simpozijuma

Thank you for your applications and we are pleased that you will participate in the Symposium.

Program and Organizing Committees of the Symposium

NACRT PROGRAMA/DRAFT AGENDA

PRVI DAN/FIRST DAY

09:30 – 10:00	Pozdravni govori/Welcome speeches
10:00 – 11:20	<p>Sesija/Session: "Compassionate use lekova"/"Compassionate use of medicines"</p> <p>Moderatori/Moderators: Jadranka Mirković, Prof. Radmila Veličković</p> <p>Teme/Topics: Programi rane dostupnosti lekova za pacijente koji su iscrpeli sve dostupne terapijske opcije/Programs of early availability of medicines for patients who have exhausted all available treatment options.</p> <p>Jadranka Mirković, ALIMS – "Perspektiva programa rane dostupnosti novih terapijskih opcija u Republici Srbiji"/"Perspective of programs of early availability of new therapeutic options in the Republic of Serbia"</p> <p>Prof. Radmila Veličković, Klinički centar Niš/Clinical Centre Nis – "Compassionate use: pogled iz prakse"/"Compassionate use: a view from practice"</p> <p>Nataša Panješević, Janssen Pharmaceutical Company of Johnson & Johnson Serbia – "Rana dostupnost inovativnih lekova iz perspektive industrije"/"Early access to innovative medicines – industry perspective"</p>
11:20 – 11:40	Pauza/Break
11:40 – 13:00	<p>Sesija/Session: "Zamenljivost/nezamenljivost lekova"/"Interchangeability of medicines"</p> <p>Moderatori/Moderators: Danka Tešić, ALIMS, Prof. Slobodan Janković</p> <p>Teme/Topics: zamenljivost/nezamenljivost lekova, uticaj na cenu, zamenljivost sa regulatornog aspekta/interchangeability/non-interchangeability of medicines, impact on prices, interchangeability from the regulatory aspect.</p> <p>Prof. Slobodan Janković, Fakultet medicinskih nauka Univerziteta u Kragujevcu, Klinički centar Kragujevac/Faculty of Medical Sciences, University of Kragujevac, Clinical Centre Kragujevac – "Odnos originala i generike i međusobna zamenljivost generičkih lekova"/"The relation between original and generic medicines and mutual interchangeability of generic medicines"</p> <p>Goran Medić, Mapi Group, Holandija/Holland – "Farmakoekonomski modeli i zamenljivost lekova"/"Health economics models and interchangeability of drugs"</p> <p>Prof. Borut Štrukelj, Farmaceutski fakultet Univerziteta u Ljubljani/The Faculty of Pharmacy, University of Ljubljana, Slovenija/Slovenia - "Značaj međusobne zamenljivosti u nabavci lekova: slučaj Biosimilara/The importance of interchangeability in the procurement of medications: Biosimilar case"</p>
13:00 – 14:00	Ručak/Lunch
14:00 – 15:40	<p>Sesija/Session: "Vigilanca medicinskih sredstava"/"Medical devices vigilance"</p> <p>Teme/Topics: Nova iskustva u ovoj oblasti, negativne reference na tenderima, pitanje nekvalitetnih medicinskih sredstava/New experiences in this field, negative references in tender procedures, the issue of low-quality medical devices.</p> <p>Moderatori/Moderators: Branislav Radivojević, ALIMS, Ana Pribaković Borštnik</p> <p>Vesna Ševaljević, ALIMS – "Pregled regulatornih aspekata iz oblasti vigilance medicinskih sredstava u Republici Srbiji"/"Review of Regulatory Aspects in The Field of Medical Devices Vigilance System in The Republic of Serbia"</p>

