



# 13. SIMPOZIJUM ALIMS 2017.

## Program

**Program 13. ALIMS simpozijuma sa međunarodnim učešćem “U susret izazovima i perspektivama: umrežavanje i komunikacija nacionalnih regulatornih tela i farmaceutske industrije”.**

**Datum i mesto:** 20-21. oktobra 2017. godine u Hotelu Šumarice u Kragujevcu

**Organizatori:** Agencija za lekove i medicinska sredstva Srbije (ALIMS), Grupacija domaćih proizvođača lekova u okviru Privredne komore Srbije, Udruženje inovativnih proizvođača lekova – INOVIA, Udruženje inostranih generičkih proizvođača lekova – GENEZIS

### *Prvi dan*

- 8:30 Registracija učesnika**
- 9:00 Otvaranje skupa**
- 09:30-11:30 I sesija: Usklađenost dokumentacije sa tipom zahteva i tok i ishod procene**  
Usklađenost dokumentacije sa tipom zahteva sa aspekta formalne procene  
Zahtev za lekove sa dobro poznatom upotrebom aktivne supstance – iskustva i perspektive  
Izazovi u proceni terapijske ekvivalentnosti polučvrstih preparata za primenu na koži sa lokalnim dejstvom  
Farmakovigilanca u postupku izdavanja dozvole za lek  
SPC, PIL i Labelling u postupku izdavanja dozvole za lek
- 11:30-12:00 Pauza**
- 12:00-13:30 II sesija: Upotreba antibiotika u Srbiji i predavanje iz nadležnosti Nacionalne kontrolne laboratorije ALIMS**  
Uticaj primene antibakterijske terapije na razvoj antimikrobne rezistencije  
Potrošnja antibiotika u Srbiji  
Regulatorni zahtevi u oblasti odstupanja od kvaliteta (defekt kvaliteta)
- 13:30-15:30 Pauza za ručak**
- 15:30-18:00 III sesija: Komunikacija nacionalnih regulatornih tela i farmaceutske industrije za eksternim javnostima i medijima – okrugli sto sa predstavnicima nadležnih državnih organa, ko-organizatorima simpozijuma, i agencijama iz regiona**
- 21:00 Svečana večera za sve učesnike simpozijuma**

### *Drugi dan*

- 09:30-11:30 IV sesija: Medicinska sredstva – praksa u regulativi u regionu**
- 11:30-12:00 pauza**
- 12:00-14:00 V sesija: Bezreceptni režim izdavanja lekova**
- 14:00-14:30 Zaključci**
- 14:45 Ručak**  
*Kraj simpozijuma*



## Program

Program of 13. ALIMS Symposium with international participation "Meeting challenges and perspectives: networking and communication of national regulatory bodies and pharmaceutical industry".

**Date and place:** 20-21. October 2017 at the Hotel Šumarice in Kragujevac

**Organizers:** Medicines and Medical Devices Agency of Serbia (ALIMS), Association of domestic medicines manufacturers within the Serbian Chamber of Commerce, Association of innovative medicines manufacturers – INOVIA, Association of foreign generic medicines manufacturers - GENEZIS

### *First day*

- 8:30** Registration of participants
- 9:00** Opening of the meeting, welcome adress
- 09:30-11:30** **I Session: Documentation Compliance with Request Type and Flow and Outcome of the Assessment**  
Compliance of documentation with the type of request from the aspect of formal assessment  
Requirements for medicines with well-known use of the active substance - experiences and perspectives  
Challenges in assessment of the therapeutic equivalence of semi-solid preparations for use on skin with local effect
- Pharmacovigilance in the procedure for issuing marketing authorisation  
SPC, PIL and Labeling in the procedure for issuing a marketing authorisation
- 11:30-12:00** *Coffee break*
- 12:00-13:30** **II Session: Use of antibiotics in Serbia and jurisdiction of the National Control Laboratory of the ALIMS**  
The effect of antibacterial therapy on the development of antimicrobial resistance  
Consumption of antibiotics in Serbia  
Regulatory requirements in the area of deviation from quality (quality defect)
- 13:30-15:30** *Lunch break*
- 15:30-18:00** **III Session: Communication of national and international regulatory bodies and pharmaceutical industry with external public and media - round table with representatives of international organizations, competent state bodies, co-organizers of symposia, and agencies from the region**
- 21:00** *Gala dinner for all participants of the symposium, Hotel Šumarice*

### *Second day*

- 09:30-11:30** **IV Session: Medical Devices - Regulatory Practice in the Balkan region**
- 11:30-12:00** *Coffee break*
- 12:00-14:00** **V Session: Clasification of medicines in regards to OTC and prescription status**
- 14:00-14:30** *Conclusions*
- 14:45** *Lunch*
- End of the Symposium*