Poštovane kolege,

Zadovoljstvo nam je da vam predstavimo program ovogodišnjeg, 12. po redu međunarodnog simpozijuma ALIMS koji nosi naslov "Kroz saradnju u oblasti lekova i medicinskih sredstava do efikasnije zdravstvene zaštite stanovništva", i biće održan 28-29.10.2016. u hotelu Šumarice, Kragujevac.

12. tradicionalni godišnji simpozijum ALIMS
"Kroz saradnju u oblasti lekova i medicinskih sredstava
do efikasnije zdravstvene zaštite stanovništva"
Hotel Šumarice, Kragujevac, 28-29.10.2016.

12th traditional annual ALIMS symposium
"Through the cooperation in the field of medicines and medical devices
to a more efficient health care of the population"
Hotel Šumarice, Kragujevac, 28-29.10.2016.

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 Auhorization 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.

NACRT PROGRAMA/DRAFT AGENDA

PRVI DAN/FIRST DAY, petak/Friday 28.10.2016.

08:30 – 09:30	**Regitracija/Registration**
09:30 – 10:00	Pozdravni govori/Welcome speeches
10:00 – 11:30	Sesija/Sesion: Zamenljivost/nezamenljivost lekova Interchangeability/non-interchangeability of medicines
	Biološki slični lekovi - zamenljivost kada postoji terapija biološkim lekom, Prof. Slobodan Janković, Univerzitet u Kragujevcu, Kragujevac, Srbija/ Biologically similar drugs - interchangeability when there is therapy with biological medicie, Prof. Slobodan Janković, University of Kragujevac, Kragujevac, Serbia
	Generički hibridi - Peter Daley-Yates, GlaxoSmithKline, London, Velika Britanija/ Generic hybrids - Peter Daley-Yates, GlaxoSmithKline, London, United Kingdom
	Biološka terapija - regulatorni aspekti - Keith Watson, Abbvie, London, Velika Britanija/ Biological therapy - regulatory aspects - Keith Watson, Abbvie, London, United Kingdom
11:30 – 12:00	Pauza/Break
12:00 – 13:30	Sesija/Sesion: Odobravanje i kontrola oglašavanja lekova i medicinskih sredstava – izazovi u praksi u Srbiji i EU/Approval and control of advertising of medicines and medical devices - challenges in practice in Serbia and the EU
	Praksa u kontroli oglašavanja u Rumuniji, Dr Nicolae Fotin, predsednik Nacionalne agencije za lekove i medicinska sredstva Rumunije/The practice of control of advertising in Romania, Dr Nicolae Fotin, President of the National Agency for Medicines and Medical Devices of Romania
	Iskustva Ministarstva zdravlja u inspekciji oglašavanja – predavač Ministarstva Zdravlja Republike Srbije TBC/ The experience of the Ministry of Health in the inspection of advertising - Lecturer from Ministry of Health of the Republic of Serbia TBC
	Specifičnosti odobrenja promotivnih materijala za lekove i medicinska sredstva u Republici Srbiji, Mladen Bogdanović, ALIMS, Beograd, Srbija/The specifics of approval of promotional materials for medicines and medical devices in the Republic of Serbia, Mladen Bogdanovic, ALIMS, Belgrade, Serbia
13:30 – 14:30	Ručak/Lunch
14:00 – 14:30	Registracija za sesiju za medicinska sredstva/Registration for the session for medical devices
14:30 – 15:45	Sesija/Sesion: Uvođenje eCTD – da li smo spremni?/The introduction of eCTD - are we ready?
	eSubmission ALIMS-a i prikaz Vodiča za farmaceutsku industriju, Tatjana Stojadinović, Ljiljana Radovanović, ALIMS, Dušica Ćuk, Direkcija za elektrosnku upravu, Ministarstvo za državnu upravu i lokalnu samoupravu Republike Srbije/eSubmission of ALIMS and presentation of the Guide for the pharmaceutical industry, Tatjana Stojadinovic, Ljiljana Radovanovic, ALIMS, Dušica Ćuk, Directorate for the Electronic Administration, Ministry of Public Administration and Local Self-Government of the Republic of Serbia
	Predstavljanje NeeS i eCTD formata u EU i regionu, standardizacija i roadmap, razvoj i perspektive za industriju i regulatorna tela, Vito Strasberger, Nanokinetik, London, Velika Britanija/ Presentation of NeeS and eCTD formats in the EU and the region, the standardization and roadmap, development and prospects for the industry and regulatory bodies, Vito Strasberger, Nanokinetik, London, United Kingdom
15:45 – 16:00	Pauza/Break