	<p>Ana Pribakovič Borštnik, SIQ, Ljubljana, Slovenija/Slovenia - "Kako na odgovarajući način uključiti post-marketinški nadzor u sistem kvaliteta?"/"How to appropriately include post-marketing surveillance in a quality system?"</p> <p>Dušan Dragović, Fresenius Medical Care Srbija d.o.o. – "Fresenius Medical Care - Vigilanca medicinskih sredstava"/"Fresenius Medical Care - Medical Device Vigilance"</p> <p>Dragana Rajinac, Klinički centar Srbije/Clinical Centre of Serbia – "Vigilanca medicinskih sredstava u sistemu zdravstvene zaštite"/"Medical Devices Vigilance in The Health Care System"</p>
15:40 – 16:00	Pauza/Break
16:00 - 18:00	<p>Sesija/Session: "Falsifikovani lekovi i medicinska sredstva"/"Falsified medicines and medical devices"</p> <p>Moderatori: Domeniko di Đorđo i Pavle Zelić, ALIMIS</p> <p>Teme/Topics: Regulatorni i praktični aspekti borbe protiv falsifikovanih lekova i medicinskih sredstava u Evropi i svetu/Regulatory and practical aspects of fight against counterfeit medicines and medical devices in Europe and the world.</p> <p>Dr Domeniko di Đorđo/Dr Domenico Di Giorgio, Agencija za lekove Italije – AIFA/Italian Medicines Agency – AIFA, Italija/Italy - "Novi regulatorni i praktični aspekti vezano za falsifikovane lekove u EU i Evropi"/"New regulatory and practical aspects relating to the falsified medicinal products in EU and Europe"</p> <p>Lynda Scammell, Agencija za lekove Velike Britanije – MHRA/Medicines and Healthcare Products Regulatory Agency, Velika Britanija/United Kingdom - ""/""</p> <p>Tbc., Federalna služba za nadzor u oblasti zdravstvene zaštite Ruske Federacije – Roszdravnadzor, Federal Service for Surveillance in Healthcare of the Russian Federation – Roszdravnadzor, Ruska Federacija/Russian Federation -</p>
20:30	Svečana večera/Official dinner

DRUGI DAN/SECOND DAY

09:00 – 10:40	<p>Sesija/Session: "Režim izdavanja"/"Classifying of medicines"</p> <p>Moderatori/Moderators: Prof. Miroslav Savić, Dobrila Bojović, ALIMIS</p> <p>Teme/Topics: Klasifikacija lekova, praktične implikacija na tržištu, dijetetski suplementi, dostupnost lekova, racionalna upotreba lekova/Classification status of medicines, practical implications on the market, dietary supplements, availability of medicines, rational use of medicines.</p> <p>Prof. Miroslav Savić, Farmaceutski fakultet Univerziteta u Beogradu/Faculty of Pharmacy, University of Belgrade – "Reklasifikacija lekova: regulatorni put ka suštinskom unapređenju primene?"/ "Reclassification of medicines: a regulatory approach to an essentially improved use?"</p> <p>Prof. Slađana Šobajić, Farmaceutski fakultet Univerziteta u Beogradu/Faculty of Pharmacy, University of Belgrade – "Regulisanost i kontrola dijetetskih suplemenata u Srbiji"/ "Regulation and control of dietary supplements in Serbia"</p> <p>Silvia Ravera - Evropski direktorata za kvalitet lekova i brigu o zdravlju – EDQM, Savet Evrope/European Directorate for Quality of Medicines and Healthcare – EDQM, Council of Europe – "Klasifikacija lekova – Uloga Komiteta eksperata Saveta Evrope za klasifikaciju lekova u odnosu na režim njihovog izdavanja "/"Classification of Medicines - The Role of the Council of Europe's Committee of Experts on the classification of medicines as regards their supply - CD-P-PH/PHO"</p>
10:40 – 11:00	Pauza/Break
11:00 – 12:30	<p>Sesija/Session: "Oglašavanje lekova, medicinskih sredstava i dijetetskih suplemenata i njihova kontrola"/"Advertising of medicines, medical devices and dietary supplements and their control"</p> <p>Moderatori/Moderators: Prof. Vesela Radonjić, Jelica Vasić</p> <p>Teme/Topics: Izdavanje dozvola za oglašavanje od strane ALIMIS, upis u registar dijetetskih suplemenata od strane Ministarstva Zdravlja Republike Srbije, kontrola oglašavanja od strane inspekcije Ministarstva zdravlja/Issuing advertising licences by ALIMIS, issuing of approval for dietary supplements by Ministry of Health, control of advertising by inspection of the Ministry of Health.</p> <p>Prof. Vesela Radonjić, ALIMIS - "Oglašavanje lekova i medicinskih sredstava"/"Advertising of medicines and medical devices"</p> <p>Jelica Vasić, Ministarstvo zdravlja Republike Srbije/Ministry of Health of the Republic of Serbia – "Kontrola oglašavanja lekova i medicinskih sredstava za humanu upotrebu: Regulatorni aspekt i praksa"/"Control of advertising of medicinal products and medical devices: regulatory aspect and practice"</p> <p>Goran Stojković, Ministarstvo zdravlja Republika Srbije/Ministry of Health of the Republic of Serbia – "Oglašavanje dijetetskih suplemenata i njihova kontrola"/"Advertising of dietary supplements and their control"</p>
12:30 – 13:00	Zaključci i zatvaranje simpozijuma/ Final remarks and closing of the symposium
13:00-14:00	Lagani ručak/Light lunch