

# 6<sup>th</sup> EGA South East Europe Pharmaceutical Symposium

## MEETING THE EUROPEAN CHALLENGE FOR NATIONAL DRUG REGULATORY AGENCIES AND THE GENERIC MEDICINES INDUSTRY

| Vršac, 29 September - 1 October 2010 |

Congress and Music Hall Millennium Center, Omladinski trg 17, 26300 Vršac (Serbia)

Organised by



*Making Medicines Affordable*

European Generic medicines Association



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



Association of Local Manufacturers of Medicinal Products - Serbian Chamber of Commerce

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## WEDNESDAY 29 September 2010

20:00 Registration and cocktail reception

## THURSDAY 30 September 2010

09:00 **Session 1- Plenary session**

**Chairs:** *Greg Perry, Director General, European Generic medicines Association (EGA) and Dragomir Marisavljevic, Vice President, Hemofarm A.D. and President of the Association of Local Manufacturers of Medicinal Products, Serbian Chamber of Commerce*

- **Welcome speech:** *Tatjana Sipetic, Director of Medicines and Medical Devices, Agency of Serbia (ALIMS)*
- **Opening speech: Generic medicines in Europe: Enhancing pharmaceutical competition and ensuring healthcare sustainability** | *Greg Perry, Director General, European Generic medicines Association (EGA)*
- **Keynote speeches:**
  - **Priorities of the ministry of health in national health policy** | *Tomica Milosavljevic, Minister of Health, Serbia*
  - **Serbia's legal and regulatory environment for generic medicines** | *Tatjana Sipetic, Director of ALIMS, Serbia*
  - **Challenges for the Serbian generic medicines industry** | *Dragomir Marisavljevic, Vice President, Hemofarm A.D. and President of the Association of Local Manufacturers of Medicinal Products, Serbian Chamber of Commerce*

10:30 - 11:00 Coffee break

10:30 - 11:00 Press conference

11:00 - 13:00 **Session 2 - Overview of the regulatory environment for generics in South East Europe**  
**Co-Chairs:** *Tijana Radojičić, Head of Sector for Medicines and Medical Devices, Ministry of Health of the Republic of Serbia and Vesna Koblar, Deputy Director of the Slovenian Medicines Agency (JAZMP)*

**The latest development in the regulatory environment in South-East Europe. Presentations by regulatory authorities followed by a Q&A session**

- *Albania*
- *Bosnia and Herzegovina*
- *Croatia*
- *Kosovo under UNSCR 1244*
- *Macedonia*
- *Montenegro*
- *Turkey*

13:00 - 14:00 Networking lunch buffet

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**ROUND TABLE - DAY ONE**  
**MOVING IN THE SAME DIRECTION: TO CREATE A HARMONISED ENVIRONMENT**  
**FOR GENERIC MEDICINES IN THE EU AND IN SOUTH-EAST EUROPE**

14:00 - 15:00 **Session 3** - EU Pharmaceutical Sector Inquiry - One year on  
Co-Chairs: *Greg Perry, Director General, European Generic medicines Association (EGA)*  
and *Daniel Boda, Head of the Romanian Medicines Agency (ANM)*

- Implementation of the recommendations of the Pharmaceutical Sector Inquiry's report at EU and national level | *Greg Perry, Director General, EGA*
- Implementation of the regulatory recommendations of the Pharmaceutical Sector Inquiry by the national competent authorities | *Vesna Koblar (SI), Daniel Boda (RO), Tamas Paal (HU), Jasmina Mircheva (BG)*
- Implementation of recommendations for improvement of the patent system | *Mirela Georgescu, Deputy Head of Chemistry Pharmaceuticals Examining Division, State Office for Inventions and Trademarks, Romania*
- Round table discussion and exchange of views and experiences by representatives of Drug Regulatory Agencies and the Generic Medicines Industry from Albania, Bosnia and Herzegovina, Bulgaria, Croatia, Hungary, Kosovo under UNSCR 1244, Macedonia, Montenegro, Romania, Serbia, Slovenia, Turkey

15:00 - 15:30 Coffee break

15:30 - 17:00 **Session 4** - Changes in the EU regulatory and legal environment - Implications for regulatory authorities and the generic medicines industry in the SEE Region  
Co-Chairs: *Vesna Koblar, Deputy Director of the Slovenian Medicines Agency (JAZMP)*  
and *Greg Perry, Director General, European Generic medicines Association (EGA)*