16:00 – 18:00	Sesija/Sesion: Medicinska sredstva – nova iskustva i regulatorne perspective/Medical devices - new experiences and regulatory perspective Ispitivanje biokompatibilnosti medicinskog sredstva za tehnički fajl proizvođača u svrhu dobijanja CE znaka, Jasminka Markov, Galenika a.d., Beograd/ Testing of Biocompatibility of a medical device for the technical file of the manufacturers for the purpose of obtaining CE mark. Jasminka Markov, Galenika a.d., Belgrade Priprema kliničke dokumentacije za medicinsko sredstvo u postupku dobijanja CE znaka, Zoran Spasić, SGS, Beograd/ Preparation of clinical documentation for a medical device in the process of obtaining the CE mark, Zoran Spasić, SGS, Belgrade; ISO 13485 kao potvrda kvaliteta proizvodnje medicinskog sredstva sa CE znakom, Alenka Toplak, SIQ, Ljubljana, Slovenija/ ISO 13485 as a confirmation of the quality of production of a medical device with CE mark, Alenka Toplak, SIQ, Ljubljana, Slovenia. Vigilanca medicinskih sredstava u procesu "Post Market Surveillance" kao obaveza proizvođača medicinskog sredstva sa CE znakom, Vesna Koblar, raPHARM, Ljubljana, Slovenija./Vigilance of medical devices in the "Post Market Surveillance" process as an obligation of the manufacturer of a medical device with CE mark, Vesna Koblar, raPHARM, Ljubljana, Slovenia. Postupak registracije i pravila za promet medicinskih sredstava u Ruskoj Federaciji - Anton Juzefovič, zamenik generalnog direktora, Ruski državni naučni institut za istraživanje i testiranje medicinskih sredstava Federalne službe za nadzor u oblasti zdravstva Ruske Federacije – Roszdravnadzor / Registration procedure and Rules for circulation for medical devices in Russian Federation - Anton Yuzefovich, Deputy General Director, Russian Federal State Scientific Institute for Research and Testing of medical devices of Federal service for surveillance in healthcare of Russian Federation – Roszdravnadzor
20:00	Svečana večera/Official dinner

DRUGI DAN/SECOND DAY, subota/Saturday 29.10.2016.

09:00 – 10:40	Sesija/Sesion: Farmakovigilanca – inovacije u regulatornoj praksi /Pharmacovigilance - innovations in regulatory practice Sistem farmakovigilance nosioca dozvole za lek - usklađivanje sa zahtevima EU legislative - mr.sc. Tatjana Ajhler Đuretek, dr.med. Belupo, Zagreb, Hrvatska/ Pharmacovigilance system of the marketing authorization holder - compliance with the requirements of EU legislation, M.Sc. Tatjana Ajhler Đuretek, dr.med. Belupo, Zagreb, Croatia Mere minimizacije rizika - perspektiva ALIMS-a, Ivana Jović, ALIMS, Beograd, Srbija/ Risk minimization measures - ALIMS perspective, Ivana Jovic, ALIMS, Belgrade, Serbia Praksa u minimiziranju rizika u Italiji: nacionalne specifičnosti i zahtevi EU, Ilaria Baldelli, Agencija za lekove Italije - AIFA, Rim, Italija/Risk minimization practice in Italy: national specifics and EU requirements, Ilaria Baldelli, Italian Medicines Agency - AIFA, Rome, Italy Zajednička akcija SCOPE – učešće AIFA i iskustvo u komunikaciji rizika, Amelija Cupelli, Agencija za lekove Italije - AIFA, Rim, Italija/SCOPE Joint Action – AIFA involvement and experience in risk communication, Amelia Cupelli, Italian Medicines Agency – AIFA, Rome, Italy
10:40 – 11:00	Pauza/Break
11:00 – 12:00	Sesija/Sesion: Serijalizacija – nove obaveze za sve aktere sistema, pogled iz EU/Serialization - new obligations for all the actors of the system, view from EU Iskustva i perspektive u serijalizaciji sa askpekta farmaceutskih kompanija, Francoise Hirth, F.Hoffmann-La Roche ltd, Bazel, Švajcarska/Experiences and Perspectives in the serialization of pharmaceutical companies askpekta, Francoise Hirth, F.Hoffmann-La Roche ltd, Basel, Switzerland Iskustva i perspektive sa aspekta Evropske komisije i država članica EU, TBC/Experiences and Perspectives in Serialization in terms of the European Commission and EU member states, TBC
12:00 – 12:30	Zaključci i zatvaranje simpozijuma/Final remarks and closing of the symposium
12:30 – 14:00	Lagani ručak/Light lunch