# 6th 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)

Under the Auspices of the Ministry of Health of the Republic of Serbia

Organised by

EGA

*Making Medicines Affordable*

European Generic medicines Association

alims

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

PRIVREDNA KOMORA SRBIJE

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 **(Villa Breg)**

## THURSDAY 30 September 2010 (Millennium Center)

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**

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

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, ALIMS*

- **Recognition of the GMP inspections**
- **Possible simplification of batch analysis for imported products-** ***Semir Attar*****,** ***Richter Gedeon***

**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 (Villa Breg)

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## FRIDAY 1 October 2010 (Millennium Center)

**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*,** *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, ALIMS*

**Other possible areas for improvement - suggestions from the industry**

- **Improvement of fast track procedures**
- **Harmonization of labeling between originator and generic medicinal products- *Marija Milovanovic*,** *Actavis*
- **Multilingual packaging/ leaflet**

**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 ALIMS (invitations)

## SATURDAY 2 October 2010

Transfer to the airport in Belgrade and departure (in accordance with individual planning)

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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