Possible changes in the legal and regulatory environment related to quality | *Vesna Koblar (SI)*

- Reinforcement of the GMP for APIs, particularly coming from non-EU countries and measures against falsified medicines as a part of new legislation

Possible changes in the legal and regulatory environment related to quality in the SEE region | *Svjetlana Mihaljica, Head of Pharmaceutical Department, ALIMIS and industry speaker (TBN)*

- Recognition of the GMP inspections
- Possible simplification of batch analysis for imported products

Exchange of views and experiences by authorities and industry from Albania, Bosnia and Herzegovina, Bulgaria, Croatia, Hungary, Kosovo under UNSCR 1244, Macedonia, Montenegro, Romania, Serbia, Slovenia, Turkey

17:30 - 19:30 Visit of Hemofarm (optional)

20:00 Conference dinner sponsored by HEMOFARM

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FRIDAY 1 October 2010

ROUND TABLE - DAY TWO  
MOVING IN THE SAME DIRECTION: TO CREATE A HARMONISED ENVIRONMENT  
FOR GENERIC MEDICINES IN THE EU AND IN SOUTH-EAST EUROPE

09:00 - 11:00 **Session 5** - Moving in the same direction - Specific aspects of market authorisations  
Co-Chairs: *Sinisa Tomic*, Head of Croatian Agency for Medicinal Products and Medical Devices (ALMP) and *Beata Stepniewska*, Regulatory Affairs Director, European Generic medicines Association (EGA)

- Final outcome of revision of pharmacovigilance legislation in the EU
  - Key changes provided by the new legislation | *Birte van Elk*, Medicines Evaluation Board (MEB), NL
  - Possible impact on regulatory procedures in non-EU countries and possible alignment in non EU countries with EU developments | *Morana Simundic*, PLIVA
- Latest changes in the EU bioequivalence guideline | *Andrzej Dzierbicki*, Head of Clinical Department, Polpharma
  - Possible impact on future generic applications in non-EU countries
- Implementation of a new variations system in the EU | *Beata Stepniewska*, EGA
  - Impact on approval of variations in non-EU countries
  - What can be implemented in non-EU countries in harmony with the EU legislation?

Exchange of views by representatives of Drug Regulatory Agencies and the Generic Medicines Industry from Albania, Bosnia and Herzegovina, Bulgaria, Croatia, Hungary, Kosovo under UNSCR 124, Macedonia, Montenegro, Romania, Serbia, Slovenia, Turkey

11:00 - 11:30 Coffee break

11:30 - 13:00 **Session 6** - Moving in the same direction - Specific aspects of regulatory hurdles for generic applications in the SEE region  
Co-Chairs: *Tamas Paal*, Hungarian Medicines Agency (OGYI) and *Beata Stepniewska*, Regulatory Affairs Director, European Generic medicines Association (EGA)

Electronic submission

- Current status of electronic submission in the EU | *Vito Strasberger*, Billev Pharma
  - Lesson to be learned from the EU experience
- Readiness to accept eCTD application in non-EU countries - the way forward | *Gordana Pejović*, Quality Management Manager, ALIMIS

Other possible areas for improvement - suggestions from the industry

- Multilingual packaging/ leaflet
- Improvement of fast track procedures
- Harmonization of labeling between originator and generic medicinal products

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*Exchange of views by representatives of Drug Regulatory Agencies and the Generic Medicines Industry from Albania, Bosnia and Herzegovina, Bulgaria, Croatia, Hungary, Kosovo under UNSCR 1244, Macedonia, Montenegro, Romania, Serbia, Slovenia, Turkey*

13:30 - 15:00 Lunch

15:30 - 18:00 Wine tasting sponsored by HEMOFARM



20:00 Dinner for the authorities hosted by ALIMIS (invitations)

## SATURDAY 2 October 2010

09:30 Transfer to the airport in Belgrade and departure

For further information and to register on-line, please visit:

FOR COMPANY: <http://www.gpaconferences.com/ser2010reg.htm>

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Registrations close officially on 10 September 2010 & are subject to availability.

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