



AGENCIJA ZA LIJEKOVE I MEDICINSKE PROIZVODE  
AGENCY FOR MEDICINAL PRODUCTS AND MEDICAL DEVICES

## 3<sup>rd</sup> South East Europe Pharmaceutical Symposium

| Split, 24-25<sup>th</sup> May 2007 |

Hotel Le Meridien Lav

### Meeting the European Challenge for the National Drug Regulatory Agencies and the Generic Medicines Industry

Organised by the European Generic Medicines Association (EGA)  
with the kind cooperation of  
the Croatian Agency for Medicinal Products and Medical Devices  
(ALMP)

Sponsored by:



## WEDNESDAY 23<sup>rd</sup> May 2007

20:00 Cocktail Reception - Hotel Le Meridien Lav

## THURSDAY 24<sup>th</sup> May 2006

08:00 Registration and Networking Coffee

09:00 Open part

### Opening Session:

**Chairs** | *Adrijana Ilic-Martinac, the Croatian Agency for Medicinal Products and Medical Devices* | *Vladimir Afenliev, Chair EGA Accession Committee, Actavis, Bulgaria*

- **Opening Speeches:** | *Neven Ljubičić, Croatian Ministry of Health, Sinisa Tomic, Head of the Croatian Agency for Medicinal Products and Medical Devices, Greg Perry, Director General, European Generic medicines Association (EGA)*
- **Key Note Speech:** “*Priorities of the Ministry of Health in the National Health Policy*” | *Neven Ljubičić, Minister of Health, Croatia*
- **Croatia’s way to the EU Accession - impact of the negotiation process on the pharmaceutical sector**
  - **Current status of the negotiation process in area affecting pharmaceutical sector** - *Dunja Siuc Valković*
- **Challenges of the Accession for the Croatian Drug Agency”** | *Sinisa Tomic-Head of Croatian Agency for Medicinal Products and Medical Devices (ALMP)*

Panel discussion and QA session

10:30 Coffee Break

**10:45 Session 1**

**Chair** | *Beata Stepniewska, EGA and Croatian industry representative*

- **Challenges of the EU Accession for the Croatian Generic Medicines Industry”** | *industry representative,*
- **New Croatian Legislation as the part of harmonization process with the EU legislation-** *Andreja Smolcic- Croatian Agency for Medicinal Products and Medical Devices (ALMP)*
- **The Croatian Agency policy regarding the update of the dossiers** | *Zeljika Davosir Klaric, Croatian Agency for Medicinal Products and Medical Devices (ALMP)*
- **IP protection issues as the part of harmonization process with the EU legislation** | *Zeljko Topic, Head of Croatian Patent Office*

Panel discussion and QA session

**12.30 -13.00 Press Conference**

**13:00- 14.00 Lunch Buffet**

**14.00 - 15.45 Session 2** Overview of the latest legal and regulatory development in the region

**Co-Chairs** | *Vesna Koblar and Greg Perry*

Presentations made by the Regulatory Authorities from Albania, Bosnia and Hercegovina, Macedonia, Montenegro, Serbia.

**15.45 Coffee Break**

**16. 00 - 16.45 Panel discussion and QA session**

**18. 00 Tour in Split (only with invitations)**

**19. 30 Dinner (only with invitations)**

---

FRIDAY 25<sup>th</sup> May 2006

9:00- 13.00 Closed Part (only with invitations)

## Session 2

Future environment for generic medicines in South East Europe

**Co- Chairs** | *Sinisa Tomic, Head of Croatian Agency for Medicinal Products and Medical Devices (ALMP)*

*Greg Perry, Director General, European Generic Medicines Association (EGA)*

- 5 months experience with the full membership- Bulgaria, Romania  
*Emil Hristov, Executive Director, Bulgarian Drug Agency and Rodica Badescu Vice President of the Romanian National Medicines Agency*
- Current status of Harmonization with the EU legislation in Turkey- Eda Cindoglu - Ministry of Health, Turkey
- Experience with the dossier update process- Jitka Sabartova (Czech Republic) Tamas Paal (Hungary)
- Level of the harmonization with the EU legislation: what should be the priority? - Vesna Koblar (Slovenia)
- Benefit of the cooperation with EU Agencies- common projects/ sharing of experience - Jitka Sabartova (Czech Republic), Rodica Badescu (Romania)

Exchange of views and experiences by: *Representatives of Drug Regulatory Agencies, Patent Offices, EU Accession negotiators and Generic Medicines Industry from Albania, Bosnia and Herzegovina, Bulgaria, Czech Rep, Croatia, Hungary, Macedonia, Montenegro, Romania, Serbia, Slovenia, Turkey.*

- Update regarding key provisions for generics
  - Data Exclusivity
  - SPC
  - Update of the existing dossiers
  - Bolar provision
  - Transitional measures

**Round Table:** *Representatives of Drug Regulatory Agencies, Patent Offices, EU Accession negotiators and Generic Medicines Industry from Albania, Bosnia and Hercegovina, Bulgaria, Croatia, Macedonia, Montenegro, Romania, Serbia, Turkey.*

13:00 Lunch